# AstraZeneca PLC

# **FOURTH QUARTER AND FULL YEAR RESULTS 2014**

London, 5 February 2015

## Financial results for 2014 in line with upgraded Company guidance given with third quarter 2014 results.

- Full year revenue up 3% at constant exchange rates (CER)<sup>1</sup> to \$26,095m.
  - A change in accounting for the US Branded Pharmaceutical Fee reduced revenue by \$113m; excluding this effect growth was 4%.
- Core EPS for the full year was \$4.28, down 8%, following investment in the growth platforms and accelerated pipeline.
- Fourth quarter revenue up 2% to \$6,683m: fourth consecutive quarter of revenue growth.
- Core EPS for the quarter was \$0.76, down 28%.

# Growth platforms up 15% in 2014, contributing 53% of total revenue.

- Brilinta: +70%, continued global progress.
- Diabetes: +139%, successful integration of BMS assets, strong Farxigal Forxiga launch and good uptake of new Bydureon Pen in the US.
- Respiratory: +10%, with Emerging Markets growth of 27% and decelerating US growth of 15%.
- Emerging Markets: +12%, with China growth of 22%, making China AstraZeneca's second largest national market.
- Japan: -3%, due to mandated price cuts, increased use of generics and Nexium recall in the fourth quarter.

#### A record six product approvals in 2014.

# Pipeline progress since Q3 2014 results:

- *Duaklir Genuair*. EU approval for COPD. Brodalumab<sup>2</sup>: superior to ustekinumab in second and third pivotal Phase III studies in psoriasis. Lesinurad: submission for gout treatment accepted in the EU.
- Brilinta: PEGASUS study met its primary endpoints. Saxagliptin/dapagliflozin FDC: filed in the US.
- Lynparza: US and EU approvals for advanced BRCA-mutated ovarian cancer. Iressa: NDA accepted.
- Moventig: EU approval for opioid-induced constipation. Movantik: descheduled by the US DEA.

The Board has declared a second interim dividend of \$1.90 per share, bringing the dividend for the full year to \$2.80. The Board reaffirms its commitment to the Company's progressive dividend policy.

**2015 Guidance:** Sales revenue is expected to decline by mid single-digit percent at CER<sup>3</sup>. Consistent with its business model, the Company will continue to seek externalisation revenue from partnerships and licensing select products and technologies. Core EPS is expected to increase by low single-digit percent at CER.

#### 2015 Newsflow:

- Pivotal data: MEDI4736 3L NSCLC; tremelimumab mesothelioma; selumetinib uveal melanoma; PT003 COPD.
- Filings: AZD9291 2L NSCLC; cediranib ovarian cancer (EU); brodalumab psoriasis.
- Potential approval decisions: saxagliptin/dapagliflozin FDC; Iressa; lesinurad.

#### **Financial Summary**

Group	Q4 2014 <u>\$m</u>	Actual <u>%</u>	CER <u>%</u>	FY 2014 <u>\$m</u>	Actual <u>%</u>	CER <u>%</u>
Revenue	6,683	(2)	2	26,095	1	3
Core*						
Operating Profit	1,184	(40)	(33)	6,937	(17)	(13)
Earnings per Share	\$0.76	(38)	(28)	\$4.28	(15)	(8)
Reported		, ,	, ,		, ,	, ,
Operating (Loss)/Profit	(349)	(41)	(59)	2,137	(42)	(31)
(Loss)/Earnings per Share	(\$0.25)	(40)	(69)	\$0.98	(52)	(34)

<sup>\*</sup> See Operating and Financial Review on pages 6 and 8 for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

<sup>&</sup>lt;sup>1</sup>All growth rates are shown at CER unless specified otherwise.

<sup>&</sup>lt;sup>2</sup>Brodalumab developed in collaboration with Amgen.

<sup>&</sup>lt;sup>3</sup>Assumes imminent launch of a *Nexium* generic in the US market.

# Pascal Soriot, Chief Executive Officer, commenting on the results, said:

"2014 was a remarkable year for AstraZeneca. We achieved a record six product approvals as we accelerated our pipeline across all main therapy areas. Alongside this, we delivered four quarters of revenue growth, with growth platforms now contributing over half of our revenues. Our strong performance in Emerging Markets is a particular highlight, with China becoming our second largest national market, while the delay in the introduction of *Nexium* generics in the US helped to direct additional investment towards our launch brands and our rapidly advancing pipeline.

"Our guidance for 2015 reflects our focus on creating value by investing in our new brands and exciting pipeline while we continue improving productivity to protect our profitability in the face of patent expiries. With the depth of our science and the momentum we have built across our organisation, we are on track to return to growth by 2017 and are well positioned to deliver our long-term goals."

# **Research and Development Update**

A comprehensive update of the AstraZeneca R&D pipeline is presented in conjunction with this fourth quarter and full year results announcement and can be found at the end of this release.

As at 31 December 2014, the AstraZeneca pipeline included 133 projects, of which 118 are in the clinical phase of development. There are 13 NME projects currently in late stage development, either in pivotal studies or under regulatory review. During 2014, across the portfolio, 50 projects successfully progressed to their next phase. This includes two first launches and four first approvals in a major market, and 14 NME progressions. In addition, 21 projects entered first human testing. Nine projects were withdrawn.

There has been notable progress in the following areas since the third quarter 2014 results announcement:

#### Symbicort SYGMA trial start

During the fourth quarter of 2014, AstraZeneca randomised the first patients into the *Symbicort* SYGMA clinical programme.

Between 50% and 75% of asthma patients have mild asthma, yet, despite the availability of conventional treatment regimens, the disease remains uncontrolled. For many patients with mild asthma, an over-reliance on short-acting beta2-agonist (SABA) reliever or 'rescue' medications, and failure to adhere to prescribed daily maintenance doses of an anti-inflammatory drug, lead to an under-treatment of the underlying inflammation. This increases the risk of exacerbations and progression of the disease.

The SYGMA programme will test the hypothesis that, as compared to a short-acting beta2-agonist rescue inhaler administered 'as needed', better asthma control could be achieved with *Symbicort* (budesonide/formoterol) Turbuhaler administered 'as needed'. In addition, SYGMA will also evaluate the relative efficacy of a more flexible dosing regimen with *Symbicort* Turbuhaler administered 'as needed', and a 'fixed-dose' regular inhaled corticosteroid plus SABA 'as needed'.

#### **Duaklir Genuair approval**

On 24 November 2014, AstraZeneca announced that *Duaklir Genuair* (aclidinium bromide/formoterol fumarate 340/12mcg) had been granted Marketing Authorisation by the European Commission (EC) to be used as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Approximately 300 million people around the world live with COPD, a progressive and chronic disease where people find breathing difficult due to limited airflow. Improving the lung function and reducing daily symptoms such as breathlessness are important to the management of COPD.

Duaklir is a fixed-dose combination of already-approved *Eklira* (aclidinium bromide), a long-acting muscarinic-antagonist (LAMA), with the long-acting beta-agonist (LABA) formoterol. The twice-daily therapy is the only LAMA/LABA combination to show statistically significant improvement in breathlessness compared to individual therapies and is administered by the *Genuair* dry powder inhaler device.

AstraZeneca owns the rights to develop and commercialise *Duaklir Genuair* in the EU following the strategic transaction with Almirall S.A. (Almirall) in respiratory disease, which was completed in October 2014. The EU approval of *Duaklir Genuair* marks an important further step in AstraZeneca's inhaled therapy strategy of

providing physicians and patients with a choice of products uniquely available in both dry powder and pressurised metered dose devices.

#### Lesinurad

On 22 January 2015, AstraZeneca announced that the European Medicines Agency had accepted the marketing authorisation application (MAA) for lesinurad 200mg tablets. Lesinurad is a selective uric acid reabsorption inhibitor developed for the chronic treatment of hyperuricaemia in combination with xanthine oxidase inhibitors allopurinol or febuxostat in gout patients when additional therapy is warranted.

The MAA filing was based on data from the CLEAR1, CLEAR2 and CRYSTAL pivotal Phase III combination therapy studies. CLEAR1 and CLEAR2 were 12-month, multicentre, randomised, placebo-controlled studies that evaluated the efficacy and safety of a once-daily dose of lesinurad in combination with allopurinol versus allopurinol alone, in symptomatic gout patients not achieving target serum uric acid levels on their current allopurinol therapy. CRYSTAL was a 12-month, multicentre, randomised, placebo-controlled study that evaluated the efficacy and safety of a once-daily dose of lesinurad in combination with febuxostat compared to febuxostat alone in gout patients with tophi (deposits of uric acid crystals in joints and skin).

#### **Brodalumab**

On 11 November 2014, AstraZeneca and Amgen announced that AMAGINE-3, a study with an identical design to AMAGINE-2, met its primary endpoints when compared with both ustekinumab and placebo at week 12. Brodalumab was shown to be superior to ustekinumab on the primary endpoint of achieving total clearance of skin disease, as measured by the Psoriasis Area Severity Index (PASI 100). When compared with placebo, a significantly greater proportion of patients treated with brodalumab achieved at least a 75% improvement from baseline in disease severity at week 12, as measured by the PASI 75. A significantly greater proportion of patients treated with brodalumab also achieved clear, or almost clear, skin at week 12 compared with placebo, according to the static Physician Global Assessment (sPGA 0 or 1).

Results showed that 36.7% of patients in the brodalumab 210mg group, 27% of patients in the brodalumab 140mg group, 18.5% of patients in the ustekinumab group and 0.3% of patients in the placebo group achieved total clearance of skin disease (PASI 100). In addition, 85.1% of patients in the brodalumab 210mg group, 69.2% of patients in the brodalumab 140mg group, 69.3% of patients in the ustekinumab group and 6% of patients in the placebo group achieved PASI 75.

On 25 November 2014, AstraZeneca and Amgen announced that AMAGINE-2, a pivotal, multi-arm Phase III trial evaluating two doses of brodalumab in more than 1,800 patients with moderate-to-severe plaque psoriasis, met its primary endpoints when compared with both ustekinumab and placebo at week 12. Brodalumab 210mg given every two weeks and the brodalumab weight-based analysis group were each shown to be superior to ustekinumab on the primary endpoint of achieving total clearance of skin disease, as measured by the PASI 100. When compared with placebo, a significantly greater proportion of patients treated with brodalumab achieved at least a 75% improvement from baseline in disease severity at week 12, as measured by the PASI 75. A significantly greater proportion of patients treated with brodalumab also achieved clear, or almost clear, skin at week 12 compared with placebo, according to the sPGA 0 or 1.

Results showed that 44.4% of patients in the brodalumab 210mg group, 33.6% of patients in the brodalumab weight-based group, 25.7% of patients in the brodalumab 140mg group, 21.7% of patients in the ustekinumab group and 0.6% of patients in the placebo group achieved total clearance of skin disease (PASI 100). In addition, 86.3% of patients in the brodalumab 210mg group, 77.0% of patients in the brodalumab weight-based group, 66.6% of patients in the brodalumab 140mg group, 70.0% of patients in the ustekinumab group and 8.1% of patients in the placebo group achieved PASI 75.

Brodalumab is being developed in collaboration with Amgen.

# American College of Rheumatology 2014 Annual Meeting

AstraZeneca and MedImmune presented new data from the Company's growing inflammation and autoimmunity portfolio at the American College of Rheumatology (ACR) 2014 Annual Meeting in Boston, Massachusetts, held between 14 and 19 November 2014.

More than 15 abstracts were featured at the ACR meeting, providing evidence of the depth and continued progress of AstraZeneca's inflammation and autoimmunity pipeline. Positive Phase III data was presented on lesinurad in gout, as well as earlier stage data around a number of innovative investigational medicines

including sifalimumab and anifrolumab in systemic lupus erythematosus (lupus), mavrilimumab in rheumatoid arthritis, and brodalumab in psoriatic arthritis.

## MEDI4736 (PD-L1)

During the first quarter of 2015 AstraZeneca dosed the first patients in the MEDI4736 (anti-PD-L1 monoclonal antibody) ARCTIC Phase III third line non-small cell lung cancer (NSCLC) trial's monotherapy substudy as well as to the ADJUVANT Phase III adjuvant NSCLC trial.

#### Lynparza

On 18 December 2014, AstraZeneca announced that the European Commission (EC) had granted Marketing Authorisation for *Lynparza* (olaparib) capsules (400mg twice-daily) as the first therapy for the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response or partial response to platinum-based chemotherapy.

On 19 December 2014, AstraZeneca announced that the FDA had approved *Lynparza* capsules (400mg twice-daily) as the first monotherapy for patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer, who have been treated with three or more prior lines of chemotherapy. *Lynparza* was approved under the FDA's Accelerated Approval programme, based on existing objective response rate and duration of response data. Continued approval for this indication is contingent upon verification of clinical benefit in ongoing confirmatory Phase III trials.

#### Iressa

On 2 December 2014, AstraZeneca announced that the FDA had accepted for filing the NDA for *Iressa* (gefitinib) as a targeted monotherapy for the first line treatment of patients with advanced or metastatic epidermal growth factor receptor mutation positive (EGFRm) NSCLC, as identified through a companion diagnostic test. The Prescription Drug User Fee Act goal date for *Iressa* will be in the third guarter of 2015.

*Iressa* is an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor that acts by blocking the transmission of signals involved in the growth and spread of tumours. AstraZeneca's NDA submission for *Iressa* was based on data from the Phase IV IFUM clinical trial, providing evidence of *Iressa*'s efficacy in Caucasian patients. This was supported by results from the IPASS clinical trial, as well as other collaborative group studies.

*Iressa* is already approved in 90 countries for the treatment of adult patients with locally advanced or metastatic NSCLC with activating mutations of the EGFR tyrosine kinase.

# **Epanova STRENGTH trial start**

During the fourth quarter of 2014, AstraZeneca initiated a long-term outcomes study to assess statin residual risk reduction with *Epanova* in high cardiovascular risk patients with hypertriglyceridaemia. This trial, denoted STRENGTH, is a randomised, double-blind, well-controlled (corn oil), parallel group design that will enroll approximately 13,000 patients with hypertriglyceridaemia and high risk for cardiovascular disease. Patients are randomised one to one to either corn oil plus statin or *Epanova* plus statin, once-daily, for approximately three to five years as determined when the number of major adverse cardiac events (MACE) outcomes is reached.

#### Brilinta

On 14 January 2015, AstraZeneca announced that the PEGASUS-TIMI 54 study, a large scale outcomes trial involving over 21,000 patients, had successfully met its primary efficacy endpoint. The study assessed *Brilinta* (ticagrelor) tablets at either 60mg twice-daily or 90mg twice-daily plus low-dose aspirin for the secondary prevention of atherothrombotic events in patients who had experienced a heart attack one to three years prior to the study start. The primary efficacy endpoint was a composite of cardiovascular death, myocardial infarction or stroke.

Preliminary analysis did not reveal any unexpected safety issues. Full evaluation of the data is ongoing.

Complete results from the PEGASUS-TIMI 54 study will be presented at the American College of Cardiology Annual Scientific Sessions in San Diego, California, in March 2015. Pending further analysis, AstraZeneca plans to file this data with regulatory health authorities.

#### Moventig

On 9 December 2014, AstraZeneca announced that *Moventig* (naloxegol) had been granted Marketing Authorisation by the EC for the treatment of opioid-induced constipation in adult patients who have had an inadequate response to laxative(s). *Moventig* is the first once-daily oral peripherally-acting mu-opioid receptor antagonist to be approved in the EU.

The approval of *Moventig* was based on data from the KODIAC clinical programme, which comprised four studies: KODIAC-4, -5, -7 and -8. KODIAC-4 and -5 were both placebo controlled, double-blind, 12-week studies assessing safety and efficacy, while KODIAC-7 was a 12-week safety extension to KODIAC-4, and KODIAC-8 was a 52-week open label, long-term safety study.

Movantik/Moventig is part of an exclusive worldwide licence agreement between AstraZeneca and Nektar Therapeutics.

### Start of pivotal trial for BACE inhibitor AZD3293

On 1 December 2014, AstraZeneca and Eli Lilly & Company announced enrolment of the first patient into AMARANTH, a Phase II/III study of AZD3293, an oral beta-site amyloid precursor protein cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for Alzheimer's disease.

AZD3293, also known as LY3314814, has been shown in Phase I studies to reduce levels of amyloid-beta in the cerebro-spinal fluid of Alzheimer's patients and healthy volunteers. The progression of Alzheimer's disease is characterised by the accumulation of amyloid plaque in the brain. BACE is an enzyme associated with the development of beta-amyloid. Inhibiting BACE is expected to prevent the formation of amyloid plaque and eventually slow the progression of the disease.

The pivotal study will investigate the safety and efficacy of AZD3293 compared with placebo in the treatment of early Alzheimer's disease.

## **Business Development**

#### Licensing agreement with Omnis Pharmaceuticals for oncolytic viruses in immuno-oncology

On 12 January 2015, AstraZeneca announced that MedImmune had entered into a licensing agreement with Omnis Pharmaceuticals (Omnis), a privately-held biotechnology company focused on the development of oncolytic viruses. This agreement will allow MedImmune to combine key agents from its investigational immunotherapy portfolio with Omnis' lead investigational oncolytic virus programme, a genetically engineered strain of vesicular stomatitis virus. The programme is currently being studied in a Phase I clinical trial as a monotherapy for the treatment of hepatocellular carcinoma and other cancers that have metastasised to the liver.

## Collaborations to use CRISPR technology for genome editing in drug discovery

On 29 January 2015, AstraZeneca announced four research collaborations aimed at harnessing the power of CRISPR, a pioneering genome-editing technique, across its entire discovery platform in the Company's key therapeutic areas. The technology will allow AstraZeneca to identify and validate new drug targets in preclinical models that closely resemble human disease. AstraZeneca will share cell lines and compounds with its partners and work with them to publish findings of its application of CRISPR technology in peer-reviewed journals, contributing to broader scientific progress in the field. The collaborations complement AstraZeneca's in-house CRISPR programme and will build on the Company's 'open innovation' approach to research and development.

AstraZeneca's CRISPR research collaborations are with the following institutions: The Wellcome Trust Sanger Institute, Cambridge, UK; The Innovative Genomics Initiative, University of California, Berkley and San Francisco; Thermo Fisher Scientific, Waltham, Massachusetts; The Broad Institute/ The Whitehead Institute, Cambridge, Massachusetts.

# **Operating and Financial Review**

All narrative in this section refers to growth rates at constant exchange rates (CER) and on a Core basis unless otherwise indicated. Core measures, which are presented in addition to our Reported financial information, are non-GAAP measures which management believes useful to enhance understanding of the Group's underlying financial performance of our ongoing business and the key business drivers thereto. Core financial measures are adjusted to exclude certain significant items, such as:

- amortisation and impairment of intangibles, including impairment reversals but excluding any charges relating to IT assets
- charges and provisions related to our global restructuring programmes (this will include such charges that relate to the impact of our global restructuring programmes on our capitalised IT assets)
- other specified items, principally comprising legal settlements and transaction-related costs, which include fair value adjustments and the imputed finance charge relating to contingent consideration on business combinations

More detail on the nature of these measures is given on page 76 of our Annual Report and Form 20-F Information 2013.

#### **Fourth Quarter**

All financial figures, except earnings per share, are in \$ millions (\$m). Weighted average shares in millions. The performance shown below covers the three months to 31 December 2014 (the quarter) compared to the three months to 31 December 2013 (the prior period).

			Intangible	Acquisition of the BMS share of					
	Reported Q4 2014	Restructuring	Amortisation & Impairments	diabetes alliance	Other	Core Q4 2014	Core Q4 2013	Actual %	CER %
Revenue	6,683	-	-	-	-	6,683	6,844	(2)	2
Cost of Sales	(1,667)	35	273	-	-	(1,359)	(1,289)		
<b>Gross Profit</b>	5,016	35	273	-	-	5,324	5,555	(4)	1
% sales	75.1%					79.7%	81.2%	-1.5	-0.6
Distribution	(88)	-	-	-	-	(88)	(72)	22	28
% sales	1.3%					1.3%	1.1%	-0.2	-0.3
R&D	(1,499)	97	42	-	-	(1,360)	(1,205)	13	17
% sales	22.5%					20.4%	17.6%	-2.8	-2.6
SG&A	(4,084)	259	211	636	25	(2,953)	(2,483)	19	23
% sales	61.1%					44.2%	36.3%	-7.9	-7.6
Other Income	306	-	53	-	(98)	261	188	39	47
% sales	4.6%					3.9%	2.8%	+1.1	+1.2
Operating (Loss)/ Profit	(349)	391	579	636	(73)	1,184	1,983	(40)	(33)
% sales	(5.2%)					17.7%	29.0%	-11.3	-9.9
Net Finance Expense	(227)	-	-	96	19	(112)	(124)		
Joint Ventures	(4)	-	-	-	-	(4)	-		
(Loss)/ Profit before Tax	(580)	391	579	732	(54)	1,068	1,859	(43)	(34)
Taxation	259	(65)	(116)	(203)	6	(119)	(315)		
(Loss)/ Profit after Tax	(321)	326	463	529	(48)	949	1,544	(39)	(28)
Non-controlling Interests	-	-	-	-	-	-	(4)		
Net (Loss)/ Profit	(321)	326	463	529	(48)	949	1,540	(38)	(27)
Weighted Average Shares	1,263	1,263	1,263	1,263	1,263	1,263	1,254		
(Loss)/ Earnings per Share	(0.25)	0.26	0.37	0.42	(0.04)	0.76	1.23	(38)	(28)

Revenue in the quarter was up 2% at CER to \$6,683m. Based on actual exchange rates revenue declined by 2% reflecting the strengthening of the US dollar against key currencies. Major patent expiries to date have now largely annualised. Excluding both the additional revenue from the acquisition of BMS's share of the global diabetes alliance and the \$113m impact of the Branded Pharmaceutical Fee restatement (see below), revenue in the quarter was stable versus the prior period.

In July 2014, the US Internal Revenue Service issued final regulations that affected how the annual Branded Pharmaceutical Fee (the Fee), imposed by the health care reform legislation in 2010, is recognised. As a result, entities covered by the legislation will now accrue for the obligation as each sale occurs. AstraZeneca recorded a catch-up charge to SG&A, reflecting this new basis, as part of its third quarter results. Under the new regulations the Fee will be based on actual sales in the current year. It is therefore more appropriate to account for the Fee as a deduction from revenue rather than a charge to SG&A. From the fourth quarter, AstraZeneca has changed its income statement categorisation accordingly, and reclassified the charge of \$113m relating to the second half from SG&A to revenue in the fourth quarter. The Company has not restated its third quarter 2014 performance. This income statement reclassification has no impact on earnings.

Core gross margin as a percentage of revenue was 79.7% in the quarter, down by 0.6 percentage points. Excluding the impact of the Fee restatement, the Core gross margin was 80.0%.

Core R&D costs were up 17% to \$1,360m, primarily reflecting the acceleration in the late-stage pipeline and additional costs incurred on assets acquired through business development activities.

Core SG&A costs were up 23% to \$2,953m. A decline in G&A costs was more than offset by significant investments in Sales and Marketing costs that have increased from the prior period with the acquisition of BMS's share of the global diabetes alliance. Additional costs were incurred in the fourth quarter to support ongoing launches, including *Farxiga/Forxiga* and *Lynparza*, as well as for pre-launch activities for *Movantik/Moventig* and the late-stage pipeline, including the oncology portfolio.

Core other income of \$261m was up 47% in the quarter reflecting gains on disposals, as well as development income relating to blinatumomab and *Duaklir*.

Core operating profit was down 33% to \$1,184m. Core operating margin was down 9.9 percentage points to 17.7% of revenue as the Company continued to invest in the pipeline and the growth platforms.

Core earnings per share were down 28% to \$0.76, broadly in line with the decrease in Core operating profit, as the impact of a higher number of shares was outweighed by a lower tax rate versus the prior quarter.

The Reported operating loss was \$349m, 59% lower than the loss last year. Reported loss per share was similarly down by 69% at \$0.25. The lower Core operating profit detailed above was more than offset by lower Core adjustments, as the prior period included a one-off intangible impairment charge relating to *Bydureon*.

## Full year

All financial figures, except earnings per share, are in \$ millions (\$m). Weighted average shares in millions. The performance shown below covers the twelve months to 31 December 2014 (the year) compared to the twelve months to 31 December 2013 (the prior year).

				Acquisition of the BMS					
	Reported FY 2014	Restructuring	Intangible Amortisation & Impairments	share of diabetes alliance	Other	Core FY 2014	Core FY 2013	Actual %	CER %
Revenue	26,095	-	-	-	-	26,095	25,711	1	3
Cost of Sales	(5,842)	107	701	146	-	(4,888)	(4,633)		
Gross Profit	20,253	107	701	146	-	21,207	21,078	1	3
% sales	77.6%					81.3%	82.0%	-0.7	-0.4
Distribution	(324)	-	-	-	-	(324)	(306)	6	7
% sales	1.3%					1.3%	1.2%	-0.1	-
R&D	(5,579)	497	141	-	-	(4,941)	(4,269)	16	15
% sales	21.3%					18.9%	16.6%	-2.3	-1.9
SG&A	(13,000)	662	811	932	379	(10,216)	(8,865)	15	16
% sales	49.8%					39.1%	34.5%	-4.6	-4.4
Other Income	787	292	230	-	(98)	1,211	752	61	64
% sales	3.0%					4.6%	2.9%	+1.7	+1.7
Operating Profit	2,137	1,558	1,883	1,078	281	6,937	8,390	(17)	(13)
% sales	8.2%					26.6%	32.6%	-6.0	-5.0
Net Finance Expense	(885)	-	-	345	47	(493)	(445)		
Joint Ventures	(6)	-	-	-	-	(6)	1		
Profit before Tax	1,246	1,558	1,883	1,423	328	6,438	7,945	(19)	(13)
Taxation	(11)	(255)	(376)	(356)	(42)	(1,040)	(1,611)		
Profit after Tax	1,235	1,303	1,507	1,067	286	5,398	6,334	(15)	(8)
Non-controlling Interests	(2)	-	-	-	-	(2)	(15)		
Net Profit	1,233	1,303	1,507	1,067	286	5,396	6,319	(15)	(8)
Weighted Average Shares	1,262	1,262	1,262	1,262	1,262	1,262	1,252		
Earnings per Share	0.98	1.03	1.19	0.85	0.23	4.28	5.05	(15)	(8)

Revenue in the year was up 3% at CER to \$26,095m, in line with upgraded Company guidance, and up 1% on an actual basis as a result of the negative impact of exchange rate movements. Accelerating performance of the Company's growth platforms more than offset the impact of loss of exclusivity. US revenue was up 4% to \$10,120m, with Europe down 1% at \$6,638m, Established Rest of World (ROW) was down 4% at \$3,510m and Emerging Markets were up 12% to \$5,827m, the latter, driven by growth in China of 22%, to \$2,242m. China became the Company's second largest national market in 2014. Global revenue in the year was stable, excluding the additional revenue from the acquisition of BMS's share of the global diabetes alliance and the impact of the Fee restatement.

Core gross margin as a percentage of revenue was 81.3% in the year, down by 0.4 percentage points.

Core R&D expense in the year was up 15% to \$4,941m, reflecting the expansion of the late-stage pipeline.

Expenditures in Core SG&A were up 16% to \$10,216m, driven by the investment in sales and marketing dedicated to the growth platforms. The selective investment in the growth platforms is partially funded by the decline in G&A costs during the year.

Core other income in the year was up 64% at \$1,211m, with milestone income related to the launch of *Nexium* OTC being the largest driver of the increase.

Core operating profit in the year was down 13% to \$6,937m. Core operating margin was 26.6% of revenue, down 5.0 percentage points. The Company continues to focus on delivering the flexibility needed to underpin the progressive dividend, strong pipeline progress and the return to growth.

Core earnings per share were \$4.28, down 8% versus the prior year and in line with upgraded Company guidance. The smaller decline compared with Core operating profit is largely due to a lower tax rate. This favourable comparison arising from the tax rate was partially offset by an increase in the number of shares outstanding and a marginally higher Core finance expense in the year compared with the prior year.

Core operating profit adjustments totalled \$4,800m this year, marginally higher than the \$4,678m in the prior year. The deduction of these broadly similar Core adjustments naturally leads to a larger percentage decline in

Reported operating profit than Core operating profit. Accordingly, Reported operating profit is down 31% to \$2,137m; and, as a consequence, Reported EPS is down to 34%.

#### **Enhancing Productivity**

Restructuring charges of \$391m were taken in the quarter, bringing the full-year total to \$1,558m. The Company is making good progress in implementing the fourth phase of restructuring announced in the first quarter of 2013 and the expansion of this programme announced in the first half of 2014. In addition to costs of this programme the restructuring charge for the year includes \$261m incurred on integration of businesses acquired in the year and as a consequence of our decision to exit the Westborough site.

#### Finance Income and Expense

Core net finance expense was \$493m versus \$445m in the prior year. Reported net finance expense includes a charge of \$391m relating to the discount unwind on contingent consideration creditors recognised on business combinations, principally relating to the acquisition of BMS's share of the global diabetes alliance.

#### **Taxation**

The tax paid for the year was \$1,201m which is 96% of reported profit and 19% of Core profit.

Both the underlying Reported and underlying Core tax rates for the year were around 18%.

Taking into account the one-off benefits totalling \$309m in respect of a transfer pricing matter, non-Core revaluations of contingent consideration arising on business combinations, and the benefit of the UK Patent Box, the Reported and Core tax rates fall to 1% and 16% respectively.

The Reported and Core tax rates for the year ended 31 December 2013 were 21% and 20% respectively.

#### Cash Flow

Cash generated from operating activities in the year was \$7,058m, compared with \$7,400m in the prior year, with improvements in working capital negating the lower operating profit and higher tax payments.

Net cash outflows from investing activities were \$7,032m compared with \$2,889m in the prior year. The increase is primarily due to upfront and contingent consideration payments of \$4,461m made in respect of acquisitions including BMS's share of the global diabetes alliance and the strategic transaction with Almirall in respiratory disease.

Net cash distributions to shareholders were \$3,242m through dividends of \$3,521m offset by proceeds from the issue of shares of \$279m due to the exercise of stock options.

# **Debt and Capital Structure**

At 31 December 2014, outstanding gross debt (interest-bearing loans and borrowings) was \$10,843m (31 December 2013: \$10,376m). Of the gross debt outstanding at 31 December 2014, \$2,446m was due within one year (31 December 2013: \$1,788m).

The Company's net debt position at 31 December 2014 was \$3,223m.

# Shares in Issue

During 2014, 6.0 million shares were issued in respect of share option exercises for a consideration of \$279m.

The total number of shares in issue at 31 December 2014 was 1,263 million.

# Dividends and share repurchases

The Board has recommended a second interim dividend of \$1.90 (125.0 pence, 15.62 SEK) to be paid on 23 March 2015. This brings the full year dividend to \$2.80 (178.1 pence, 21.82 SEK). This dividend is consistent with the progressive dividend policy, by which the Board intends to maintain or grow the dividend each year.

The Board regularly reviews its distribution policy and its overall financial strategy to continue to strike a balance between the interests of the business, financial creditors and shareholders. The Board continues to target a strong, investment grade credit rating. Having regard for business investment, funding the progressive dividend policy and meeting debt service obligations, the Board currently has no intention to resume the share buyback

## programme.

# **Future Prospects**

- Sales revenue is expected to decline by mid single-digit percent at CER<sup>1</sup>. Consistent with its business model, the Company will continue to seek externalisation revenue from partnerships and licensing select products and technologies. Core EPS is expected to increase by low single-digit percent at CER.
- The Company also provides the following non-guidance information related to currency sensitivity: Based on current exchange rates<sup>2</sup>, sales revenue is expected to decline by low double-digit percent with Core EPS expected to be broadly in line with 2014. For additional currency sensitivity information, please see below.

		Average ex rates versu				cening in exchange S USD (\$m) <sup>3</sup>
_	Primary relevance	2014	January 2015 <sup>2</sup>	Change %	Sales revenue	Core operating profit
EUR	Sales revenue	0.75	0.86	(12)	(196)	(120)
JPY	Sales revenue	105.87	118.44	(11)	(105)	(75)
SEK	Costs	6.86	8.09	(15)	(5)	96
GBP	Costs	0.61	0.66	(8)	(34)	104
Other <sup>4</sup>					(214)	(123)

<sup>&</sup>lt;sup>1</sup>Assumes imminent launch of a Nexium generic in the US market. <sup>2</sup>Based on average daily spot rates in January 2015.

<sup>&</sup>lt;sup>3</sup>Based on 2014 actual group currency exposures.

<sup>&</sup>lt;sup>4</sup>Other important currencies include AUD, BRL, CAD, KRW, RUB.

#### Revenue

All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated. Financial figures are in \$ millions (\$m). A full analysis of the Group's revenue by product and geographic areas is shown in Notes 9 and 10.

	Fourth	Quarter			Full \	⁄ear		
	2014	2013	% Ch	ange	2014	2013	% Ch	ange
	\$m	\$m	Actual	CER	\$m	\$m	Actual	CER
Cardiovascular and Metabolic								
disease								
Crestor	1,388	1,463	(5)	(2)	5,512	5,622	(2)	(1)
Seloken/Toprol-XL	174	170	2	8	758	750	1	4
Onglyza	200	93	115	122	820	378	117	119
Atacand	117	134	(13)	(7)	501	611	(18)	(16)
Brilinta/Brilique	133	92	45	52	476	283	68	70
Byetta	69	54	28	31	327	206	59	59
Bydureon	123	49	151	153	440	151	191	191
Oncology								
Zoladex	227	247	(8)	(2)	924	996	(7)	(4)
Iressa	150	158	(5)	2	623	647	(4)	(1)
Faslodex	182	182	-	4	720	681	6	7
Arimidex	68	86	(21)	(15)	298	351	(15)	(12)
Casodex	74	95	(22)	(16)	320	376	(15)	(10)
			(/	(10)	0_0	0.0	(10)	(10)
Respiratory, Inflammation and								
Autoimmunity								
Symbicort	978	976	-	5	3,801	3,483	9	10
Pulmicort	269	245	10	15	946	867	9	11
Infection Neuropsians and								
Infection, Neuroscience and Gastrointestinal								
Nexium	832	991	(16)	(13)	3,655	3,872	(6)	(4)
Synagis	404	515	(22)	(22)	900	1,060	(15)	(15)
Seroquel XR	309	337	`(9)	`(6)	1,224	1,337	(9)	(8)
Seroquel IR	(28)	35	n/m	n/m	178	345	(48)	(46)

#### Cardiovascular and Metabolic disease

- In the US, Crestor sales in the fourth quarter were \$760m, down 2% due primarily to the impact of the accounting changes for the Branded Pharmaceutical Fee (the Fee). Crestor total prescriptions decreased by 4%, but were fully offset by higher stocking in the fourth quarter. Crestor sales for 2014 were stable, as net price realisation including prior year rebate adjustments offset the Fee impact and volume declines.
- Crestor sales in the ROW in the fourth quarter were down 1% to \$628m. This reflected the annualisation of the impact of generic competition in Australia and price pressure in Japan, partially offset by growth in Emerging Markets, driven by 36% growth in China. Crestor sales in the ROW for 2014 were down 2% to \$2,594m.
- US sales of the *Toprol-XL* product range, which includes sales of the authorised generic, were down 21% in the quarter to \$15m due to additional generic entrants. *Seloken* sales in the ROW were up 12% to \$159m driven by Emerging Markets which were up 19% in the quarter. Global *Seloken* sales in 2014 (excluding the authorised generic) were up 7% to \$715m.
- Onglyza franchise revenue was up 122% in the fourth quarter to \$200m. In the US, Onglyza franchise sales were up 60% in fourth quarter as the benefit from the change in ownership was partially offset by 7% lower prescription volume and lower net price driven primarily by more competition. Onglyza fourth quarter revenue in the ROW was up 250% with strength across all regions. Global revenue in 2014 was \$820m, up 119%.
- Sales of Atacand were down 7% in the quarter to \$117m as generic competition in Europe and Established ROW overshadowed 18% growth in Emerging Markets. Sales for 2014 were down 16% to \$501m.
- Sales of Brilinta/Brilique were \$133m in the fourth quarter, up 52%. Excluding the US, growth in revenue terms

was driven primarily by Europe which grew by 25% and the smaller, but faster growing, Emerging Markets which were up 118%. Sales for 2014 were up 70% to \$476m.

- Brilinta sales in the US in the fourth quarter were \$43m, up 79%. Total prescriptions for Brilinta in the US in the fourth quarter of 2014 were 13% higher than the third quarter of 2014. New to brand share increased by 0.7 percentage points to 8.2% in December and Brilinta achieved US branded leadership for the first time during the fourth quarter and in December weekly exit share. The impact of the accounting changes for the Fee reduced revenue in the fourth quarter by 4%. 2014 Brilinta sales in the US doubled to \$146m.
- Byetta and Bydureon fourth quarter revenues in the US were \$142m, up 87%. Bydureon total prescriptions grew 40% in the quarter and grew 9% over the prior quarter, driven by the launch of the Bydureon Pen in September. ROW revenue was \$50m, up 96% driven by European Bydureon revenue. Global 2014 revenue was \$767m, up 115%.

## Oncology

- Zoladex sales were \$227m in the fourth quarter down 2% as 50% growth in China was offset by overall declines. 2014 revenue was \$924m, down 4%.
- *Iressa* sales in the fourth quarter were up 2% to \$150m, driven by 13% growth in Emerging Markets. 2014 sales of *Iressa* were down 1% at \$623m.
- Arimidex sales were down 15% in the fourth quarter at \$68m and 12% for the year, as growth in the Emerging
  Markets was more than offset by the ongoing impact of loss of exclusivity.
- Sales of *Casodex* in 2014 were \$320m, down 10%. Generic competition drove the reduction, most significantly in Japan which was down 19%. These losses were only partially offset by 14% growth in Emerging Markets.

#### Respiratory, Inflammation and Autoimmunity

- Symbicort sales in the US were \$395m in the fourth quarter, a 13% increase over last year but decelerating. Total prescriptions for Symbicort were up 32% in the fourth quarter. Symbicort share of total prescriptions for fixed combination products reached 33.1% in December 2014, increasing 6.8 percentage points over 2014. Higher retail demand was partially offset by lower non-retail demand and lower price due to the Fee and higher fourth quarter co-pay assistance costs beginning in advance of expected unfavourable formulary changes in 2015. 2014 Symbicort sales in the US were up 23% to \$1,511m.
- Symbicort sales in the ROW in the fourth quarter were stable at \$583m. Sales in Europe were down 7% due to
  price pressure driven by increasing competition from recently-launched competitive analogues. European
  declines were partially offset by 25% growth in Emerging Markets and 2% growth in Established ROW.
  Symbicort sales in the ROW in 2014 were up 4% to \$2,290m.
- Sales of *Pulmicort* were up 15% to \$269m in the fourth quarter driven by 39% growth in Emerging Markets. Excluding Emerging Markets, *Pulmicort* sales were down 4% to \$125m. 2014 sales were up 11% to \$946m driven by 35% growth in Emerging Markets.

## Infection, Neuroscience and Gastrointestinal

- In the US, *Nexium* sales in the fourth quarter were \$469m, down 14% driven by volume erosion and the impact of the accounting changes for the Fee. 2014 *Nexium* sales were down 12% to \$1,876m with lower volume also the driver.
- Nexium sales in the ROW in the fourth quarter were down 13% to \$363m. The decline was driven by generic competition in many markets as well as year-end destocking in China and a recall related to packaging in Japan. For 2014 ROW Nexium sales were up 6% to \$1,779m, driven by 38% growth in Japan and 21% growth in China.
- In the US, sales of *Synagis* in the fourth quarter were \$234m, down 22%. The decline was driven by approximately 50% lower volume related to the American Academy of Pediatrics Committee on Infectious Disease guidelines issued in mid-2014. These new guidelines further restrict patients' eligibility for preventive therapy with *Synagis*. While these guideline changes are inconsistent with the approved label, there has been a significant impact to volumes which is expected to extend into 2015. Partially offsetting the lower volume was a favourable adjustment to Medicaid provisions. Outside the US, sales in the fourth quarter were \$170m, down 21%, which mostly reflects the lower price and quarterly phasing of revenues related to shipments to AbbVie, the distributor outside the US. 2014 sales were down 15% at \$900m, driven by a 9% decline outside the US and 19% decline in the US, where a 29% reduction in volume was offset by favourable price adjustments.

- Sales of Seroquel XR in the US were \$196m in the fourth quarter, up 1% due primarily to underlying net price, partially offset by the impact related to the change in accounting for the Fee. 2014 US sales were \$738m, down 1%.
- Sales of Seroquel XR in the ROW were down 15% to \$113m in the fourth quarter, as a result of generic competition (including some "at risk" launches) in Europe where sales were down 18%.
- Sales of Seroquel IR in the US were negative \$92m in the fourth quarter driven by refinements to our returns
  provision to incorporate a higher rate of product returns experienced in the second half of 2014. The increase in
  returns coincides with the shelf-life expiration of product in the channel at the date of loss of exclusivity. For
  2014 sales were negative \$72m for the same reason.
- Sales of Seroquel IR in the ROW were \$64m in the fourth quarter and \$250m for 2014, down 28% for the year largely due to generic competition.

### **Regional Revenue**

US
Europe
Established ROW<sup>1</sup>
Japan
Canada
Other Established ROW
Emerging Markets<sup>2</sup>
China
Total

Fourth (	Quarter			Full	Year		
2014	2013	% Change		2014	2013	% Ch	ange
\$m	\$m	Actual	CER	\$m	\$m	Actual	CER
2,641	2,634	-	-	10,120	9,691	4	4
1,713	1,822	(6)	-	6,638	6,658	-	(1)
851	1,023	(17)	(8)	3,510	3,973	(12)	(4)
543	668	(19)	(9)	2,227	2,485	(10)	(3)
157	161	(2)	4	590	637	(7)	(1)
151	194	(22)	(16)	693	851	(19)	(13)
1,478	1,365	8	14	5,827	5,389	8	12
566	477	18	19	2,242	1,840	22	22
6,683	6,844	(2)	2	26,095	25,711	1	3

<sup>&</sup>lt;sup>1</sup>Established ROW comprises Canada, Japan, Australia and New Zealand.

- Revenue in the US was stable in the fourth quarter at \$2,641m. Growth platforms were strong, aided in part by the impact of completing the acquisition of BMS's share of the global diabetes alliance. Diabetes products provided \$157m of incremental revenue, with growth from *Symbicort* and *Brilinta* also helping to offset declines in revenue from brands such as *Nexium*, *Seroquel IR*, and *Synagis*, in addition to the \$113m reduction in fourth quarter revenue taken against product brands related to the change in accounting for the Branded Pharmaceutical Fee.
- In the fourth quarter, revenue in Europe was also stable as the favourable impact from the acquisition of BMS's share of the global diabetes alliance and continued growth for Brilinta were offset by impact of Symbicort analogues in Europe, continuing impact from loss of exclusivity on brands including Seroquel and Atacand, and lower net pricing on Synagis.
- Revenue in Established ROW was down 8% in the quarter due to generic pressure, only partially moderated by performance of growth platforms. Revenue in Japan declined by 9% in the fourth quarter, impacted by a recall of *Nexium* in December due to a packaging defect, de-stocking, and the mandated April 2014 biennial price cut.
- Revenue in Emerging Markets was up 14% in the quarter. Strong growth was seen across the Emerging Markets business with China growing 19%, despite higher destocking in the quarter. Excluding China, the Emerging Markets grew by 12% in the fourth quarter. Primary drivers of growth were Respiratory and Cardiovascular products.

<sup>&</sup>lt;sup>2</sup>Emerging Markets comprises all remaining ROW markets, including Brazil, China, India, Mexico, Russia, and Turkey.

# **Condensed Consolidated Statement of Comprehensive Income**

For the <b>year</b> ended 31 December	2014 \$m	2013 \$m
Revenue	26,095	25,711
Cost of sales	(5,842)	(5,261)
Gross profit	20,253	20,450
Distribution costs	(324)	(306)
Research and development expense	(5,579)	(4,821)
Selling, general and administrative costs	(13,000)	(12,206)
Other operating income and expense	787	595
Operating profit	2,137	3,712
Finance income	78	50
Finance expense	(963)	(495)
Share of after tax losses of joint ventures	(6)	
Profit before tax	1,246	3,267
Taxation	(11)	(696)
Profit for the period	1,235	2,571
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(766)	8
Tax on items that will not be reclassified to profit or loss	216	(82)
	(550)	(74)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(823)	(166)
Foreign exchange arising on designating borrowings in net investment hedges	(529)	(58)
Fair value movements on derivatives designated in net investment hedges	100	111
Amortisation of loss on cash flow hedge	1	1
Net available for sale gains taken to equity	245	69
Tax on items that may be reclassified subsequently to profit or loss	50	4
	(956)	(39)
Other comprehensive income for the period, net of tax	(1,506)	(113)
Total comprehensive income for the period	(271)	2,458
Profit attributable to:		
Owners of the Parent	1,233	2,556
Non-controlling interests	2	15
	1,235	2,571
Total commonly in the same of		
Total comprehensive income attributable to:	45 1	<u>.</u> .=.
Owners of the Parent	(266)	2,470
Non-controlling interests	(5)	(12)
	(271)	2,458
Basic earnings per \$0.25 Ordinary Share	\$0.98	\$2.04
Diluted earnings per \$0.25 Ordinary Share	\$0.98	\$2.04
Weighted average number of Ordinary Shares in issue (millions)	1,262	1,252
	· ,— • —	.,

# **Condensed Consolidated Statement of Comprehensive Income**

For the <b>quarter</b> ended 31 December	2014 \$m	2013 \$m
Revenue	6,683	6,844
Cost of sales	(1,667)	(1,440)
Gross profit	5,016	5,404
Distribution costs	(88)	(72)
Research and development expense	(1,499)	(1,429)
Selling, general and administrative costs	(4,084)	(4,642)
Other operating income and expense	306	148
Operating loss	(349)	(591)
Finance income	33	13
Finance expense	(260)	(137)
Share of after tax losses of joint ventures	(4)	-
Loss before tax	(580)	(715)
Taxation	259	195
Loss for the period	(321)	(520)
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(268)	247
Tax on items that will not be reclassified to profit or loss	89	(44)
	(179)	203
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(411)	(26)
Foreign exchange arising on designating borrowings in net investment hedges	(237)	(35)
Fair value movements on derivatives designated in net investment hedges	64	51
Net available for sale gains taken to equity	172	10
Tax on items that may be reclassified subsequently to profit or loss	20	3
	(392)	3
Other comprehensive income for the period, net of tax	(571)	206
Total comprehensive income for the period	(892)	(314)
Loss attributable to:		
Owners of the Parent	(224)	(524)
	(321)	(524)
Non-controlling interests	(321)	(520)
	(021)	(020)
Total comprehensive income attributable to:		
Owners of the Parent	(892)	(315)
Non-controlling interests		1
	(892)	(314)
Basic (loss)/earnings per \$0.25 Ordinary Share	(\$0.25)	(\$0.42)
Diluted (loss)/earnings per \$0.25 Ordinary Share	(\$0.25)	(\$0.42)
	<del></del>	
Weighted average number of Ordinary Shares in issue (millions)  Diluted weighted average number of Ordinary Shares in issue (millions)	1,263	1,254 1,256
Direct weighted average number of Ordinary Shares in Issue (millions)	1,265	1,256

# **Condensed Consolidated Statement of Financial Position**

	At 31 Dec 2014 \$m	At 31 Dec 2013 \$m
ASSETS	ψιιι	ΨΠ
Non-current assets		
Property, plant and equipment	6,010	5,818
Goodwill	11,550	9,981
Intangible assets	20,981	16,047
Derivative financial instruments	465	365
Investments in joint ventures	59	-
Other investments	502	281
Other receivables	1,112	1,867
Deferred tax assets	1,219	1,205
	41,898	35,564
Current assets		
Inventories	1,960	1,909
Trade and other receivables	7,232	7,879
Other investments	795	796
Derivative financial instruments	21	40
Income tax receivable	329	494
Cash and cash equivalents	6,360	9,217
	16,697	20,335
Total assets	58,595	55,899
LIABILITIES		
Current liabilities		
Interest-bearing loans and borrowings	(2,446)	(1,788)
Trade and other payables	(11,886)	(10,362)
Derivative financial instruments	(21)	(2)
Provisions	(623)	(823)
Income tax payable	(2,354)	(3,076)
	(17,330)	(16,051)
Non-current liabilities		
Interest-bearing loans and borrowings	(8,397)	(8,588)
Derivative financial instruments	-	(1)
Deferred tax liabilities	(1,796)	(2,827)
Retirement benefit obligations	(2,951)	(2,261)
Provisions	(484)	(566)
Other payables	(7,991)	(2,352)
	(21,619)	(16,595)
Total liabilities	(38,949)	(32,646)
Net assets	19,646	23,253
EQUITY		
Capital and reserves attributable to equity holders of the Company		
Share capital	316	315
Share premium account	4,261	3,983
Other reserves	2,021	1,966
Retained earnings	13,029	16,960
	19,627	23,224
Non-controlling interests	19	29
Total equity	19,646	23,253
···		

# **Condensed Consolidated Statement of Cash Flows**

For the <b>year</b> ended 31 December	2014 \$m	2013 \$m
Cash flows from operating activities		
Profit before tax	1,246	3,267
Finance income and expense	885	445
Share of after tax losses of joint ventures	6	-
Depreciation, amortisation and impairment	3,282	4,583
Decrease in working capital and short-term provisions	2,508	166
Non-cash and other movements	865	258
Cash generated from operations	8,792	8,719
Interest paid	(533)	(475)
Tax paid	(1,201)	(844)
Net cash inflow from operating activities	7,058	7,400
Cash flows from investing activities	<del></del>	
Movement in short-term investments and fixed deposits	34	130
Purchase of property, plant and equipment	(1,012)	(742)
Disposal of property, plant and equipment	158	69
Purchase of intangible assets	(1,740)	(1,316)
Disposal of intangible assets	-	35
Purchase of non-current asset investments	(130)	(91)
Disposal of non-current asset investments	59	38
Payments to joint ventures	(70)	-
Upfront payments on business acquisitions	(3,804)	(1,158)
Payment of contingent consideration on acquisitions	(657)	-
Interest received	140	114
Payments made by subsidiaries to non-controlling interests	(10)	(10)
Payments received by subsidiaries from non-controlling interests	-	42
Net cash outflow from investing activities	(7,032)	(2,889)
Net cash inflow before financing activities	26	4,511
Cash flows from financing activities		
Proceeds from issue of share capital	279	482
Issue of loans	919	-
Repayment of loans	(750)	-
Dividends paid	(3,521)	(3,461)
Hedge contracts relating to dividend payments	(14)	(36)
Repayment of obligations under finance leases	(36)	(27)
Payments to acquire non-controlling interest	(102)	-
Movement in short-term borrowings	520	(5)
Net cash outflow from financing activities	(2,705)	(3,047)
Net (decrease)/increase in cash and cash equivalents in the period	(2,679)	1,464
Cash and cash equivalents at the beginning of the period	8,995	7,596
Exchange rate effects	(152)	(65)
Cash and cash equivalents at the end of the period	6,164	8,995
Cash and cash equivalents consists of:		
Cash and cash equivalents	6,360	9,217
Overdrafts	(196)	(222)
	6,164	8,995

# **Condensed Consolidated Statement of Changes in Equity**

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non- controlling interests \$m	Total equity \$m
At 1 Jan 2013	312	3,504	1,960	17,955	23,731	215	23,946
Profit for the period	-	-	-	2,556	2,556	15	2,571
Other comprehensive income	-	-	-	(86)	(86)	(27)	(113)
Transfer to other reserves	-	-	6	(6)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,499)	(3,499)	-	(3,499)
Issue of Ordinary Shares	3	479	-	-	482	-	482
Share-based payments	-	-	-	(57)	(57)	-	(57)
Transfer from non- controlling interests to payables	-	-	-	-	-	(6)	(6)
Dividend paid to non- controlling interests	-	-	-	-	-	(3)	(3)
Net acquisition of non- controlling interests	-	-		97	97	(165)	(68)
Net movement	3	479	6	(995)	(507)	(186)	(693)
At 31 Dec 2013	315	3,983	1,966	16,960	23,224	29	23,253
	Share	Share premium	Other	Retained	Tatal	Non- controlling	Total
	capital \$m_	account \$m	reserves* \$m	earnings \$m	Total \$m	interests \$m_	equity \$m
At 1 Jan 2014							
At 1 Jan 2014  Profit for the period	<u>\$m</u>	\$m	\$m	\$m	\$m	\$m	\$m_
	<u>\$m</u>	\$m	\$m	\$m 16,960	\$m 23,224	\$m	23,253
Profit for the period Other comprehensive	<u>\$m</u>	\$m	\$m	16,960 1,233	23,224 1,233	*m 29	23,253 1,235
Profit for the period Other comprehensive income	<u>\$m</u>	\$m	\$m 1,966 - -	16,960 1,233 (1,499)	23,224 1,233	*m 29	23,253 1,235
Profit for the period Other comprehensive income Transfer to other reserves Transactions with	<u>\$m</u>	\$m	\$m 1,966 - -	16,960 1,233 (1,499)	23,224 1,233	*m 29	23,253 1,235
Profit for the period Other comprehensive income Transfer to other reserves Transactions with owners:	<u>\$m</u>	\$m	\$m 1,966 - -	16,960 1,233 (1,499) (40)	23,224 1,233 (1,499)	*m 29	23,253 1,235 (1,506)
Profit for the period Other comprehensive income Transfer to other reserves Transactions with owners: Dividends	315 - - -	\$m 3,983 - - -	\$m 1,966 - -	16,960 1,233 (1,499) (40)	23,224 1,233 (1,499) - (3,532)	*m 29	23,253 1,235 (1,506)
Profit for the period Other comprehensive income Transfer to other reserves Transactions with owners: Dividends Issue of Ordinary Shares	315 - - -	\$m 3,983 - - -	\$m 1,966 - -	\$m 16,960 1,233 (1,499) (40)	23,224 1,233 (1,499) - (3,532) 279	*m 29	23,253 1,235 (1,506) - (3,532) 279
Profit for the period Other comprehensive income Transfer to other reserves Transactions with owners: Dividends Issue of Ordinary Shares Share-based payments Transfer from non-controlling interests to	315 - - -	\$m 3,983 - - -	\$m 1,966 - -	\$m 16,960 1,233 (1,499) (40)	23,224 1,233 (1,499) - (3,532) 279		23,253 1,235 (1,506) - (3,532) 279 (93)
Profit for the period Other comprehensive income Transfer to other reserves Transactions with owners: Dividends Issue of Ordinary Shares Share-based payments Transfer from non-controlling interests to payables True-up to Astra AB non-	315 - - -	\$m 3,983 - - -	1,966	\$m 16,960 1,233 (1,499) (40)	\$m 23,224 1,233 (1,499) - (3,532) 279 (93)		23,253 1,235 (1,506) - (3,532) 279 (93) (5)

<sup>\*</sup> Other reserves includes the capital redemption reserve and the merger reserve.

# Notes to the Interim Financial Statements

#### 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the year ended 31 December 2014 has been prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB). There have been no significant changes in accounting policies from those set out in AstraZeneca PLC's Annual Report and Form 20-F Information 2013.

The annual financial statements of the Group are prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the EU and as issued by the IASB. As required by the Disclosure and Transparency Rules of the Financial Conduct Authority, the interim financial statements have been prepared applying the accounting policies and presentation that were applied in the preparation of the Company's published consolidated financial statements for the year ended 31 December 2013. There have been no significant new or revised accounting standards applied in the year ended 31 December 2014.

The information contained in Note 8 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2013.

The Group has considerable financial resources available. As at 31 December 2014, the Group has \$7.0bn in financial resources (cash balances of \$6.4bn and undrawn committed bank facilities of \$3.0bn which are available until April 2019, with only \$2.4bn of debt due within one year).

The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully.

On the basis of the above paragraph and after making enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the preliminary announcement has been prepared on a going concern basis.

The financial information included in the preliminary announcement does not constitute statutory accounts of the Group for the years ended 31 December 2014 and 2013 but is derived from those accounts. Statutory accounts for 2013 have been delivered to the registrar of companies and those for 2014 will be delivered in due course. Those accounts have been reported on by the Group's auditor; their reports were (i) unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

## 2 NET FUNDS

The table below provides an analysis of net funds and a reconciliation of net cash flow to the movement in net funds.

	At 1 Jan 2014 \$m	Cash Flow \$m	Non-cash Movements \$m	Exchange Movements \$m	At 31 Dec 2014 \$m
Loans due after one year	(8,516)	(919)	1,049	49	(8,337)
Finance leases due after one year	(72)		8	4	(60)
Total long term debt	(8,588)	(919)	1,057	53	(8,397)
Current instalments of loans	(766)	750	(1,019)	123	(912)
Current instalments of finance leases	(30)	36	(57)	3	(48)
Total current debt	(796)	786	(1,076)	126	(960)
Other investments - current	796	(38)	85	(48)	795
Net derivative financial instruments	402	18	45	-	465
Cash and cash equivalents	9,217	(2,702)	-	(155)	6,360
Overdrafts	(222)	23	-	3	(196)
Short-term borrowings	(770)	(520)			(1,290)
	9,423	(3,219)	130	(200)	6,134
Net funds/(debt)	39	(3,352)	111	(21)	(3,223)

Non-cash movements in the period include fair value adjustments under IAS 39.

#### 3 RESTRUCTURING COSTS

Profit before tax for the year ended 31 December 2014 is stated after charging restructuring costs of \$1,558m (\$391m for the fourth quarter 2014). These have been charged to profit as follows:

	4 <sup>th</sup> Quarter 2014 \$m	4 <sup>th</sup> Quarter 2013 \$m	Full Year 2014 \$m	Full Year 2013 \$m
Cost of sales	35	22	107	126
Research and development expense	97	84	497	490
Selling, general and administrative costs	259	279	662	805
Other income	-	-	292	-
Total	391	385	1,558	1,421

#### 4 ACQUISITION OF BMS SHARE OF GLOBAL DIABETES ALLIANCE ASSETS

On 1 February 2014, AstraZeneca completed the acquisition of Bristol-Myers Squibb's (BMS) interests in the companies' diabetes alliance. The acquisition provides AstraZeneca with 100% ownership of the intellectual property and global rights for the development, manufacture and commercialisation of the diabetes business, which includes Onglyza (saxagliptin), Kombiglyze XR (saxagliptin and metformin HCl extended release), Komboglyze (saxagliptin and metformin HCl), Farxiga (dapagliflozin, marketed as Forxiga outside the US), Byetta (exenatide), Bydureon (exenatide extended release for injectable suspension), Myalept (metreleptin) and Symlin (pramlintide acetate).

The transaction consolidates worldwide ownership of the diabetes business within AstraZeneca, leveraging its primary and specialty care capabilities and its geographical reach, especially in emerging markets. The transaction included the acquisition of 100% of the share capital of Amylin Pharmaceuticals, LLC, and the asset purchase of the additional intellectual property and global rights not already owned by AstraZeneca, for the development, manufacture and commercialisation of Onglyza, Kombiglyze XR, Komboglyze and Farxiga, including associated BMS employees. This combination of intangible product rights and manufacturing assets with an established work force and their associated operating processes, principally those related to the global manufacturing and selling and marketing operations, requires that the acquisition is accounted for as a business combination in accordance with IFRS 3 Business Combinations.

Upfront consideration for the acquisition of \$2.7bn was paid on 1 February 2014, with further payments of up to \$1.4bn being payable for future regulatory, launch and sales-related milestones. AstraZeneca has also agreed to pay various sales-related royalty payments up until 2025. The amount of royalties payable under the agreement is inherently uncertain and difficult to predict, given the direct link to future sales and the range of outcomes cannot be reliably estimated. The maximum amount payable in each year is with reference to net sales. AstraZeneca also agreed to make payments up to \$225m upon the transfer of certain additional assets. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success, consideration of potential delays and the expected level of future revenues. In accordance with IFRS 3, the fair value of contingent consideration, including future royalties, is recognised immediately as a liability.

In addition to the acquired interests, AstraZeneca has entered into certain agreements with BMS to maintain the manufacturing and supply chain of the full portfolio of diabetes products. BMS will also continue to deliver specified clinical trials in line with the ongoing clinical trial plan, with an agreed number of R&D and manufacturing employees dedicated to diabetes remaining with BMS to progress the diabetes portfolio and support the transition for these areas. These arrangements will continue to be carried out over future periods and future payments by AstraZeneca to BMS in relation to these arrangements will be expensed as incurred. No amounts have been recognised in the initial acquisition accounting in relation to these arrangements but have been separated, at fair value, from the business combination accounting in accordance with IFRS 3.

The terms of the agreement partially reflect settlement of the launch and sales-related milestones under the pre-existing *Onglyza* and *Farxiga* collaboration agreements, which have been terminated in relation to the acquisition. The expected value of those pre-existing milestones is \$0.3bn and has been recognised as a separate component of consideration and excluded from the business combination accounting in accordance with IFRS 3. Subsequently, these separate intangible assets have been recognised.

Goodwill of \$1.5bn arising on the transaction is underpinned by a number of elements, which individually cannot be quantified. Most significant among these are the synergies AstraZeneca expect to be able to generate through more efficient manufacturing processes and the incremental value accessible through strategic and operational independence upon taking full control of the alliance.

The fair value of receivables acquired as part of the acquisition approximates the gross contractual amounts receivable. There are no significant amounts which are not expected to be collected.

The results from the additional acquired interests in the diabetes alliance have been consolidated into the Company's results from 1 February 2014, which have added revenue of \$895m in the period to 31 December 2014. Due to the highly integrated nature of the diabetes alliance, and the fact that it is not operated through a separate legal entity, the incremental direct costs associated with the additional acquired interest are not separately identifiable and it is impracticable therefore to disclose the profit or loss recognised in the period since acquisition.

	Fair value \$m
Non-current assets	
Intangible assets	5,746
Property, plant and equipment	478
	6,224
Current assets	480
Current liabilities	(278)
Non-current liabilities	(84)
Total net assets acquired	6,342
Goodwill	1,530
Fair value of total consideration	7,872
Less: fair value of contingent consideration	(5,169)
Total upfront consideration	2,703
Less: cash and cash equivalents acquired	-
Net cash outflow	2,703

As detailed above, future contingent consideration has been recognised initially at fair value and is revalued to fair value at each balance sheet date. Changes in fair value can arise as a result of a number of factors, including external news flow and internal re-forecasts, which may affect the likelihood of specific milestones becoming payable or the expected quantum of future royalty payments. These changes, which are potentially volatile and material, are included within selling, general and administrative costs. They are excluded from the Group's Core results.

The fair value of contingent consideration is also affected over time by the unwinding effect of discounting. This effect gives a charge to finance income and expense which reduces over time as the liability reduces. As a direct result of a material business acquisition, this effect is excluded from the Group's Core results.

In the period between acquisition and 31 December 2014, the effect of discounting increased the contingent consideration liability by \$345m and revaluations increased fair value by \$529m. Cash payments in the period since acquisition totaled \$657m.

In addition, inventory acquired at completion has been recorded at fair value, which is higher than manufacturing cost. The adjustment to increase the inventory to fair value is held in inventory until product is sold, at which time it is released to profit as a cost of sale. This results in a lower gross margin in the first turn of inventory and, since this arises as a direct result of a material business acquisition, this effect is excluded from the Group's Core results. The charge to cost of sales in the period since acquisition was \$146m and represents the entirety of the total adjustment to the fair value of inventory.

#### 5 STRATEGIC TRANSACTION WITH ALMIRALL IN RESPIRATORY DISEASE

On 31 October 2014, AstraZeneca completed the agreement with Almirall to transfer the rights to Almirall's respiratory franchise to AstraZeneca. The transaction provides AstraZeneca with 100% of the rights for the development and commercialisation of Almirall's existing proprietary respiratory business, including rights to revenues from Almirall's existing partnerships, as well as its pipeline of investigational novel therapies. The franchise includes *Eklira* (aclidinium); *Duaklir Genuair*, the combination of aclidinium with formoterol has been approved in the EU and is being developed in the US; LAS100977 (abediterol), a once-daily long-acting beta2-agonist (LABA) in Phase II; an M3 antagonist beta2-agonist (MABA) platform in pre-clinical development (LAS191351, LAS194871) and Phase I (LAS190792); and multiple pre-clinical programmes. Almirall Sofotec, an Almirall subsidiary focused on the development of innovative proprietary devices, has also transferred to AstraZeneca. In addition, Almirall employees dedicated to the respiratory business, including Almirall Sofotec employees, have transferred to AstraZeneca.

Upfront consideration for the acquisition of \$878m was paid in November, with further payments of up to \$1.22bn being payable for future development, launch, and sales-related milestones. AstraZeneca has also agreed to make various sales-related payments. The amount of royalties payable under the agreement is inherently uncertain and difficult to predict, given the direct link to future sales and the range of outcomes cannot be reliably estimated. The maximum amount payable in each year is with reference to net sales. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success, consideration of potential delays and the expected levels of future revenues.

Almirall's pipeline of novel respiratory assets and its device capabilities further strengthen AstraZeneca's respiratory portfolio, which includes *Symbicort* and *Pulmicort*, as well as the Company's investigational medicines in development. The addition of aclidinium and the combination of aclidinium with formoterol, both in proprietary *Genuair* device, will allow AstraZeneca to offer patients a choice between dry powder inhaler and metered dose inhaler devices across a range of molecules and combinations.

The combination of intangible product rights with an established work force and their associated operating processes, principally those related to the selling and marketing operations, requires that the transaction is accounted for as a business combination in accordance with IFRS 3 *Business Combinations*.

Goodwill of \$311m is underpinned by a number of elements, which individually cannot be quantified. Most significant among these is the premium attributable to the significant competitive advantage associated with AstraZeneca's complimentary portfolio and that attributable to a highly skilled workforce.

Almirall's respiratory franchise results have been consolidated into the Company's results from 31 October 2014, which have added revenue of \$13m in the period to 31 December 2014. Due to the highly integrated nature of the respiratory franchise, and the fact that it is not operated through a separate legal entity, the incremental direct costs associated with the additional acquired interest are not separately identifiable and it is impracticable therefore to disclose the profit or loss recognised in the period since acquisition.

	Fair value \$m
Non-current assets	
Intangible assets	1,400
Property, plant and equipment	37
	1,437
Current assets	24
Current liabilities	(2)
Non-current liabilities	(11)
Total net assets acquired	1,448
Goodwill	311
Fair value of total consideration	1,759
Less: fair value of contingent consideration	(881)
Total upfront consideration	878
Less: cash and cash equivalents acquired	(2)
Net cash outflow	876

#### 6 ACQUISITION OF DEFINIENS

On 25 November 2014, AstraZeneca completed the acquisition of Definiens, a privately-held company that has pioneered a world-leading imaging and data analysis technology, known as Tissue Phenomics™, which dramatically improves the identification of biomarkers in tumour tissue.

Definiens' proprietary Cognition Network Technology® was developed by Professor Gerd Binnig, the 1986 Nobel Laureate in Physics, and unlocks information from cancer tissue samples by measuring the identity, locations and, most importantly, the relationships between the many and varied components of the complex tumour microenvironment.

Under the terms of the agreement, AstraZeneca acquired 100 percent of Definiens' shares for an initial consideration of \$150m and may make additional predetermined milestone payments of up to a further \$150m. Definiens will continue to operate its business with third-party customers.

The acquisition will strengthen AstraZeneca's focus on the discovery of novel predictive biomarkers in immunooncology. It is believed that using biomarkers to select patients for clinical trials could potentially shorten clinical timelines and increase response rates. As a result, the technology will serve as an important tool in the advancement of the most promising combination therapies across AstraZeneca's combined small molecule and biologics pipeline, around 80 percent of which currently has a personalised healthcare approach.

The combination of intangible product rights with an established work force and their associated operating processes requires that the transaction is accounted for as a business combination in accordance with IFRS 3 *Business Combinations*.

No goodwill has been recognised.

The results of Definiens have been consolidated into the Company's results from 25 November 2014. For the period from acquisition to 31 December 2014, Definiens' revenues and loss was immaterial.

	Fair value \$m
Non-current assets	
Intangible assets	355
	355
Non-current liabilities	(117)
Total net assets acquired	238
Goodwill	-
Fair value of total consideration	238
Less: fair value of contingent consideration	(88)
Total upfront consideration	150

#### 7 FINANCIAL INSTRUMENTS

As detailed in our most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the accounting policies, including fair value measurement, for financial instruments from those disclosed on pages 139 and 140 of the Company's Annual Report and Form 20-F Information 2013. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include \$1,297m of other investments, \$1,198m of loans, and \$465m of derivatives as at 31 December 2014. The total fair value of interest-bearing loans and borrowings at 31 December 2014, which have a carrying value of \$10,843m in the Condensed Consolidated Statement of Financial Position, was \$12,168m. Contingent consideration liabilities arising on the Company's acquisitions of business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	Acquisition of the BMS share of diabetes alliance \$m	Other \$m	2014 \$m
At 1 January	<u> </u>	514	514
Acquisitions	5,169	969	6,138
Settlements	(657)	-	(657)
Revaluations	529	(17)	512
Discounting	345	46	391
Foreign exchange	-	1	1
At 31 December	5,386	1,513	6,899

#### 8 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2013 and Interim Management Statement 2014 as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 2014 and the Third Quarter and Nine Months Results 2014 (together the "Disclosures"). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the Company's Annual Report and Form 20-F Information 2013, for the majority of claims in which AstraZeneca is involved it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect only to the nature and facts of the cases but no provision is made.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, we record the loss absorbed or make a provision for our best estimate of the expected loss.

The position could change over time and the estimates that we have made and upon which we have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Company's Annual Report and Form 20-F Information 2013 and herein.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property.

#### Matters disclosed in respect of the fourth quarter of 2014 and to 5 February 2015

#### Patent litigation

#### Byetta (exenatide)

Patent proceedings in the US

As previously disclosed, in October 2014, AstraZeneca received a Paragraph IV notice from Teva Pharmaceuticals USA, Inc. (Teva). Teva is seeking FDA approval to market a generic version of *Byetta* prior to the expiration of certain AstraZeneca patents listed in the FDA Orange Book with reference to *Byetta*. In December 2014, AstraZeneca commenced patent litigation against Teva in the US District Court for the District of Delaware. AstraZeneca is asserting several patents. In January 2015, Teva filed a complaint in the same court for a declaratory judgment that its proposed generic version of *Byetta* would not infringe US Patent Nos. 7,297,761 and 7,741,269.

## Epanova (omega-3-carboxylic acids)

Patent proceedings in the US

As previously disclosed, in March 2014 and subsequently, AstraZeneca received complaints from Amarin Pharmaceuticals Ireland Ltd (Amarin) alleging that AstraZeneca's *Epanova* product infringes Amarin's US Patent No. 8,663,662. In November 2014, the US District Court for the District of Delaware dismissed Amarin's complaint. Amarin may file a complaint again at a later date.

#### Faslodex (fulvestrant)

Patent proceedings in the US

As previously disclosed, in June and September 2014, AstraZeneca filed patent infringement lawsuits against Sandoz Inc. and Sandoz International GmbH (together, Sandoz) and Sagent Pharmaceuticals, Inc. in the US District Court in New Jersey relating to four patents listed in the FDA Orange Book with reference to *Faslodex*, after those companies sent Paragraph IV notices that they are seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. In January 2015, AstraZeneca received a Paragraph IV notice from Glenmark Generics, Inc. USA (Glenmark), which is also seeking FDA approval to market a generic version of *Faslodex* prior to the expiration of the same four patents, and AstraZeneca filed a patent infringement lawsuit against Glenmark in the US District Court in New Jersey. The lawsuits remain pending.

# Nexium (esomeprazole magnesium)

Patent proceedings in the US

As previously disclosed, in October 2014 AstraZeneca received a Paragraph IV notice from Actavis Laboratories FL, Inc. (Actavis). Subsequently, AstraZeneca has received Paragraph IV notices from Andrx Labs, LLC (Andrx) and Perrigo Company PLC (Perrigo). Actavis, Andrx and Perrigo are seeking FDA approval to market generic versions of Nexium 24HR (OTC) prior to the expiration of AstraZeneca's patents listed in the FDA Orange Book with reference to Nexium 24HR. In November 2014, AstraZeneca commenced patent litigation against Actavis in the US District Court for the District of New Jersey. In December 2014 and in February 2015, AstraZeneca commenced patent litigation against Andrx and Perrigo, respectively, in the same court.

#### Seroquel XR (quetiapine fumarate)

Patent proceedings in the US

In October 2014, AstraZeneca received a Paragraph IV Notice from Pharmadax, Inc. and Pharmadax USA, Inc. (together, Pharmadax) alleging that the patent listed in the FDA Orange Book with reference to Seroquel XR is invalid, unenforceable and/or is not infringed by the Pharmadax proposed generic product. Pharmadax has submitted an

Abbreviated New Drug Application (ANDA) seeking to market quetiapine fumarate 50mg tablets. In November 2014, AstraZeneca filed a patent infringement lawsuit against Pharmadax in the US District Court for the District of New Jersey.

#### Patent proceedings outside the US

As previously disclosed, in Germany, in November 2012, the Federal Patent Court (the Federal Court) determined that the *Seroquel XR* patent was invalid. In January 2015, the Federal Court of Justice denied AstraZeneca's appeal of the November 2012 Federal Court decision.

#### Zestril (lisinopril dihydrate)

Patent proceedings outside the US

As previously disclosed, in Canada, in 1996, AstraZeneca and Merck & Co., Inc., Merck Frosst Canada & Co., Merck Frosst Canada Ltd., (together, Merck) sued Apotex Inc. for infringement of Merck's US Patent No. 1,275,350. In 2006, Apotex was found to infringe the patent. AstraZeneca and Merck commenced a reference to determine the quantum of damages. In December 2014, the parties settled the reference.

# **Product liability litigation**

#### Crestor (rosuvastatin calcium)

As previously disclosed, AstraZeneca is defending a number of lawsuits alleging multiple types of injuries caused by the use of *Crestor*, including diabetes mellitus, various cardiac injuries, rhabdomyolysis, and/or liver and kidney injuries. The claims of 594 plaintiffs, comprising 102 California residents and 492 non-California residents, were aggregated in one coordinated proceeding in Los Angeles, California. The claims of additional plaintiffs are waiting to be added to the coordination. In October 2014, the coordination judge dismissed the claims of the 492 non-California plaintiffs whose claims were in the coordinated proceeding. Plaintiffs have appealed the October 2014 order dismissing the non-California plaintiffs from the proceeding. There are now a total of 707 plaintiffs remaining with claims pending in California state court, and 2 plaintiffs with claims pending in the Eastern District of Kentucky.

# **Commercial litigation**

#### **Crestor Texas Attorney General litigation**

In January 2015, following a previously disclosed investigation by the State of Texas into AstraZeneca's sales and marketing activities involving *Crestor*, AstraZeneca was served with a lawsuit in which the Texas Attorney General's Office intervened in a state whistleblower action pending in Travis County Court, Texas. The lawsuit alleges that AstraZeneca engaged in inappropriate promotion of *Crestor* and improperly influenced the formulary status of *Crestor*.

# Nexium settlement anti-trust litigation

As previously disclosed, AstraZeneca is a defendant in a Multi-District Litigation class action and individual lawsuits alleging that AstraZeneca's settlements of certain patent litigation in the US relating to *Nexium* violated US anti-trust law and various state laws. A trial in the US District Court for the District of Massachusetts commenced on 20 October 2014 on certain liability issues for claims that remain in the case. On 5 December 2014, a jury returned a verdict in favour of AstraZeneca. On 31 December, 2014, the Plaintiffs filed motions for a new trial. On 7 January 2015, Plaintiffs filed motions for a permanent injunction. AstraZeneca opposed those motions. A hearing on the Plaintiffs' motions for a permanent injunction is scheduled for 6 February 2015.

On 10 December 2014, following the favourable jury verdict, AstraZeneca filed a motion requesting dismissal of its appeal of the District Court's procedural decision to certify a class of end payers. On 21 January 2015, the Court of Appeals denied AstraZeneca's request to dismiss the appeal and issued a decision affirming the District Court's class certification ruling.

The two lawsuits filed in Pennsylvania state court by various indirect purchasers of *Nexium* are pending. The cases are in their initial stages.

## **Government investigations**

## **Dutch National Competition Authority investigation**

As previously disclosed, in December 2011 the Dutch competition authority, the ACM, issued a report alleging that AstraZeneca had abused a dominant position in the Netherlands by foreclosing generics of other proton pump inhibitors. In December 2014, the ACM issued its decision dismissing the allegations against AstraZeneca and closed its file.

#### Medco

As previously disclosed, the US Attorney's Office for the District of Delaware, Criminal Division, conducted an investigation relating to AstraZeneca's relationship with Medco and sales of *Nexium, Plendil, Prilosec* and *Toprol-XL*. In addition, the US Attorney's Office for the District of Delaware and the US Department of Justice investigated potential civil claims relating to the same conduct. This matter has been resolved and a provision was previously taken.

#### 9 FULL YEAR PRODUCT REVENUE ANALYSIS

	World		US		Europe		Established ROW		Emerging Markets	
	FY 2014	CER	FY 2014	CER	FY 2014	CER	FY 2014	CER	FY 2014	CER
	\$m	<u>%</u>	\$m	<u>%</u>	\$m	<u></u> %	\$m	%_	\$m	%
Cardiovascular and Metabolic disease:	5.540	(4)	0.040		4.000	(0)	007	(40)	707	44
Crestor	5,512	(1)	2,918	- (04)	1,200	(3)	667	(10)	727	11
Seloken/Toprol-XL	758	4	91	(31)	124	(4)	19	(13)	524	17
Onglyza	820	119	481	82	155	175	59	210	125	251
Atacand	501	(16)	44	(39)	169	(26)	43	(35)	245	5
Brilinta/Brilique	476	70	146	100	231	40	33	106	66	133
Byetta	327	59	199	31	81	119	27	164	20	200
Bydureon	440	191	374	185	57	235	5	n/m	4	100
Plendil	249	(4)	=	-	19	(10)	9	(10)	221	(3)
Tenormin	161	(15)	8	(47)	48	(6)	54	(23)	51	(4)
Others	558	52	190	280	199	14	35	48	134	12
Total Cardiovascular and Metabolic disease	9,802	12	4,451	17	2,283	8	951	(3)	2,117	17
Oncology:										
Zoladex	924	(4)	26	13	226	(12)	322	(6)	350	4
Iressa	623	(1)	-	-	166	(7)	177	(4)	280	6
Faslodex	720	7	340	5	245	10	59	3	76	14
Arimidex	298	(12)	15	150	76	(19)	108	(24)	99	5
Casodex	320	(10)	5	-	42	(21)	169	(18)	104	14
Others	142	4	25	-	33	14	48	(13)	36	36
Total Oncology	3,027	(2)	411	7	788	(6)	883	(11)	945	8
Respiratory, Inflammation and Autoimmunity:										
Symbicort	3,801	10	1,511	23	1,462	(4)	458	17	370	22
Pulmicort	946	11	211	(6)	162	(6)	97	(6)	476	35
Others	316	(2)	26	(55)	123	7	27	(15)	140	19
Total Respiratory, Inflammation and Autoimmunity	5,063	10	1,748	15	1,747	(4)	582	11	986	27
Infection, Neuroscience and Gastrointestinal:										
Nexium	3,655	(4)	1,876	(12)	368	2	606	9	805	5
Synagis	900	(15)	499	(19)	401	(9)	-	-	-	-
Seroquel XR	1,224	(8)	738	(1)	343	(18)	44	(35)	99	-
Seroquel IR	178	(46)	(72)	n/m	89	(16)	36	(63)	125	(13)
Local Anaesthetics	488	-	-	-	197	(5)	168	(1)	123	9
Losec/Prilosec	422	(11)	28	(7)	129	(2)	106	(30)	159	1
Merrem	253	(10)	6	(45)	32	(35)	4	(20)	211	(3)
FluMist/Fluenz	295	20	218	10	70	64	7	100	-	-
Others	788	(6)	217	(24)	191	(3)	123	(1)	257	9
Total Infection, Neuroscience and Gastrointestinal	8,203	(7)	3,510	(12)	1,820	(7)	1,094	(7)	1,779	3
Total	26,095	3	10,120	4	6,638	(1)	3,510	(4)	5,827	12
I VIAI	20,033		10,120		0,000	(1)	5,510	(+)	5,021	14

## 10 FOURTH QUARTER PRODUCT REVENUE ANALYSIS

	World		US			Europe		Established ROW		/larkets
	Q4 2014	CER	Q4 2014	CER	Q4 2014	CER	Q4 2014	CER	Q4 2014	CER
	\$m	%	\$m	%	\$m	%	\$m	<u>%</u>	\$m	<u>%</u>
Cardiovascular and Metabolic disease:	4 200	(2)	760	(2)	200	(4)	464	(40)	178	0
Crestor	1,388	(2)	760 15	(2)	286	(1)	164	(10)		9 19
Seloken/Toprol-XL	174	8		(21)	30	-	4	(43)	125	
Onglyza	200	122	101	60	44	n/m	17	n/m	38	n/m
Atacand	117	(7)	11	10	36	(30)	9	(31)	61	18
Brilinta/Brilique	133	52	43	79	60	25	9	50	21	118
Byetta	69	31	39	8	20	91	7	100	3	, <del>-</del>
Bydureon	123	153	103	158	18	233	1	-	1	n/m
Plendil	59	(9)	-	-	5	(17)	1	(67)	53	(5)
Tenormin	40	(7)	2	(33)	11	(8)	12	(26)	15	36
Others	171	89	66	n/m	55	40	13	150	37	23
Total Cardiovascular and Metabolic disease	2,474	13	1,140	15	565	12	237	(3)	532	21
Oncology:					·			·		
Zoladex	227	(2)	8	60	52	(8)	83	(3)	84	1
Iressa	150	2	-	-	42	-	43	(9)	65	13
Faslodex	182	4	90	3	58	7	15	-	19	5
Arimidex	68	(15)	3	(25)	16	(23)	27	(21)	22	5
Casodex	74	(16)	-	n/m	10	(15)	40	(23)	24	9
Others	39	5	5	(29)	8	-	16	-	10	67
Total Oncology	740	(2)	106	1	186	(4)	224	(10)	224	8
Respiratory, Inflammation and Autoimmunity:										
Symbicort	978	5	395	13	347	(7)	121	2	115	25
Pulmicort	269	15	56	(5)	41	-	28	(9)	144	39
Others	89	11	4	(75)	39	46	6	(22)	40	32
Total Respiratory, Inflammation and Autoimmunity	1,336	7	455	7	427	(3)	155	(1)	299	32
Infection, Neuroscience and Gastrointestinal:										
Nexium	832	(13)	469	(14)	89	4	105	(30)	169	(6)
Synagis	404	(22)	234	(22)	170	(21)	-	-	-	-
Seroquel XR	309	(6)	196	1	79	(18)	10	(9)	24	(7)
Seroquel IR	(28)	n/m	(92)	n/m	20	(8)	13	n/m	31	-
Local Anaesthetics	117	(3)	-	-	45	(8)	43	(2)	29	3
Losec/Prilosec	110	(5)	8	14	30	(9)	26	(29)	46	21
Merrem	63	(13)	(1)	n/m	7	(27)	1	n/m	56	(8)
FluMist/Fluenz	134	170	75	241	54	108	5	n/m	-	-
Others	192	(4)	51	(22)	41	(7)	32	(11)	68	21
Total Infection, Neuroscience and Gastrointestinal	2,133	(11)	940	(16)	535	(8)	235	(15)	423	1
Total	6,683	2	2,641	<del></del>	1,713	-	851	(8)	1,478	14

# **ASTRAZENECA DEVELOPMENT PIPELINE, 31 DECEMBER 2014**

# Phase III / Pivotal Phase II / Registration

# NMEs and significant additional indications

Submission dates shown for assets in Phase III and beyond. As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

		Area Under Da			ed Filing	Filing	
Compound	Mechanism	Investigation	Commenced Phase	US	EU	Japan	China
Cardiovascular an	d Metabolism						
Brilinta / Brilique <sup>1</sup>	ADP receptor antagonist	arterial thrombosis		Launched	Launched	Filed	Launched
Epanova <sup>#</sup>	omega-3 free fatty acids	hypertriglyceridaemia		Approved		2017	2019
Farxiga / Forxiga <sup>2</sup>	SGLT-2 inhibitor	type 2 diabetes		Launched	Launched	Launched	Filed
Myalept <sup>3</sup>	leptin analogue	lipodystrophy		Launched	Q4 2015	N/A	
roxadustat#	hypoxia-inducible factor inhibitor	anaemia in CKD / ESRD	Q3 2014	2018	N/A	N/A	H2 2016
Oncology							
AZD9291	EGFR tyrosine kinase inhibitor	advanced EGFRm T790M NSCLC	Q2 2014	Q2 2015	Q2 2015	Q3 2015	2017
Caprelsa	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer		Launched	Launched	Filed	Filed
MEDI4736 <sup>#</sup> PACIFIC	anti-PD-L1 MAb	stage III NSCLC	Q2 2014	2017	2020	2020	
MEDI4736 <sup>#</sup> ATLANTIC <sup>¶</sup>	anti-PD-L1 MAb	3rd line NSCLC	Q1 2014	H1 2016	2017	2017	
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2018	2018		
Lynparza (olaparib)	PARP inhibitor	BRCAm PSR ovarian cancer		Launched <sup>4</sup>	Approved		
Lynparza (olaparib) SOLO-1	PARP inhibitor	1st line BRCAm ovarian cancer	Q3 2013	2017	2017	2017	2018
Lynparza (olaparib) SOLO-2	PARP inhibitor	BRCAm PSR ovarian cancer	Q3 2013	H1 2016	H1 2016	H2 2016	2018
Lynparza (olaparib) GOLD	PARP inhibitor	2nd line gastric cancer	Q3 2013			2017	2018
Lynparza (olaparib) OlympiA	PARP inhibitor	adjuvant breast cancer	Q2 2014	2020	2020	2020	2021
<i>Lynparza</i> (olaparib) OlympiAD	PARP inhibitor	metastatic breast cancer	Q2 2014	2016	2016	2016	2018
selumetinib <sup>#</sup> SELECT-1	MEK inhibitor	2nd line KRAS+ NSCLC	Q4 2013	2017	2017		
selumetinib <sup>#</sup> ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2017	2017		
selumetinib <sup>#</sup> SUMIT	MEK inhibitor	uveal melanoma	Q2 2014	Q4 2015	Q4 2015		
tremelimumab <sup>¶</sup>	anti-CTLA-4 MAb	mesothelioma	Q2 2014	H1 2016	H2 2016		

# Phase III / Pivotal Phase II / Registration (continued)

		Area Under	Date		Estimate	ed Filing	
Compound	Mechanism	Investigation	Commenced Phase	US	EU	Japan	China
Respiratory, Inflar	nmation and Autoimn	nunity					
benralizumab <sup>#</sup> CALIMA SIROCCO ZONDA BORA	anti-IL-5R MAb	severe asthma	Q4 2013	H2 2016	H2 2016		
benralizumab <sup>#</sup> TERRANOVA GALATHEA	anti-IL-5R MAb	COPD	Q3 2014	2018	2018		
brodalumab <sup>#</sup> AMAGINE-1,2,3	anti-IL-17R MAb	psoriasis	Q3 2012	2015++	2015++		
brodalumab <sup>#</sup> AMVISION-1,2	anti-IL-17R MAb	psoriatic arthritis	Q1 2014	++	++		
lesinurad CLEAR 1,2 CRYSTAL	selective uric acid reabsorption inhibitor (SURI)	chronic treatment of patients with gout	Q4 2011	Q1 2015 <sup>5</sup>	Filed <sup>6</sup>		
PT003 GFF	LAMA / LABA	COPD	Q2 2013	Q3 2015	H1 2016	2017	2017
PT001 GP	LAMA	COPD	Q2 2013				
tralokinumab STRATOS 1,2 TROPOS	anti-IL-13 MAb	severe asthma	Q3 2014	2018	2018	2018	
Infection							
CAZ AVI <sup>#</sup> RECLAIM	cephalosporin / beta lactamase inhibitor	serious infections	Q1 2012	N/A	Q1 2015		H2 2016
CAZ AVI <sup>#</sup> REPROVE	cephalosporin / beta lactamase inhibitor	hospital-acquired pneumonia / ventilator- associated pneumonia	Q2 2013	N/A	2017		2018
Zinforo <sup>#</sup>	extended spectrum cephalosporin with affinity to penicillin- binding proteins	pneumonia / skin infections		N/A	Launched	N/A	Filed
Neuroscience							
Movantik / Moventig <sup>7#</sup>	oral peripherally- acting mu-opioid receptor antagonist	opioid-induced constipation		Approved	Approved		

- Partnered product.

- # Partnered product.
  Registrational Phase II / III study.
  ++ Filing is the responsibility of the partner.
  Brilinta in the US; Brilique in rest of world.
  Farxiga in the US; Forxiga in rest of world.
  Divestment to Aegerion Pharmaceuticals announced November 2014.
  Launched simultaneously with US approval December 2014.
  Submission made in US in December 2014, acceptance anticipated Q1 2015.
  Filing accepted January 2015.
  Movantik in the US; Moventig in EU.

# Phases I and II

# NMEs and significant additional indications

		Area Under		Date		Estimat	ed Filing	
Compound	Mechanism	Investigation	Phase	Commenced Phase	US	EU	Japan	China
Cardiovascular	and Metabolism							
tenapanor (AZD1722)#	NHE3 inhibitor	ESRD-Pi / CKD with T2DM <sup>1</sup>	II	Q1 2013				
AZD4901	hormone modulator	polycystic ovarian syndrome	II	Q2 2013				
MEDI6012	LCAT	ACS	I	Q1 2012				
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014				
Oncology								
AZD1775 <sup>#</sup>	WEE-1 inhibitor	ovarian cancer	II	Q4 2012				
AZD2014	mTOR serine / threonine kinase inhibitor	solid tumours	II	Q1 2013				
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011				
MEDI-551 <sup>#</sup>	anti-CD19 MAb	CLL / DLBCL	II	Q1 2012				
MEDI-573 <sup>#</sup>	anti-IGF MAb	metastatic breast cancer	II	Q2 2012				
<i>Lynparza</i> (olaparib)	PARP inhibitor	prostate cancer	II	Q3 2014				
selumetinib#	MEK inhibitor	2nd line KRAS- NSCLC	II	Q1 2013				
AZD5363 <sup>#</sup>	AKT kinase inhibitor	breast cancer	II	Q1 2014				
MEDI4736 <sup>#</sup>	anti-PD-L1 MAb	solid tumours	II	Q3 2014				
moxetumomab pasudotox <sup>#</sup>	anti-CD22 recombinant immunotoxin	pALL	II	Q3 2014				
AZD6094 (volitinib)#	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 2014				
AZD9291	EGFR tyrosine kinase inhibitor	1 <sup>st</sup> line advanced EGFRm NSCLC	II	Q4 2014				
AZD3759	EGFR tyrosine kinase inhibitor	advanced EGFRm NSCLC	I	Q4 2014				
AZD5312 <sup>#</sup>	androgen receptor inhibitor	solid tumours	I	Q2 2014				
AZD6738	ATR serine / threonine kinase inhibitor	solid tumours	I	Q4 2013				
AZD8186	PI3 kinase beta inhibitor	solid tumours	I	Q2 2013				
AZD8835	PI3 kinase alpha inhibitor	solid tumours	I	Q4 2014				
AZD9150 <sup>#</sup>	STAT3 inhibitor	haematological malignancies	I	Q1 2012				
AZD9291 + (MEDI4736 <sup>#</sup> or selumetinib <sup>#</sup> or volitinib <sup>#</sup> ) TATTON	EGFR tyrosine kinase inhibitor + (anti-PD-L1 or MEK inhibitor or MET tyrosine kinase inhibitor)	advanced EGFRm NSCLC	I	Q3 2014				

# Phases I and II (continued)

		Area Under		Date	Estimated Filing			
Compound	Mechanism	Investigation	Phase	Commenced Phase	US	EU	Japan	China
Oncology (cont	inued)							
AZD9496	selective oestrogen receptor downregulator (SERD)	ER+ breast cancer	I	Q4 2014				
MEDI4736 <sup>#</sup> after (AZD9291 or <i>Iressa</i> or (selumetinib <sup>#</sup> +docetaxel) or tremelimumab)	anti-PD-L1 MAb + (EGFR tyrosine kinase inhibitor or MEK inhibitor or anti-CTLA-4 MAb)	NSCLC	I	Q3 2014				
MEDI-565 <sup>#</sup>	anti-CEA BiTE MAb	solid tumours	I	Q1 2011				
MEDI0639 <sup>#</sup>	anti-DLL-4 MAb	solid tumours	I	Q2 2012				
MEDI0680	anti-PD-1 MAb	solid tumours	I	Q4 2013				
MEDI3617 <sup>#</sup>	anti-ANG-2 MAb	solid tumours	I	Q4 2010				
MEDI4736 <sup>#</sup>	anti-PD-L1 MAb	various cancers	I	Q3 2014				
MEDI4736 <sup>#</sup> + MEDI0680	anti-PD-L1 MAb + anti-PD-1 MAb	solid tumours	I	Q2 2014				
MEDI4736 <sup>#</sup> + MEDI6469 <sup>#</sup>	anti-PD-L1 MAb + murine OX40 agonist	solid tumours	I	Q3 2014				
MEDI4736# + dabrafenib + trametinib <sup>2</sup>	anti-PD-L1 MAb + BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014				
MEDI4736 <sup>#</sup> + Iressa	anti-PD-L1 MAb + EGFR tyrosine kinase inhibitor	NSCLC	I	Q2 2014				
MEDI4736 <sup>#</sup> + tremelimumab	anti-PD-L1 MAb + anti-CTLA-4 MAb	solid tumours	I	Q4 2013				
MEDI-551 <sup>#</sup> + MEDI0680	anti-CD19 MAb + anti-PD-1 MAb	DLBCL	I	Q4 2014				
MEDI-551 <sup>#</sup> + rituximab <sup>3</sup>	anti-CD19 MAb + anti-CD20 MAb	haematological malignancies	I	Q2 2014				
MEDI6383 <sup>#</sup>	OX40 agonist	solid tumours	I	Q3 2014				
MEDI6469 <sup>#</sup>	murine OX40 agonist	solid tumours	I	Q1 2006				
MEDI6469 <sup>#</sup> + tremelimumab	murine OX40 agonist + anti- CTLA-4 MAb	solid tumours	I	Q4 2014				
Respiratory, Inf	lammation and Aut	oimmunity						
AZD0548	LABA	asthma / COPD	П	Q4 2007				
AZD2115 <sup>4#</sup>	MABA	COPD	II	Q2 2012				
AZD7624	inhaled P38 inhibitor	COPD	II	Q4 2014				
AZD9412 <sup>#</sup>	inhaled interferon β	asthma / COPD	II	Q1 2010				
anifrolumab#	anti-IFN-alphaR MAb	SLE	II	Q1 2012				
brodalumab#	anti-IL-17R MAb	asthma	II	Q2 2013				
mavrilimumab <sup>#</sup>	anti-GM-CSFR MAb	rheumatoid arthritis	II	Q1 2010				
MEDI2070 <sup>#</sup>	anti-IL-23 MAb	Crohn's disease	II	Q1 2013				
MEDI7183 <sup>#</sup>	anti-a4b7 MAb	Crohn's disease / ulcerative colitis	II	Q4 2012				
MEDI9929 <sup>#</sup>	anti-TSLP MAb	asthma	II	Q2 2014				
PT010	LAMA / LABA / ICS	COPD	II	Q2 2014				

RDEA3170	· ·	chronic management of hyperuricaemia in patients with gout	II	Q3 2013		
sifalimumab <sup>#</sup>	anti-IFN-alpha MAb	SLE	II	Q3 2008		
tralokinumab	anti-IL-13 MAb	IPF	П	Q4 2012		

# Phases I and II (continued)

		Area Under		Date	Estimated Filing			
Compound	Mechanism	Investigation	Phase	Commenced Phase	US	EU	Japan	China
Respiratory, In	flammation and Aut	oimmunity (continued	d)					
AZD1419 <sup>#</sup>	TLR9 agonist	asthma	I	Q3 2013				
AZD7594	inhaled SGRM	asthma / COPD		Q3 2012				
AZD8999	MABA	COPD		Q4 2013				
MEDI-551 <sup>#</sup>	anti-CD19 MAb	multiple sclerosis		Q3 2012				
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014				
MEDI5872 <sup>#</sup>	anti-B7RP1 MAb	SLE	I	Q4 2008				
Infection								
AZD0914	GyrAR	serious bacterial infections	II	Q4 2014				
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis	II	Q4 2012				
CXL <sup>#</sup>	beta lactamase inhibitor / cephalosporin	MRSA	II	Q4 2010				
MEDI4893	MAb binding to S. aureus toxin	hospital-acquired pneumonia / serious <i>S. aureus</i> infection	II	Q4 2014				
ATM AVI	monobactam / beta lactamase inhibitor	targeted serious bacterial infections	I	Q4 2012				
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	I	Q2 2006				
MEDI-559	paediatric RSV vaccine	RSV prophylaxis	I	Q4 2008				
MEDI3902	anti-Psl/PcrV	pseudomonas	I	Q3 2014				
MEDI7510	RSV sF+GLA-SE	prevention of RSV disease in older adults	I	Q2 2014				
MEDI8897 <sup>#</sup>	anti-RSV MAb- YTE	passive RSV prophylaxis	I	Q2 2014				
Neuroscience								
AZD3241	myeloperoxidase inhibitor	multiple system atrophy <sup>5</sup>	II	Q2 2012				
AZD3293 <sup>#</sup>	beta-secretase inhibitor	Alzheimer's disease	II	Q4 2014				
AZD5213	histamine-3 receptor antagonist	Tourette's syndrome / neuropathic pain	II	Q4 2013				
AZD8108	NMDA antagonist	suicidal ideation	I	Q4 2014				
MEDI1814	anti-amyloid beta MAb	Alzheimer's disease	I	Q2 2014				

- Partnered product.

- Fartnered product.
  Fluid retention indication for tenapanor terminated in Q2 2014.
  MedImmune-sponsored study in collaboration with GSK.
  MedImmune-sponsored study in collaboration with Genentech.
  Development on hold pending further preclinical evaluation.
  Multiple system atrophy is now the lead indication for this molecule.

# **Significant Life-Cycle Management**

		Area Under	Date	Estimated Filing			
Compound	Mechanism	Investigation	Commenced Phase	US	EU	Japan	China
Cardiovascular a	nd Metabolism						
Brilinta / Brilique <sup>1</sup> EUCLID	ADP receptor antagonist	outcomes study in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018
Brilinta / Brilique <sup>1</sup> PEGASUS- TIMI 54	ADP receptor antagonist	outcomes study in patients with prior myocardial infarction	Q4 2010	Q2 2015	Q2 2015	Q4 2015	2017
Brilinta / Brilique <sup>1</sup> SOCRATES	ADP receptor antagonist	outcomes study in patients with stroke or TIA	Q1 2014	H1 2016	H1 2016	H2 2016	2017
Brilinta / Brilique <sup>1</sup> THEMIS	ADP receptor antagonist	outcomes study in patients with type 2 diabetes and CAD, but without a previous history of MI or stroke	Q1 2014	2017	2017	2018	2018
Brilinta / Brilique <sup>1</sup> HESTIA	ADP receptor antagonist	prevention of vaso- occlusive crises in paediatric patients with sickle cell disease	Q4 2014	2020	2020		
Bydureon Dual Chamber Pen	GLP-1 receptor agonist	type 2 diabetes		Launched	Approved	Filed	
Bydureon EXSCEL	GLP-1 receptor agonist	type 2 diabetes outcomes study	Q2 2010	2018	2018	2018	
Bydureon weekly suspension	GLP-1 receptor agonist	type 2 diabetes	Q1 2013	Q4 2015	Q4 2015		
Epanova STRENGTH	omega-3 free fatty acids	outcomes study in statin-treated patients at high CV risk, with persistent hypertriglyceridemia plus low HDL- cholesterol	Q4 2014	2020	2020	2020	2020
Farxiga / Forxiga <sup>2</sup> DECLARE- TIMI 58	SGLT-2 inhibitor	type 2 diabetes outcomes study	Q2 2013	2020	2020		
Farxiga / Forxiga <sup>2</sup>	SGLT-2 inhibitor	type 1 diabetes	Q4 2014	2018	2017	2018	
Kombiglyze XR FDC / Komboglyze FDC <sup>3</sup>	DPP-4 inhibitor / metformin FDC	type 2 diabetes		Launched	Launched		Filed
Onglyza SAVOR- TIMI 53	DPP-4 inhibitor	type 2 diabetes outcomes study	Q2 2010	Filed	Launched		2015
saxagliptin / dapagliflozin FDC	DPP-4 inhibitor / SGLT-2 inhibitor FDC	type 2 diabetes	Q2 2012	Q1 2015 <sup>6</sup>	Q2 2015		
Xigduo XR FDC / Xigduo FDC <sup>4</sup>	SGLT-2 inhibitor / metformin FDC	type 2 diabetes		Launched	Launched		
Oncology							
Caprelsa	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	differentiated thyroid cancer	Q2 2013	H1 2016	H1 2016	H1 2016	
Faslodex FALCON	oestrogen receptor antagonist	1st line hormone receptor +ve advanced breast cancer	Q4 2012	H2 2016	H2 2016	H2 2016	H2 2016
Respiratory, Inflan	nmation and Autoimm	unity					
Duaklir Genuair	LAMA / LABA	COPD			Approved		
Symbicort SYGMA-1	ICS / LABA	as needed use in mild asthma	Q4 2014	N/A	2018		

Symbicort <sup>5</sup>	ICS / LABA	Breath Actuated			
		Inhaler asthma /			
		COPD			

# Significant Life-Cycle Management (continued)

	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing					
Compound				US	EU	Japan	China		
Neuroscience	Neuroscience								
Diprivan <sup>#</sup>	sedative and anaesthetic	conscious sedation		N/A	Launched	Filed	Launched		
Gastrointestina	Gastrointestinal								
Entocort	glucocorticoid steroid	Crohn's disease / ulcerative colitis		Launched	Launched	Q3 2015	N/A		
linaclotide <sup>#</sup>	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	Q4 2015		
Nexium	proton pump inhibitor	refractory reflux esophagitis				Filed			
Nexium	proton pump inhibitor	stress ulcer prophylaxis					2017		
Nexium	proton pump inhibitor	paediatrics		Launched	Launched	H2 2016			

- Partnered product.

- Partitiered product.

  Brilinta in the US; Brilique in rest of world.

  Farxiga in the US; Forxiga in rest of world.

  Kombiglyze XR in the US; Komboglyze FDC in the EU.

  Xigduo XR FDC in the US; Xigduo FDC in the EU.

- Development of a new BAI device is ongoing.
   Submission made in US in December 2014, acceptance anticipated Q1 2015

# Terminations (discontinued projects between 1 October and 31 December 2014)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD1979	Safety / efficacy	obesity
NME	AZD6423	Safety / efficacy	suicidal ideation

<sup>#</sup> Partnered product.

## **Shareholder Information**

#### **ANNOUNCEMENTS AND MEETINGS**

Announcement of first quarter 2015 results

Annual General Meeting

Announcement of second quarter and half year 2014 results

Announcement of third quarter and nine months 2014 results

5 November 2015

#### DIVIDENDS

The record date for the first interim dividend, paid on 15 September 2014, was 15 August 2014. Shares traded ex-dividend from 13 August 2014.

The record date for the second interim dividend for 2014, payable on 23 March 2015, will be 20 February 2015. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 19 February 2015. American Depositary Shares listed in New York will trade ex-dividend from 18 February 2015.

Future dividends will normally be paid as follows:

First interim

Announced with second quarter and half year results and paid in September Second interim

Announced with fourth quarter and full year results and paid in March

The Company is in the process of transferring its US American Depositary Receipt (ADR) Programme to Citibank, N.A. The Company will implement a dividend fee of \$0.03 per ADR annually to cover ADR Programme costs, commencing with a fee of \$0.02 per ADR on the second interim dividend for 2014, payable on 23 March 2015.

#### **TRADEMARKS**

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#### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement: The preliminary announcement contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of the preliminary announcement and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of patents, marketing exclusivity or trademarks, or the risk of failure to obtain patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions will be unsuccessful; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure to manage a crisis; the risk of obtaining and maintaining regulatory approvals for products; the risk of sobtaining and ma