

ASTRAZENECA PLC  
Form 6-K  
October 31, 2013

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For the month of October 2013

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If "Yes" is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b):  
82-\_\_\_\_\_

AstraZeneca PLC

THIRD QUARTER AND NINE MONTHS RESULTS 2013

---

London, 31 October 2013

As expected, third quarter revenue declined due to the ongoing impact from products with recent losses of exclusivity. The 4 percent decline in revenue on a constant currency basis, combined with continued investment in our growth platforms and scientific leadership resulted in a greater decline in Core earnings per share. The late-stage pipeline continued to grow; since the half year update there have been three new Phase III programme starts and three regulatory filings were accepted for review.

Revenue in the third quarter was \$6,250 million, down 4 percent at constant exchange rates (CER).

-Loss of exclusivity on several brands accounted for around \$350 million in CER revenue decline in the quarter.

-Five growth platforms (Emerging Markets, Japan, Brilinta, diabetes franchise and respiratory franchise) achieved an 8 percent revenue increase at CER in the quarter.

Core operating profit in the third quarter was down 29 percent at CER to \$2,027 million.

-The \$250 million gain within Core other income from the sale of OTC rights for Nexium in the third quarter last year accounted for 9 percentage points of the decline in the quarter. The balance of the decline was largely driven by lower revenue combined with an increase in Core operating costs.

Core EPS was \$1.21 in the third quarter, a 26 percent decline at CER.

Reported EPS in the third quarter was down 16 percent at CER to \$0.99.

-Reported EPS in the third quarter this year includes \$0.18 per share benefit from the reversal of an intangible asset impairment related to the initiation of Phase III clinical trials for olaparib.

Late stage pipeline strengthened by three new Phase III clinical programme starts: olaparib, selumetinib and benralizumab. Regulatory filings were accepted for review for olaparib and naloxegol in Europe and for Epanova in the US.

New collaborations with Merck (WEE1 kinase inhibitor) and Janssen (co-promotion of abiraterone acetate in Japan) and acquisitions of Amplimmune and Spirogen strengthen our oncology portfolio.

Financial Summary

---

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Group	3rd Quarter	3rd Quarter	Actual	CER	9 Months	9 Months	Actual	CER		
	2013	2012**							%	%
	\$m	\$m								
Revenue	6,250	6,682	-6	-4	18,867	20,691	-9	-7		
Reported										
Operating Profit	1,706	2,156	-21	-19	4,303	6,184	-30	-27		
Profit before Tax	1,592	2,030	-22	-20	3,982	5,810	-31	-28		
Earnings per Share	\$0.99	\$1.21	-18	-16	\$2.46	\$3.74	-34	-31		
Core*										
Operating Profit	2,027	2,924	-31	-29	6,407	8,364	-23	-21		
Profit before Tax	1,913	2,798	-32	-30	6,086	7,990	-24	-21		
Earnings per Share	\$1.21	\$1.68	-28	-26	\$3.82	\$5.12	-25	-23		

\* Core financial measures are supplemental non-GAAP measures which management

\*\* believe enhance understanding of the Company's performance; it is upon these measures that financial guidance for 2013 is based. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

Core results for 2012 have been restated according to the Group's updated definition of Core financial measures, which has been implemented with effect from the first quarter 2013 results. Reported and Core results have also been restated to reflect adoption of the amendments to IAS 19 Employee Benefits, which is effective from 1 January 2013.

Pascal Soriot, Chief Executive Officer, commenting on the results, said: "We continue to focus on the strategic priorities of returning to growth and achieving scientific leadership, and this is reflected in continued investment in our growth platforms and our pipeline. I am pleased with the progress we are making, particularly on the pipeline, with three regulatory filings, three Phase III starts and four business development transactions since our last update. As expected, our financial performance this year reflects the ongoing impact from the loss of exclusivity for several key brands."

### 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 believe 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 charges and provisions related to our global restructuring programmes, all intangible asset amortisation charges and impairments, except for IS-related intangibles, and other specified items. More detail on the nature of these measures is given on pages 88 and 97 of our Annual Report and Form 20-F Information 2012.

### Third Quarter

All financial figures, except earnings per share, are in \$ millions. Weighted average shares in millions.

	Reported	Intangible	Intangible	Legal	Restated		Actual	CER	
					Core	Core			
	2013	Restructuring	Amortisation	Impairments	& Other	2013	2012	%	%
Revenue	6,250	-	-	-	-	6,250	6,682	(6)	(4)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Cost of Sales	(1,238)	6	129	-	-	(1,103)	(1,130)		
Gross Profit	5,012	6	129	-	-	5,147	5,552	(7)	(6)
% sales	80.2%					82.4%	83.1%	-0.7	-1.2
Distribution	(81)	-	-	-	-	(81)	(90)	(10)	(9)
% sales	1.3%					1.3%	1.3%	+0.0	+0.0
R&D	(858)	53	5	(261)	-	(1,061)	(993)	7	7
% sales	13.7%					17.0%	14.9%	-2.1	-1.8
SG&A	(2,503)	126	223	-	-	(2,154)	(1,978)	9	11
% sales	40.1%					34.5%	29.6%	-4.9	-4.6
Other Income	136	-	40	-	-	176	433	(59)	(60)
% sales	2.2%					2.8%	6.5%	-3.7	-3.8
Operating Profit	1,706	185	397*	(261)	-	2,027	2,924	(31)	(29)
% sales	27.3%					32.4%	43.8%	-11.4	-11.4
Net Finance Expense	(114)	-	-	-	-	(114)	(126)		
Profit before Tax	1,592	185	397	(261)	-	1,913	2,798	(32)	(30)
Taxation	(344)	(37)	(67)*	60	-	(388)	(691)		
Profit after Tax	1,248	148	330	(201)	-	1,525	2,107	(28)	(26)
Non-controlling Interests	(2)	-	-	-	-	(2)	(8)		
Net Profit	1,246	148	330	(201)	-	1,523	2,099	(27)	(26)
Weighted Average Shares	1,252	1,252	1,252	1,252	1,252	1,252	1,250		
Earnings per Share	0.99	0.11	0.26	(0.15)	-	1.21	1.68	(28)	(26)

\* Intangible amortisation includes Merck related amortisation, of which \$87 million carries no tax adjustment.

Revenue in the third quarter was down 4 percent at CER and declined by 6 percent on an actual basis as a result of the negative impact of exchange rate movements, chiefly the Japanese yen. The estimated \$350 million revenue impact from products which have recently lost exclusivity is the lowest experienced in the trailing four quarters. The five growth platforms contributed \$232 million in revenue growth, an increase of 8 percent compared with last year.

US revenues were down 8 percent in the third quarter. Loss of exclusivity accounted for around half of the \$213 million revenue decline; the balance is driven by declines in Crestor and Nexium (both of which were somewhat affected by inventory destocking in the quarter), partially offset by growth for Symbicort, the diabetes franchise, FluMist and Brilinta. The negative impact of US healthcare reform on third quarter revenue and costs was approximately \$199 million.

Revenue in the Rest of World (ROW) was down 2 percent in the third quarter. Revenue in Europe was down 4 percent. Revenue declines related to the loss of exclusivity for Atacand, Nexium, and Seroquel IR, combined with generic competition for Seroquel XR (which included some "at risk" launches), were partially offset by revenue increases for Brilique and the diabetes franchise. Revenue in Established ROW was down 8 percent, largely due to generic competition for Nexium in Canada, and for Crestor in Canada and Australia. Revenue in Emerging Markets was up 5 percent, reflecting slower revenue growth in China (up 13 percent) which was impacted by inventory destocking in the quarter. Quarterly sales evolution in 2012 in Emerging Markets was also impacted by the supply chain issues we encountered last year, particularly in the first half. The Company expects a high single-digit revenue increase in Emerging Markets for the full year.

Core gross profit in the third quarter declined by 6 percent. Core gross margin was 82.4 percent, 120 basis points lower than last year. An unfavourable product mix contributed to the decline. The improvements to Core gross margin related to the accounting impact from the amendments to the Merck second option have now annualised.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Expenditures in Core SG&A were \$2,154 million, in line with the stepped-up levels of investment behind Brilinta, the diabetes franchise and Emerging Markets that commenced in the second quarter 2013. Core SG&A expense in the third quarter last year was the lowest single quarter in 2012, so the 11 percent increase compared with last year should be viewed in this context. The excise fee imposed by the enactment of US healthcare reform measures amounted to 3.0 percent of Core SG&A expense in the quarter.

Core other income of \$176 million was 60 percent lower than the third quarter last year, which included \$250 million from the agreement with Pfizer for OTC rights for Nexium.

Core Pre-R&D operating profit was down 20 percent to \$3,088 million in the third quarter. Core Pre-R&D operating margin was 49.4 percent of revenue, 9.6 percentage points lower than last year, largely on the higher Core SG&A expense and the significantly lower Core other income, with lower Core gross margin also a contributing factor.

Core R&D expense was up 7 percent in the third quarter, as increased spending on in-licensed, acquired or partnered projects was partially offset by productivity savings from ongoing restructuring.

Core operating profit in the third quarter was down 29 percent to \$2,027 million. Core operating margin was 32.4 percent of revenue, 11.4 percentage points lower than last year, the result of the decline in Core Pre-R&D operating margin combined with higher Core R&D expense as a percentage of revenue.

Core earnings per share in the third quarter were down 26 percent to \$1.21, a slightly smaller decline than for Core operating profit as a result of a lower tax rate.

Reported operating profit in the third quarter was down 19 percent to \$1,706 million; Reported EPS was down 16 percent to \$0.99. The smaller declines compared with the respective Core profit measures are largely due to the \$285 million (\$0.18 per share) reversal in the third quarter this year of the intangible impairment charge associated with olaparib.

Nine Months

All financial figures, except earnings per share, are in \$ millions. Weighted average shares in millions.

	Reported	Intangible	Intangible	Legal	Restated	Restated	Actual	CER	
	2013	Restructuring	Amortisation	Provisions	Core	Core	%	%	
			Impairments	& Other	2013	2012			
Revenue	18,867	-	-	-	18,867	20,691	(9)	(7)	
Cost of Sales	(3,821)	104	373	-	(3,344)	(3,722)			
Gross Profit	15,046	104	373	-	15,523	16,969	(9)	(7)	
% sales	79.7%				82.3%	82.0%	+0.3	+0.3	
Distribution	(234)	-	-	-	(234)	(241)	(3)	(2)	
% sales	1.2%				1.3%	1.2%	-0.1	-0.1	
R&D	(3,392)	406	15	(93)	(3,064)	(3,061)	-	-	
% sales	18.0%				16.2%	14.8%	-1.4	-1.1	
SG&A	(7,564)	526	669	(13)	(6,382)	(6,185)	3	5	
% sales	40.1%				33.8%	29.9%	-3.9	-3.7	
Other Income	447	-	117	-	564	882	(36)	(36)	
% sales	2.4%				3.0%	4.3%	-1.3	-1.4	
Operating Profit	4,303	1,036	1,174*	(93)	(13)	6,407	8,364	(23)	(21)
% sales	22.8%				34.0%	40.4%	-6.4	-6.0	
Net Finance Expense	(321)	-	-	-	(321)	(374)			
Profit before Tax	3,982	1,036	1,174	(93)	(13)	6,086	7,990	(24)	(21)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Taxation	(891)	(232)	(197)*	21	3	(1,296)	(1,493)		
Profit after Tax	3,091	804	977	(72)	(10)	4,790	6,497	(26)	(24)
Non-controlling Interests	(11)	-	-	-	-	(11)	(17)		
Net Profit	3,080	804	977	(72)	(10)	4,779	6,480	(26)	(24)
Weighted Average Shares	1,251	1,251	1,251	1,251	1,251	1,251	1,266		
Earnings per Share	2.46	0.64	0.78	(0.05)	(0.01)	3.82	5.12	(25)	(23)

\* Intangible amortisation includes Merck related amortisation, of which \$294 million carries no tax adjustment.

Revenue for the nine months was down 7 percent at CER and declined by 9 percent on an actual basis as a result of the negative impact of exchange rate movements. Loss of exclusivity on several key brands accounted for approximately \$1.8 billion in revenue decline at CER compared with last year. US revenue was down 10 percent; revenue in the Rest of World was down 5 percent.

Core gross margin was 82.3 percent, 0.3 percentage points higher than last year.

Expenditures in Core SG&A were 5 percent higher than last year, as a result of increased investment in support of growth platforms in the second and third quarters this year, an effect that is magnified when compared with the relatively low level of expenditures in the third quarter 2012.

Core other income for the nine months was down 36 percent compared with last year, which included the income from the sale of OTC rights for Nexium.

Core Pre-R&D operating profit was down 15 percent to \$9,471 million. Core Pre-R&D operating margin was 50.2 percent of revenue, 4.9 percentage points lower than last year, largely the result of higher Core SG&A expense as a percentage of revenue combined with lower Core other income.

Core R&D expense for the nine months was unchanged from last year.

Core operating profit for the nine months was down 21 percent to \$6,407 million. Core operating margin was 34.0 percent of revenue, down 6.0 percentage points.

Core earnings per share were \$3.82, down 23 percent compared with last year and somewhat greater than the decline in Core operating profit. The benefits to Core EPS as a result of lower number of shares outstanding and lower net finance expense this year were more than offset by a higher tax rate compared with last year, which included a tax settlement that benefited the tax rate in the second quarter 2012.

Reported operating profit for the nine months was down 27 percent to \$4,303 million; Reported EPS was down 31 percent to \$2.46. Net adjustments to Core financial measures were broadly similar this year (\$2,104 million) compared with last year (\$2,180 million), but they are applied to a lower baseline Core operating profit and Core EPS in the current period.

#### Enhancing Productivity

The Company is making good progress in implementing the fourth phase of restructuring announced in the first quarter of 2013. Restructuring charges of \$185 million were taken in the third quarter. The year-to-date total is \$1,036 million out of an estimated \$1.3 billion expected to be charged in 2013.

This phase of restructuring is expected to deliver benefits of \$800 million per annum by the end of 2016, half of which should be realised by the end of 2014.

#### Finance Income and Expense

Net finance expense was \$114 million for the third quarter 2013, versus \$126 million in 2012. For the nine months, net finance expense was \$321 million, versus \$374 million for the same period of 2012. Interest payable on defined benefit pension scheme liabilities fell by \$14 million in the nine months, and there were fair value gains of \$4 million recorded on long-term bonds in 2013, versus \$12 million losses in 2012. Interest on long-term bonds for the nine months was \$15 million lower than the comparative period in 2012.

#### Taxation

The Reported tax rate for the nine months was 22.4 percent, compared with 18.2 percent for the same period last year. The Reported tax rate for the quarter was 21.6 percent, compared with 25.2 percent for the same period last year. The Reported tax rate for the nine months ended 30 September 2012 included an adjustment of \$240 million in respect of prior periods following the settlement of a transfer pricing matter. Excluding this benefit, the effective tax rate for the nine months ended 30 September 2012 was 22.4 percent.

The Group's Reported tax rate for 2013 is still anticipated to be around 23 percent.

#### Cash Flow

Cash generated from operating activities was \$4,922 million in the nine months to 30 September 2013, compared with \$4,100 million in the same period of 2012. Lower tax and interest payments partially offset the lower operating profit in 2013, which included higher non-cash costs, whilst working capital movements and a one-off pension fund contribution drove higher outflows in the prior year.

Net cash outflows from investing activities were \$1,885 million in the nine months compared with \$1,345 million in the same period of 2012. 2013 included \$825 million on completion of the acquisitions of Pearl Therapeutics and Omthera Pharmaceuticals. The comparative period of 2012 included a \$3,631 million inflow from the maturity of short-term investments and higher intangible asset purchases, primarily those associated with our collaboration with Bristol-Myers Squibb on Amylin.

Net cash distributions to shareholders were \$3,193 million through dividends of \$3,461 million partially offset by proceeds from the issue of shares of \$268 million.

#### Debt and Capital Structure

At 30 September 2013, outstanding gross debt (interest-bearing loans and borrowings) was \$10,275 million (31 December 2012: \$10,310 million). Of the gross debt outstanding at 30 September 2013, \$1,709 million is due within one year (31 December 2012: \$901 million).

Net debt of \$1,606 million has increased by \$237 million during the nine months as a result of the net cash outflow as described in the cash flow section above.

#### Shares in Issue

In the nine months, 6.0 million shares were issued in respect of share schemes for a consideration of \$237 million.

The total number of shares in issue at 30 September 2013 was 1,253 million.

#### Future Prospects

The revenue impact from the loss of exclusivity has continued to moderate sequentially through the first three quarters of this year, with revenue for the nine months down 7 percent in constant currency terms. Based on performance to date, and the outlook for the remainder of the year, the Company continues to anticipate a mid-to-high single-digit decline in revenue on a constant currency basis for the full year.

Productivity and efficiency programmes are providing some of the headroom necessary to invest behind key growth platforms and to progress the pipeline; nevertheless, given the opportunities that we see to drive growth and value, Core operating costs (combined Core R&D and Core SG&A expense) will be higher than last year. The Company expects the increase in Core operating costs on a constant currency basis for the full year will be towards the upper end of its low-to-mid single-digit guidance range.

For Core other income, based on performance to date and the outlook for the remainder of the year, Core other income is expected to be around \$700 million, providing some mitigation to Core operating costs.

With a revenue and cost profile in line with this guidance, the Company continues to expect Core EPS to decline at a rate that is significantly higher than the decline in revenue in 2013.

Financial guidance for 2013 has been based on January 2013 average exchange rates for our principal currencies. Movements versus guidance rates have lowered revenue by around 2 percent and Core earnings per share by around 3 percent for the nine months, and may make a further impact in the fourth quarter if rates remain where they are. Financial guidance takes no account of the likelihood that average exchange rates for the remainder of 2013 may differ materially from the rates upon which our financial guidance is based. An estimate of the sales and earnings sensitivity to movements of our major currencies versus the US dollar was provided in conjunction with the Full Year 2012 results announcement, and can be found on the AstraZeneca website, [www.astrazeneca.com/investors](http://www.astrazeneca.com/investors).

#### Research and Development Update

---

A comprehensive update of the AstraZeneca R&D pipeline was presented in conjunction with the Half Year 2013 results announcement, and remains available on the Company's website, [www.astrazeneca.com](http://www.astrazeneca.com), under information for investors.

Significant pipeline developments since the half year update include:

Regulatory submissions accepted for review

##### Epanova

On 18 September 2013, AstraZeneca announced that the US Food and Drug Administration (FDA) has accepted for review a New Drug Application (NDA) for Epanova, an investigational compound for the treatment of patients with severe hypertriglyceridaemia (triglyceride levels greater than or equal to 500mg/dL). The NDA submission for Epanova was filed by Omthera Pharmaceuticals, now a wholly-owned subsidiary of AstraZeneca, as a 505(b)(1) application in July 2013. The Prescription Drug User Fee Act (PDUFA) goal date for the FDA is 5 May 2014.

##### Naloxegol

On 27 September 2013, the Company announced that the European Medicines Agency (EMA) has accepted the Marketing Authorisation Application (MAA) for naloxegol, an investigational peripherally-acting mu-opioid receptor



antagonist, which has been specifically designed for the treatment of opioid-induced constipation (OIC) for adult patients 18 years and older, including patients with inadequate response to laxatives.

The MAA filing was based on comprehensive data from the core Phase III KODIAC programme, comprised of four clinical trials designed to investigate the safety and efficacy of naloxegol for the treatment of OIC. Two pivotal Phase III studies, KODIAC-04 (n=652) and KODIAC-05 (n=700), both 12-week, multicentre, randomised, double-blind, placebo-controlled trials, evaluated 12.5mg and 25mg doses of naloxegol administered once-daily. KODIAC-07 was a 12-week safety extension of KODIAC-04, and KODIAC-08 (n= 534) was an open-label, randomised, 52-week, long-term safety trial.

Naloxegol is covered by the exclusive worldwide license agreement announced on 21 September 2009 between AstraZeneca and Nektar Therapeutics.

A US NDA for naloxegol has been submitted to the US FDA, and the Company is awaiting notification of its acceptance for review.

#### Olaparib

On 27 September 2013, AstraZeneca announced that the EMA has accepted its MAA for olaparib, an investigational poly ADP-ribose polymerase (PARP) inhibitor, for the maintenance treatment of patients with BRCA mutated platinum-sensitive relapsed serous ovarian cancer.

The MAA filing was based on Phase II study 19 data, a randomised, double-blind, placebo-controlled, Phase II study, which evaluated maintenance treatment with olaparib 400 mg twice daily (n=136) versus placebo (n=129) in platinum-sensitive relapsed serous ovarian cancer patients who had received previous treatment with at least two platinum regimens and were in a partial or complete response following their last platinum regimen. The primary endpoint was progression-free survival by Response Evaluation Criteria in Solid Tumors (RECIST) guidelines. Secondary endpoints included time to progression by CA-125 (GCIG criteria) or RECIST, overall survival and safety. A pre-defined subgroup analysis was conducted of patients who have BRCA mutations (n=136), which showed the treatment benefit of olaparib was greater in patients with BRCA mutated ovarian cancer.

Olaparib has the potential to be the first PARP inhibitor available for patients with BRCA mutated platinum-sensitive relapsed serous ovarian cancer.

#### Phase III development programme starts

#### Olaparib

On 4 September 2013, the Company announced enrollment of the first patient in the Phase III clinical programme for olaparib, an innovative oral poly ADP-ribose polymerase (PARP) inhibitor being investigated for the treatment of BRCA mutated ovarian cancer. The Phase III SOLO (Study of OLaparib in Ovarian cancer) programme is designed to determine the benefit, by progression free survival (PFS), of olaparib as a maintenance monotherapy in BRCA mutated ovarian cancer patients who are in complete or partial response following platinum-based chemotherapy in the first line setting (SOLO 1), and in the relapsed setting (SOLO 2).

The SOLO 1 study is being conducted in collaboration with the Gynecologic Oncology Group and the SOLO 2 study with the European Network of Gynaecological Oncological Trial Groups. Both trials are randomised, double-blind, placebo-controlled studies that utilise the tablet formulation of olaparib at a dose of 300mg twice daily.

The initiation of these studies is based on the sub-group analysis by BRCA mutation status from Study 19, a randomised Phase II study evaluating olaparib as maintenance treatment versus placebo in platinum-sensitive relapsed

serous ovarian cancer patients. The pre-defined sub-group analysis of patients with BRCA mutations demonstrated a statistically significant improvement in PFS of 11.2 vs 4.3 months (HR 0.18,  $p < 0.00001$ ).

As a result of the initiation of this programme, the pre-tax impairment charge of \$285 million, which was incurred in December 2011 following the decision not to progress olaparib into Phase III development, has been reversed in the third quarter of 2013. The reversal of this impairment charge has been excluded from our Core financial measures.

Also in September, the first patient was enrolled in the Phase III GOLD (Gastric OLaparib stuDy) study designed to determine the benefit by overall survival (OS) of olaparib plus paclitaxel in second-line gastric cancer in Asian patients. The initiation of this study followed the results from Study 39, a randomised Phase II study evaluating the combination of olaparib and paclitaxel against paclitaxel alone in Korean patients with relapsed gastric cancer where the study population was enriched for ATM deficient gastric cancers. Study 39 demonstrated a significant OS benefit in both the overall study population (HR 0.56,  $p = 0.005$ ) and in the ATM-negative population (HR 0.35,  $p = 0.002$ ).

#### Selumetinib

On 22 October 2013, AstraZeneca announced the first patient randomised in the Phase III clinical programme for selumetinib, an oral, potent, selective MEK inhibitor, being investigated as second-line therapy in patients with advanced or metastatic non-small-cell lung cancer (NSCLC) whose tumours are KRAS mutation-positive.

The SELumetinib Evaluation as Combination Therapy-1 (SELECT-1) study is a randomised, double-blind, placebo-controlled study that will evaluate the safety and efficacy of selumetinib plus docetaxel as a second line therapy in locally advanced or metastatic KRAS mutation-positive NSCLC. The study is designed to evaluate Progression Free Survival (PFS) and Overall Survival (OS). SELECT-1 will be the largest prospective study ever conducted in this patient population, a genetic sub-type of lung cancer associated with poor prognosis and limited treatment options.

The decision to progress selumetinib to Phase III studies in NSCLC followed the results from Study 16, a randomised Phase II study evaluating the combination of selumetinib with standard of care docetaxel against docetaxel alone in KRAS mutation-positive NSCLC. Study 16 demonstrated a high rate of profound and durable tumour response - 37.2% vs 0% ( $p < 0.0001$ ), translating into a statistically significant improvement in progression free survival (PFS) of 5.3 vs 2.1 months (HR 0.58,  $p < 0.014$ ).

AstraZeneca acquired exclusive worldwide rights to selumetinib from Array BioPharma in 2003.

#### Benralizumab

On 30 October 2013, the Company announced the start of the Phase III Windward programme for benralizumab, a potential treatment for severe uncontrolled asthma developed by MedImmune, the Company's global biologics research and development arm. The goal of CALIMA, the first study in the Windward programme, is to determine whether benralizumab reduces the number of exacerbations in patients with severe asthma that remains uncontrolled, despite receiving high doses of inhaled corticosteroids in combination with a second controller such as a long-acting beta agonist.

Benralizumab is a monoclonal antibody binding to the interleukin-5 receptor (IL-5R ) that depletes eosinophils, a type of white blood cell, which play a critical role in the cause and severity of asthma and asthma exacerbations. Emerging evidence shows that for patients with elevated eosinophil counts, treatment with an IL-5 inhibitor in addition to guideline-based strategies may improve their asthma control and decrease the frequency of asthma attacks.

Initiation of this trial is based on results from the Phase IIb asthma study, conducted by MedImmune, which showed that patients with elevated eosinophils on benralizumab had a statistically significant reduction in exacerbation rate compared to placebo, as well as improvements in lung function and asthma symptoms. The efficacy and safety data

from this trial supported the progression of benralizumab into our Phase III programme. These results are expected to be shared at a scientific conference in the first half of 2014.

In addition to CALIMA, the Windward programme will include two pivotal exacerbation trials for benralizumab added to high- (SIROCCO) or medium- (PAMPERO) dose inhaled corticosteroids plus a long-acting beta agonist; an oral corticosteroid-reducing trial (ZONDA); and a long-term safety trial (BORA). These trials are designed to provide additional information about benralizumab in patients with severe uncontrolled asthma.

#### Business development transactions

##### Amplimmune

On 4 October 2013, AstraZeneca completed its acquisition of Amplimmune, a privately-held, US-based biologics company focused on developing novel therapeutics in cancer immunology.

This acquisition bolsters MedImmune's oncology pipeline by obtaining multiple early-stage assets for its immune-mediated cancer therapy (IMT-C) portfolio, including AMP-514, an anti-programmed cell death 1 (PD-1) monoclonal antibody. AMP-514 was in late-stage pre-clinical development with the aim of an investigational new drug (IND) filing before the end of 2013, which has now been achieved. Other Amplimmune assets include multiple pre-clinical molecules targeting the B7 pathways.

MedImmune, with its clinical stage programmes and a robust pre-clinical pipeline, is building one of the most comprehensive programmes in IMT-C. IMT-Cs are being designed to empower the immune system to counteract the tactics employed by cancer cells to avoid detection and attack the body.

Upon completion of the acquisition, AstraZeneca acquired 100 percent of Amplimmune's shares for an initial consideration of \$225 million and deferred consideration of up to \$275 million based on reaching predetermined development milestones.

##### License agreement with Merck

On 11 September 2013, AstraZeneca and Merck & Co Inc. announced a worldwide licensing agreement for Merck's oral small molecule inhibitor of WEE1 kinase (MK-1775). MK-1775 is currently being evaluated in Phase IIa clinical studies in combination with standard of care therapies for the treatment of patients with certain types of ovarian cancer.

WEE1 helps to regulate the cell-division cycle. The WEE1 inhibitor MK-1775 is designed to cause certain tumour cells to divide without undergoing the normal DNA repair processes, ultimately leading to cell death. Pre-clinical evidence suggests that the combination of MK-1775 and DNA damage-inducing chemotherapy agents can enhance anti-tumour properties, in comparison to chemotherapy alone.

Under the terms of the agreement, AstraZeneca will pay Merck a \$50 million upfront fee. In addition, Merck will be eligible to receive future payments tied to development and regulatory milestones plus sales-related payments and tiered royalties. AstraZeneca will be responsible for all future clinical development, manufacturing and marketing.

##### Co-promotion agreement with Janssen Pharmaceuticals KK in Japan

On 11 October 2013, AstraZeneca announced that it has entered into an agreement with Janssen Pharmaceuticals KK in Japan to co-promote abiraterone acetate, an innovative oral therapy for the treatment of patients with prostate cancer.

Currently the main treatment option available to patients in Japan is medical castration, however prostate cancer can still progress in many patients because androgens are produced in other tissues. Abiraterone acetate, a CYP17-inhibitor, inhibits the key enzyme which modulates the production of androgens, hormones which stimulate prostate cancer cells to grow, from all sources in the body. This helps lower the level of androgens available to the prostate cancer cells, which is the goal of treatment in prostate cancer.

Janssen Pharmaceuticals KK submitted a marketing approval application for abiraterone acetate to the Japanese Ministry of Health, Labour and Welfare in July 2013 for the treatment of prostate cancer. The product was approved in the US by the FDA in April 2011, and in the EU by the European Commission in September 2011 for the treatment of patients with metastatic castration-resistant prostate cancer.

Financial terms of the agreement were not disclosed.

#### Acquisition of Spirogen and collaboration with ADC Therapeutics

On 15 October 2013, AstraZeneca announced that it has acquired Spirogen, a privately-held biotech company focused on antibody-drug conjugate technology for use in oncology.

AstraZeneca has also entered into a collaboration agreement with ADC Therapeutics to jointly develop two of ADC Therapeutics' antibody-drug conjugate programmes in pre-clinical development. The Company will also make an equity investment in ADC Therapeutics, which has an existing licensing agreement with Spirogen.

AstraZeneca will acquire 100 percent of Spirogen's shares for an initial consideration of \$200 million and deferred consideration of up to \$240 million based on reaching predetermined development milestones. Existing out-licensing agreements and associated revenue streams are excluded from this acquisition.

AstraZeneca will also pay \$20 million for an equity investment in ADC Therapeutics, which will be matched by Auen Therapeutics, the majority shareholder in both ADC Therapeutics and Spirogen. The collaboration agreement will include an upfront payment with predetermined development milestones for two programmes from a defined list and a cost- and profit-sharing arrangement with AstraZeneca representing the majority share. ADC Therapeutics will also have the option to co-promote one of the products in the US.

Antibody-drug conjugates are a clinically-validated cancer drug technology that offers both high potency and selective targeting of cancer cells. Spirogen's proprietary pyrrolobenzodiazepine (PBD) technology attaches highly potent cytotoxic agents, or 'warheads' to specific cancer-targeting antibodies using biodegradable 'linkers'. This targeting optimises the delivery of the cancer drug to the tumour cells only and provides the greatest degree of tumour killing while minimising the toxicity to the patient.

#### Revenue

All narrative in this section refers to growth rates at constant exchange rates (CER) unless otherwise indicated.

A full analysis of the Group's revenue by product and geographic area is shown in Notes 10 and 11.

	Third Quarter			Nine Months		
	2013	2012	CER	2013	2012	CER
	\$m	\$m	%	\$m	\$m	%
Cardiovascular						
Crestor	1,356	1,544	-11	4,159	4,631	-9
Onglyza	93	84	+10	285	235	+21

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Byetta	57	27	+111	152	27	n/m
Bydureon	43	11	+291	102	11	n/m
Forxiga	3	-	n/m	7	-	n/m
Brilinta/Brilique	75	24	+208	191	51	+273
Atacand	143	221	-35	477	807	-40
Seloken/Toprol-XL	173	230	-23	580	662	-12
Gastrointestinal						
Nexium	918	995	-5	2,881	2,897	+1
Losec/Prilosec	118	189	-34	364	554	-31
Respiratory & Inflammation						
Symbicort	839	785	+7	2,507	2,303	+10
Pulmicort	176	191	-6	622	624	+1
Oncology						
Zoladex	246	274	-	749	822	-1
Arimidex	90	130	-26	265	421	-33
Casodex	93	111	-5	281	342	-9
Iressa	165	154	+12	489	451	+13
Faslodex	169	167	+3	499	479	+6
Neuroscience						
Seroquel	423	542	-21	1,310	2,327	-43
Seroquel IR	84	169	-47	310	1,200	-73
Seroquel XR	339	373	-10	1,000	1,127	-11
Vimovo	23	14	+64	67	47	+43
Infection and other						
Synagis	130	96	+35	545	535	+2
Merrem	67	90	-23	216	290	-24
FluMist	188	145	+30	195	149	+31
Cardiovascular						

- In the US, Crestor sales in the third quarter were \$719 million, down 14 percent, on an 8 percent decline in total prescriptions combined with some inventory destocking and slightly lower realised prices. Crestor sales for the nine months in the US were down 7 percent to \$2,133 million.
- Crestor sales in the Rest of World in the third quarter were down 7 percent to \$637 million, largely due to loss of exclusivity in Canada (down 42 percent) and Australia (down 68 percent); excluding these markets, ROW sales were up 4 percent, on growth in Emerging Markets and in Japan. Crestor sales in the Rest of World for the nine months were down 10 percent to \$2,026 million.
- Alliance revenue from the Onglyza collaboration with Bristol-Myers Squibb was up 10 percent in the third quarter to \$93 million, with most of the growth coming in markets outside the US, where revenue was up 32 percent to \$30 million. Revenue in the US was up 2 percent in the third quarter to \$63 million.  
Market share of total prescriptions in the DPP4 market in the US was 16.0 percent in September 2013, unchanged from June, despite the launch of new entrants. AstraZeneca's share of worldwide alliance revenue for the nine months was \$285 million, up 21 percent.
- Alliance revenue for Forxiga was \$3 million in the quarter and \$7 million for the nine months, chiefly in Europe, where there has been good physician acceptance since approval in November 2012, but a challenging reimbursement climate to navigate.

- The Company's share of Byetta and Bydureon revenues was \$100 million in the third quarter; comprised of \$75 million in the US and \$25 million in Rest of World. US revenue in the third quarter 2012 only reflects a partial quarter, and there were no revenues recorded in the Rest of World as the alliance only assumed responsibility for promotion in April 2013. In the US, total prescriptions for Bydureon were up 74 percent over the third quarter 2012. Total prescriptions for Byetta were down 35 percent over the same period; as a result, total prescriptions for the exenatide franchise were down 9 percent. New to brand share of total prescriptions for the exenatide franchise did improve during the third quarter compared to the exit rate at the end of June this year. Worldwide revenue for the exenatide products was \$254 million for the nine months.
- Sales of Brilinta/Brilique were \$75 million in the third quarter, up from \$65 million in the second quarter 2013. Nearly sixty percent of sales are in Europe, with third quarter sales of \$44 million, well ahead of last year. Performance in Canada, Australia and the Emerging Markets is also now making a contribution to revenue growth. Worldwide sales for Brilinta/Brilique were \$191 million for the nine months.
- Brilinta sales in the US in the third quarter were \$18 million. Total prescriptions for Brilinta in the US in the third quarter 2013 were 22 percent higher than the second quarter 2013, compared with reported sales growth over this period of 13 percent, which was dampened by an adjustment to returns reserves. We continue to see a steady increase in new to brand share in the US oral antiplatelet market, with market share now at 6.3 percent of the total OAP market in September 2013.
- US sales of Atacand were down 74 percent in the third quarter, to \$11 million. Sales for the nine months were down 47 percent to \$62 million.
- Atacand sales in other markets were down 26 percent to \$132 million in the third quarter, largely due to the loss of exclusivity in developed markets, and stable sales in Emerging Markets. Sales in the Rest of World for the nine months were \$415 million, down 39 percent.
- US sales of the Toprol-XL product range, which includes sales of the authorised generic, declined by 68 percent to \$25 million in the third quarter, due to declining prescriptions and lower prices following the launch of a third generic product late last year. Sales for the nine months in the US were down 50 percent to \$112 million.
- Sales of Seloken in other markets in the third quarter were down 1 percent to \$148 million, as some softness in China offset growth in other Emerging Markets. Sales in ROW for the nine months were up 7 percent to \$468 million.

#### Gastrointestinal

- In the US, Nexium sales in the third quarter were \$500 million, down 15 percent compared with the third quarter last year, driven by an 11 percent decline in dispensed retail tablet volume combined with some inventory destocking. Nexium sales in the US for the nine months were down 6 percent to \$1,578 million.
- As a result of various settlements of patent litigation, several generic companies were granted a license to enter the US market with their proposed ANDA versions of generic esomeprazole on 27 May 2014, subject to regulatory approval, or earlier, in certain circumstances. In line with the Company's standard practice, a returns reserve will be taken against the estimated trade inventories of Nexium at the time of the first generic launch. We will also move the brand to demand based accounting, wherein revenue will be recognised based on demand sales, indicated by dispensed prescription demand, rather than ex-factory shipments. Therefore, Nexium revenue in 2014 will reflect this accounting treatment, the loss of market share to generic substitution, and the impact of channel destocking as trade inventories contract to adjust to the declining sales trend.
- Nexium sales in other markets in the third quarter were up 8 percent to \$418 million. Continued strong growth in Japan was partially offset by declines in Canada and in Europe from generic competition. Sales in Emerging Markets were down despite 15 percent growth in China. Nexium

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

sales in other markets were up 11 percent for the nine months to \$1,303 million.

- Losec sales in markets outside the US were down 35 percent in the third quarter to \$111 million. Sales for the nine months were down 32 percent to \$341 million.

### Respiratory and Inflammation

- Symbicort sales in the US were \$307 million, a 16 percent increase over the third quarter last year. Total prescriptions for Symbicort were up 18 percent compared to a 2 percent increase in the market for fixed combination products. Symbicort share of total prescriptions for fixed combination products reached 25.0 percent in September 2013, up 2.7 percentage points since December 2012. Market share of patients newly starting combination therapy is 31.3 percent. Symbicort sales in the US for the nine months were up 21 percent to \$883 million.
- Symbicort sales in other markets in the third quarter were \$532 million, up 3 percent, as growth in Japan (up 17 percent) and in Emerging Markets (up 16 percent), more than offset a 3 percent sales decline in Europe. Symbicort sales in the Rest of World for the nine months were up 5 percent to \$1,624 million.
- US sales of Pulmicort were down 23 percent in the third quarter to \$47 million. Sales for the nine months were down 7 percent to \$165 million.
- Pulmicort sales in the Rest of World were up 2 percent in the third quarter to \$129 million, largely on a 20 percent increase in China. Rest of World sales for Pulmicort for the nine months were \$457 million, 4 percent higher than last year.

### Oncology

- Arimidex sales for the nine months were \$265 million worldwide, down 33 percent, as sales continue to decline as a result of loss of exclusivity.
- Sales of Casodex for the nine months were \$281 million, down 9 percent. All but \$3 million of these sales were in markets outside the US. Sales in Japan, which account for 57 percent of global revenue, were down 12 percent for the nine months.
- Iressa sales in the third quarter were up 12 percent to \$165 million. Sales in Emerging Markets were up 16 percent. Sales in Japan and in Europe were each up 8 percent. Worldwide sales of Iressa for the nine months increased 13 percent to \$489 million.
- In the third quarter, Faslodex sales in the US were up 4 percent to \$83 million, and increased by 2 percent in the Rest of World to \$86 million. Worldwide sales for the nine months were \$499 million, up 6 percent.

### Neuroscience

- In the US, sales of Seroquel IR for the nine months were \$2 million.
- Sales of Seroquel XR in the US were \$194 million in the third quarter, down 4 percent. Total prescriptions for Seroquel XR were down 7 percent. US sales of Seroquel XR for the nine months were down 8 percent to \$549 million.
- Sales of Seroquel IR in the Rest of World were down 28 percent to \$86 million in the third quarter, on declines in Europe and in Emerging Markets, further exacerbated by the impact of the timing of shipments to our partner in Japan. Sales in the Rest of World for Seroquel IR for the nine months were down 33 percent to \$308 million.
- Sales of Seroquel XR in the Rest of World were down 16 percent to \$145 million in the third quarter. Sales in Europe were down 20 percent, as growth in France was more than offset by declines in Germany and Italy. Sales in Emerging Markets were up 19 percent in the quarter. Seroquel XR sales in the Rest of World for the nine months were \$451 million, down 15 percent.

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

- Sales of Vimovo in the third quarter were \$23 million, comprised of \$5 million in the US and \$18 million in the Rest of World. Worldwide, sales for the nine months were \$67 million.

### Infection and Other

- Synagis sales in the US were \$6 million in the third quarter, which is out of season. Outside the US, sales in the third quarter were \$124 million, up 36 percent. This follows a 76 percent decrease in the second quarter; a reflection of the quarterly phasing of shipments to AbbVie, our international distributor.
- Sales of Merrem for the nine months were down 24 percent to \$216 million as a result of generic competition in many markets.
- Sales of FluMist in the third quarter were \$188 million, of which \$170 million were in the US and \$18 million were in the Rest of World. Sales in the US were up 21 percent, reflecting good reception for the launch of FluMist Quadrivalent.

### Regional Revenue

	Third Quarter				Nine Months		% Change	
	2013	2012	% Change		2013	2012	Actual	CER
	\$m	\$m	Actual	CER	\$m	\$m		
US	2,360	2,573	-8	-8	7,057	7,832	-10	-10
Europe <sup>1</sup>	1,630	1,612	+1	-4	4,836	5,353	-10	-11
Established ROW <sup>2</sup>	941	1,211	-22	-8	2,950	3,733	-21	-10
Japan	611	723	-15	+5	1,817	2,044	-11	+7
Canada	144	218	-34	-32	476	881	-46	-45
Other Established ROW	186	270	-31	-23	657	808	-19	-16
Emerging Markets <sup>3</sup>	1,319	1,286	+2	+5	4,024	3,773	+7	+9
China	467	399	+17	+13	1,363	1,128	+21	+18
Total	6,250	6,682	-6	-4	18,867	20,691	-9	-7

1 Europe comprises Western Europe and many markets that were formerly reported in Emerging Rest of World.

2 Established ROW comprises Canada, Japan, Australia and New Zealand.

3 Emerging Markets comprises all of the remaining Rest of World markets, including Brazil, China, India, Mexico, Russia and Turkey.

- In the US, revenue was down 8 percent in the third quarter. Revenue declines due to loss of exclusivity were largely offset by growth for Symbicort, the diabetes franchise, FluMist and Brilinta, however sales of Crestor and Nexium were both down in the quarter, partially due to some inventory destocking.
- Revenue in Europe was down 4 percent in the third quarter, as revenue declines related to loss of exclusivity (chiefly Atacand, Seroquel XR, Seroquel IR and Nexium) were partially offset by revenue increases for Brilique and the diabetes franchise.
- Revenue in Established Rest of World was down 8 percent in the third quarter, largely due to generic competition for Nexium in Canada and for Crestor in Canada and Australia. Revenue in Japan was up 5 percent. There were good volume market share gains for Nexium, Crestor and Symbicort in Japan. As previously described, reported sales growth rates in Japan are volatile, as many of our key products are affected by the timing of shipments to marketing partners. Based on the phasing of such shipments last year, the Company expects reported sales in Japan will decline in the fourth quarter, irrespective of in-market demand for our products.



Edgar Filing: ASTRAZENECA PLC - Form 6-K

Revenue in Emerging Markets was up 5 percent in the third quarter, including a 13 percent increase in China, which was impacted by some inventory destocking in the quarter. It is also important to keep in mind that the quarterly sales evolution in 2012 was impacted by the supply chain issues we encountered last year, particularly in the first half. The Company expects a high single-digit revenue increase in Emerging Markets for the full year.

Condensed Consolidated Statement of Comprehensive Income

	2013	Restated*
	2012	
For the nine months ended 30 September	\$m	\$m
Revenue	18,867	20,691
Cost of sales	(3,821)	(3,995)
Gross profit	15,046	16,696
Distribution costs	(234)	(241)
Research and development expense	(3,392)	(3,923)
Selling, general and administrative costs	(7,564)	(7,170)
Other operating income and expense	447	822
Operating profit	4,303	6,184
Finance income	37	27
Finance expense	(358)	(401)
Profit before tax	3,982	5,810
Taxation	(891)	(1,060)
Profit for the period	3,091	4,750
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(239)	(158)
Tax on items that will not be reclassified to profit or loss	(38)	(18)
	(277)	(176)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(140)	215
Foreign exchange differences on borrowings designated in net investment hedges	(23)	(25)
Fair value movements on derivatives designated in net investment hedges	60	-
Amortisation of loss on cash flow hedge	1	1
Net available for sale gains taken to equity	59	39
Tax on items that may be reclassified subsequently to profit or loss	1	3
	(42)	233
Other comprehensive income for the period, net of tax	(319)	57
Total comprehensive income for the period	2,772	4,807
Profit attributable to:		
Owners of the parent	3,080	4,733
Non-controlling interests	11	17
	3,091	4,750
Total comprehensive income attributable to:		
Owners of the parent	2,785	4,792
Non-controlling interests	(13)	15

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	2,772	4,807
Basic earnings per \$0.25 Ordinary Share	\$2.46	\$3.74
Diluted earnings per \$0.25 Ordinary Share	\$2.46	\$3.73
Weighted average number of Ordinary Shares in issue (millions)	1,251	1,266
Diluted weighted average number of Ordinary Shares in issue (millions)	1,253	1,269

\* Restatement relates to the adoption of IAS 19 (2011), see Note 1.

Condensed Consolidated Statement of Comprehensive Income

	2013	Restated*
	2012	
	\$m	\$m
For the quarter ended 30 September		
Revenue	6,250	6,682
Cost of sales	(1,238)	(1,274)
Gross profit	5,012	5,408
Distribution costs	(81)	(90)
Research and development expense	(858)	(1,204)
Selling, general and administrative costs	(2,503)	(2,359)
Other operating income and expense	136	401
Operating profit	1,706	2,156
Finance income	14	9
Finance expense	(128)	(135)
Profit before tax	1,592	2,030
Taxation	(344)	(511)
Profit for the period	1,248	1,519
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(212)	155
Tax on items that will not be reclassified to profit or loss	(48)	(60)
	(260)	95
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	212	193
Foreign exchange differences on borrowings designated in net investment hedges	(68)	(43)
Fair value movements on derivatives designated in net investment hedges	1	-
Net available for sale (losses)/gains taken to equity	(24)	32
Tax on items that may be reclassified subsequently to profit or loss	8	12
	129	194
Other comprehensive income for the period, net of tax	(131)	289
Total comprehensive income for the period	1,117	1,808
Profit attributable to:		
Owners of the parent	1,246	1,511
Non-controlling interests	2	8
	1,248	1,519

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total comprehensive income attributable to:		
Owners of the parent	1,112	1,797
Non-controlling interests	5	11
	1,117	1,808
Basic earnings per \$0.25 Ordinary Share	\$0.99	\$1.21
Diluted earnings per \$0.25 Ordinary Share	\$0.99	\$1.20
Weighted average number of Ordinary Shares in issue (millions)	1,252	1,250
Diluted weighted average number of Ordinary Shares in issue (millions)	1,254	1,252

\* Restatement relates to the adoption of IAS 19 (2011), see Note 1.

Condensed Consolidated Statement of Financial Position

	At 30 Sep 2013 \$m	Restated* At 31 Dec 2012 \$m	Restated* At 30 Sep 2012 \$m
<b>ASSETS</b>			
Non-current assets			
Property, plant and equipment	5,728	6,089	6,094
Goodwill	9,943	9,898	9,898
Intangible assets	17,256	16,448	16,677
Derivative financial instruments	328	389	330
Other investments	236	199	172
Other receivables	539	352	-
Deferred tax assets	1,299	1,111	1,248
	35,329	34,486	34,419
Current assets			
Inventories	2,075	2,061	2,090
Trade and other receivables	7,294	7,629	8,001
Other investments	864	823	799
Derivative financial instruments	25	31	-
Income tax receivable	1,081	803	1,122
Cash and cash equivalents	7,453	7,701	6,017
	18,792	19,048	18,029
Total assets	54,121	53,534	52,448
<b>LIABILITIES</b>			
Current liabilities			
Interest-bearing loans and borrowings	(1,709)	(901)	(1,566)
Trade and other payables	(9,242)	(9,221)	(8,629)
Derivative financial instruments	(1)	(3)	(1)
Provisions	(579)	(916)	(1,005)
Income tax payable	(3,144)	(2,862)	(2,927)
	(14,675)	(13,903)	(14,128)
Non-current liabilities			
Interest-bearing loans and borrowings	(8,566)	(9,409)	(9,347)
Deferred tax liabilities	(3,143)	(2,576)	(2,622)
Retirement benefit obligations	(2,588)	(2,271)	(2,490)
Provisions	(781)	(428)	(442)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other payables	(921)	(1,001)	(1,164)
	(15,999)	(15,685)	(16,065)
Total liabilities	(30,674)	(29,588)	(30,193)
Net assets	23,447	23,946	22,255
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	314	312	312
Share premium account	3,770	3,504	3,437
Other reserves	1,964	1,960	1,955
Retained earnings	17,200	17,955	16,328
	23,248	23,731	22,032
Non-controlling interests	199	215	223
Total equity	23,447	23,946	22,255

\* Restatement relates to the adoption of IAS 19 (2011), see Note 1.

Condensed Consolidated Statement of Cash Flows

	2013	Restated*
	2012	
	\$m	\$m
For the nine months ended 30 September		
Cash flows from operating activities		
Profit before tax	3,982	5,810
Finance income and expense	321	374
Depreciation, amortisation and impairment	1,978	1,754
Increase in working capital and short-term provisions	(257)	(957)
Non-cash and other movements	409	(388)
Cash generated from operations	6,433	6,593
Interest paid	(416)	(477)
Tax paid	(1,095)	(2,016)
Net cash inflow from operating activities	4,922	4,100
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	20	3,631
Purchase of property, plant and equipment	(359)	(422)
Disposal of property, plant and equipment	55	159
Purchase of intangible assets	(913)	(3,633)
Purchase of non-current asset investments	(14)	(10)
Disposal of non-current asset investments	31	25
Acquisitions of business operations	(825)	(1,187)
Interest received	88	112
Payments made by subsidiaries to non-controlling interests	(10)	(20)
Payments received by subsidiaries from non-controlling interests	42	-
Net cash outflow from investing activities	(1,885)	(1,345)
Net cash inflow before financing activities	3,037	2,755
Cash flows from financing activities		
Proceeds from issue of share capital	268	362
Repurchase of shares for cancellation	-	(2,635)
Issue of loans	-	1,980
Repayment of loans	-	(1,750)

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Dividends paid	(3,461)	(3,665)
Hedge contracts relating to dividend payments	(36)	48
Repayment of obligations under finance leases	(19)	-
Movement in short-term borrowings	-	1,262
Net cash outflow from financing activities	(3,248)	(4,398)
Net decrease in cash and cash equivalents in the period	(211)	(1,643)
Cash and cash equivalents at the beginning of the period	7,596	7,434
Exchange rate effects	(62)	10
Cash and cash equivalents at the end of the period	7,323	5,801
Cash and cash equivalents consists of:		
Cash and cash equivalents	7,453	6,017
Overdrafts	(130)	(216)
	7,323	5,801

\* Restatement relates to the adoption of IAS 19 (2011), see Note 1.

## Condensed Consolidated Statement of Changes in Equity

	Share capital	Share premium account	Other reserves*	Retained earnings	Total	Non-controlling interests	Total equity
	\$m	\$m	\$m	\$m	\$m	\$m	\$m
At 1 Jan 2012**	323	3,078	1,951	17,888	23,240	226	23,466
Profit for the period**	-	-	-	4,733	4,733	17	4,750
Other comprehensive income**	-	-	-	59	59	(2)	57
Transfer to other reserves	-	-	(10)	10	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,619)	(3,619)	-	(3,619)
Issue of Ordinary Shares	3	359	-	-	362	-	362
Repurchase of Ordinary Shares	(14)	-	14	(2,635)	(2,635)	-	(2,635)
Share-based payments	-	-	-	(108)	(108)	-	(108)
Transfer from non-controlling interests to payables	-	-	-	-	-	(7)	(7)
Dividend paid to non-controlling interests	-	-	-	-	-	(11)	(11)
Net movement	(11)	359	4	(1,560)	(1,208)	(3)	(1,211)
At 30 Sep 2012**	312	3,437	1,955	16,328	22,032	223	22,255
	Share capital	Share premium account	Other reserves*	Retained earnings	Total	Non-controlling interests	Total equity
	\$m	\$m	\$m	\$m	\$m	\$m	\$m
At 1 Jan 2013**	312	3,504	1,960	17,955	23,731	215	23,946
Profit for the period	-	-	-	3,080	3,080	11	3,091

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other comprehensive income	-	-	-	(295)	(295)	(24)	(319)
Transfer to other reserves	-	-	4	(4)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,499)	(3,499)	-	(3,499)
Issue of Ordinary Shares	2	266	-	-	268	-	268
Share-based payments	-	-	-	(75)	(75)	-	(75)
Transfer from non-controlling interests to payables	-	-	-	-	-	(3)	(3)
Dividend paid to non-controlling interests	-	-	-	-	-	(3)	(3)
Disposal to non-controlling interests	-	-	-	38	38	3	41
Net movement	2	266	4	(755)	(483)	(16)	(499)
At 30 Sep 2013	314	3,770	1,964	17,200	23,248	199	23,447

\* Other reserves includes the capital redemption reserve and the merger reserve.

\*\* Restated on adoption of IAS 19 (2011), see Note 1.

Notes to the Interim Financial Statements

1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

These unaudited condensed consolidated interim financial statements ("interim financial statements") for the nine months ended 30 September 2013 have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB). 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 2012, except where new or revised accounting standards have been applied.

With effect from 1 January 2013, the Group adopted the amendments to IAS 19 Employee Benefits. Under IAS 19 (2011), the Group determines net interest on the net retirement benefit obligation by applying the discount rate used to measure the retirement benefit obligations at the beginning of the annual period. Consequently, the net charge to 'finance expense' now comprises interest cost on the defined benefit obligation, interest income on plan assets and interest on the effect on the asset ceiling. Previously, the Group determined interest income on plan assets based on their long-term rate of expected return and recorded as 'finance income'. As a result of applying the discount rate as detailed above, the prior period net finance expense has been restated to reflect a \$54 million increase with an equal and opposite decrease recognised in other comprehensive income. The Group's net assets have reduced by \$6 million on adoption of the amendments, as previously unrecognised past service costs, which were previously recognised over the remaining service life of the employees, are recognised retrospectively in retained earnings.

The Group has also adopted the amendments to IAS 1 Presentation of Items in Other Comprehensive Income issued in 2011, resulting in a change to the presentation of items within other comprehensive income. In addition, effective 1 January 2013, the Group has adopted IFRS 10 Consolidated Financial Statements, IFRS 11 Joint Arrangements, IFRS 12 Disclosure of Interests in Other Entities and IFRS 13 Fair Value Measurement, along with consequential amendments to IAS 27 Separate Financial Statements and IAS 28 Investments in Associates and Joint Ventures, and amendments to IFRS 7 Financial Instruments: Disclosures on offsetting financial assets and liabilities, none of which have had an impact on the Group's net results, net assets or disclosures, other than additional information on financial instruments included in Note 8, arising from the adoption of IFRS 13 and its consequential impact on the disclosures required under IAS 34 Interim Financial Reporting.

The information contained in Note 9 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2012.

The Group has considerable financial resources available. As at 30 September 2013, the Group has \$8.8 billion in financial resources (cash balances of \$7.5 billion and undrawn committed bank facilities of \$3.0 billion which are available until April 2018, with only \$1.7 billion 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, recent 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 despite the current uncertain economic outlook.

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 interim financial statements have been prepared on a going concern basis.

The comparative figures for the financial year ended 31 December 2012 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and delivered to the registrar of companies. The report of the auditors was (i) unqualified, (ii) did not include a reference to any matters to which the auditors 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 DEBT

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

	At 1 Jan 2013 \$m	Cash Flow \$m	Non-cash Movements \$m	Exchange Movements \$m	At 30 Sep 2013 \$m
Loans due after one year	(9,347)	-	873	(22)	(8,496)
Finance leases due after one year	(62)	-	(7)	(1)	(70)
Total long term debt	(9,409)	-	866	(23)	(8,566)
Current instalments of loans	-	-	(776)	-	(776)
Current instalments of finance leases	(22)	19	(25)	-	(28)
Total current debt	(22)	19	(801)	-	(804)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other investments - current	823	(20)	62	(1)	864
Net derivative financial instruments	417	36	(101)	-	352
Cash and cash equivalents	7,701	(190)	-	(58)	7,453
Overdrafts	(105)	(21)	-	(4)	(130)
Short-term borrowings	(774)	-	-	(1)	(775)
	8,062	(195)	(39)	(64)	7,764
Net debt	(1,369)	(176)	26	(87)	(1,606)

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

### 3 RESTRUCTURING COSTS

Profit before tax for the nine months ended 30 September 2013 is stated after charging restructuring costs of \$1,036 million (\$185 million for the third quarter 2013). These have been charged to profit as follows:

	3rd Quarter 2013 \$m	3rd Quarter 2012 \$m	9 Months 2013 \$m	9 Months 2012 \$m
Cost of sales	6	14	104	75
Research and development expense	53	116	406	697
Selling, general and administrative costs	126	123	526	388
Total	185	253	1,036	1,160

### 4 ACQUISITION OF PEARL THERAPEUTICS

On 27 June 2013, AstraZeneca completed the acquisition of Pearl Therapeutics. Pearl is based in Redwood City, California and is focused on the development of inhaled small-molecule therapeutics for respiratory disease. AstraZeneca acquired 100 percent of Pearl's shares for an upfront consideration of \$569 million. In addition, deferred consideration of up to \$450 million will become payable if specified development and regulatory milestones in respect of any triple combination therapies and selected future products that AstraZeneca develops using Pearl's technology platform are achieved. Sales-related payments of up to a further \$140 million will become payable if pre-agreed cumulative sales thresholds are exceeded. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

In business acquisitions, any part of the cost that is not capable of being attributed in accounting terms to identifiable assets and liabilities acquired is recognised as goodwill. In the case of the acquisition of Pearl, this goodwill is underpinned by a number of elements, which individually cannot be quantified. Most significant among these is the synergistic benefit generated by acquiring Pearl's workforce, whose skills and knowhow are critical to the best and most efficient completion of the ongoing development programmes.

Pearl's results have been consolidated into the Company's results from 27 June 2013. For the period from acquisition to 30 September 2013, Pearl had no revenues and its loss was \$21 million.

For the nine months ended 30 September 2013, Pearl had no revenues and its net loss was \$53 million.

In the period since acquisition, AstraZeneca received new information regarding the future recoverability of Pearl's previously unrecognised tax losses. This new information indicates that the deferred tax assets acquired with Pearl are



Edgar Filing: ASTRAZENECA PLC - Form 6-K

\$60 million. The relevant facts and circumstances that have been highlighted by the new information were in place at the date of acquisition and have not changed since that date. Therefore, the result of this new information has been reflected by adjusting the acquisition accounting entries, that were disclosed in the Company's half year results ended 30 June 2013, by increasing the fair value adjustment on deferred tax assets by \$30 million and correspondingly reducing the value of recognised goodwill by \$30 million. The revised acquisition entries are shown below.

	Book value	Fair value adjustment	Fair value
	\$m	\$m	\$m
Non-current assets			
Intangible assets	-	985	985
Deferred tax assets	-	60	60
	-	1,045	1,045
Current assets	12	-	12
Current liabilities	(4)	-	(4)
Non-current liabilities			
Deferred tax liabilities	-	(379)	(379)
	-	(379)	(379)
Total assets acquired	8	666	674
Goodwill			44
Fair value of total consideration			718
Less: fair value of contingent consideration			(149)
Total upfront consideration			569
Less: cash and cash equivalents acquired			(4)
Net cash outflow			565

## 5 ACQUISITION OF OMTHERA PHARMACEUTICALS

On 18 July 2013, AstraZeneca completed the acquisition of Omthera Pharmaceuticals, Inc. Omthera is a specialty pharmaceutical company based in Princeton, New Jersey, focused on the development and commercialisation of new therapies for abnormal levels of lipids in the blood, referred to as dyslipidaemia. AstraZeneca acquired 100 percent of Omthera's shares for an upfront consideration of \$323 million with up to \$120 million in future development and approval milestones. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

Omthera's results have been consolidated into the Company's results from 18 July 2013. For the period from acquisition to 30 September 2013, Omthera had no revenues and its loss was \$7 million.

For the nine months ended 30 September 2013, Omthera had no revenues and its net loss was \$30 million.

	Book value	Fair value adjustment	Fair value
	\$m	\$m	\$m
Non-current assets			
Intangible assets	-	526	526
Deferred tax assets	-	18	18
	-	544	544
Current assets	67	-	67
Current liabilities	(10)	-	(10)

Non-current liabilities			
Deferred tax liabilities	-	(216)	(216)
	-	(216)	(216)
Total assets acquired	57	328	385
Goodwill			-
Fair value of total consideration			385
Less: fair value of contingent consideration			(62)
Upfront consideration			323
Less: cash acquired			(63)
Cash outflow			260

## 6 ACQUISITION OF AMPLIMMUNE

On 4 October 2013, AstraZeneca completed the acquisition of Amplimmune, a privately-held, Maryland, US-based biologics company focused on developing novel therapeutics in cancer immunology. Under the terms of the agreement, AstraZeneca has acquired 100 percent of Amplimmune's shares for an initial consideration of \$225 million and deferred consideration of up to \$275 million based on reaching predetermined development milestones. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

The acquisition bolsters AstraZeneca's oncology pipeline by obtaining multiple early-stage assets for its immune-mediated cancer therapy (IMT-C) portfolio, including AMP-514, an anti-programmed cell death 1 (PD-1) monoclonal antibody (mAb). AMP-514 was in late-stage pre-clinical development with the aim of an investigational new drug (IND) filing before the end of 2013, which has now been achieved. Other Amplimmune assets include multiple preclinical molecules targeting the B7 pathways.

In business acquisitions, any part of the cost that is not capable of being attributed in accounting terms to identifiable assets and liabilities acquired is recognised as goodwill. In the case of the acquisition of Amplimmune, this goodwill is underpinned by a number of elements, which individually cannot be quantified but include Amplimmune's very early programmes of potential interest for oncology, immunology, infectious diseases as well as research tools and animal models.

Amplimmune's results will be consolidated into the Company's results from 4 October 2013. No amounts with respect to Amplimmune's operations or activities have been included in the Company's Third Quarter and Nine Months Results ended 30 September 2013.

For the nine months ended 30 September 2013, Amplimmune had no revenues and its net loss was \$22 million.

	Book value	Fair value adjustment	Fair value
	\$m	\$m	\$m
Non-current assets			
Intangible assets	-	534	534
Property, plant and equipment	5	-	5
Deferred tax assets	-	14	14
	5	548	553
Current assets	25	-	25
Current liabilities	(6)	-	(6)
Non-current liabilities			

Deferred tax liabilities	-	(219)	(219)
	-	(219)	(219)
Total assets acquired	24	329	353
Goodwill			25
Fair value of total consideration			378
Less: fair value of contingent consideration			(153)
Total upfront consideration			225
Less: cash and cash equivalents acquired			(21)
Net cash outflow			204

## 7 ACQUISITION OF SPIROGEN

On 15 October 2013, AstraZeneca completed the acquisition of Spirogen, a privately-held biotech company focused on antibody-drug conjugate technology for use in oncology. AstraZeneca acquired 100 percent of Spirogen's shares for an initial consideration of \$200 million and deferred consideration of up to \$240 million based on reaching predetermined development milestones. Existing out-licensing agreements and associated revenue streams are excluded from this acquisition. Contingent consideration has been fair valued using decision tree analysis, with key inputs including the probability of success and consideration of potential delays.

AstraZeneca has also entered into a collaboration agreement with ADC Therapeutics to jointly develop two of ADC Therapeutics' antibody-drug conjugate programmes in preclinical development. AstraZeneca will also make an equity investment in ADC Therapeutics, which has an existing licensing agreement with Spirogen.

Spirogen's results will be consolidated into the Company's results from 15 October 2013. No amounts with respect to Spirogen's operations or activities have been included in the Company's Third Quarter and Nine Months Results ended 30 September 2013.

For the nine months ended 30 September 2013, Spirogen had no revenues and its net loss was immaterial.

	Book value	Fair value adjustment	Fair value
	\$m	\$m	\$m
Non-current assets			
Intangible assets	1	370	371
Property, plant and equipment	1	-	1
	2	370	372
Non-current liabilities			
Deferred tax liabilities	-	(4)	(4)
Total assets acquired	2	366	368
Goodwill			-
Fair value of total consideration			368
Less: fair value of contingent consideration			(168)
Total upfront consideration			200
Less: cash and cash equivalents acquired			-
Net cash outflow			200

## 8 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 148 and 149 of the Company's Annual Report and Form 20-F Information 2012. 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 \$1,100 million of other investments, \$2,006 million of loans, and \$352 million of derivatives as at 30 September 2013. The total fair value of interest-bearing loans and borrowings at 30 September 2013, which have a carrying value of \$10,275 million in the Condensed Consolidated Statement of Financial Position, was \$11,160 million. As detailed in Notes 4 to 7, contingent consideration arising on the Company's acquisitions during the year has been fair valued under Level 3 fair value methodology. For all other financial instruments which are carried at amortised costs, amortised cost approximates to fair value.

## 9 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 2012 and Interim Management Statement 2013 as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 2013 (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 2012, 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 2012 and herein.

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

Matters disclosed in respect of the third quarter of 2013 and October 2013

Patent litigation

Crestor (rosuvastatin calcium)

US patent litigation/regulatory proceedings

On 31 July 2013, a patent infringement lawsuit was filed against AstraZeneca in the US District Court for the District of South Carolina by plaintiffs Medical University of South Carolina Foundation for Research Development and Charleston Medical Therapeutic, Inc, which, among other claims, asserts that AstraZeneca's Crestor sales infringe the

plaintiffs' patent.

Faslodex (fulvestrant)

Patent proceedings outside the US

In 2008, the Opposition Division of the European Patent Office (EPO) maintained a Faslodex formulation patent, EP 1250138, following an opposition against the grant of this patent by Gedeon Richter. Gedeon Richter appealed this decision. In September 2013, the Board of Appeal at the EPO has now called the parties to oral proceedings scheduled for 18 March 2014.

Nexium (esomeprazole magnesium)

Patent proceedings in the USAs previously disclosed, in July 2013, AstraZeneca received a Paragraph IV Notice Letter (Notice) from Wockhardt Limited (Wockhardt) relating to Nexium. In August 2013, in response to the Notice, AstraZeneca commenced a patent infringement action in the US District Court for the District of New Jersey against Wockhardt. In October 2013, AstraZeneca received a Notice from Kremers Urban Pharmaceuticals Inc. and a separate Notice from Aurobindo Pharma Limited, both relating to Nexium. AstraZeneca is reviewing these Notices.

As previously disclosed, in 2011, AstraZeneca commenced a patent infringement action in the US District Court for the District of New Jersey (District Court) against Hanmi USA Inc., et al. (Hanmi) in response to the filing of a New Drug Application (NDA) under §505(b)(2) for FDA approval to market 20mg and 40mg esomeprazole strontium capsules. In June 2013, AstraZeneca entered into an agreement with Hanmi and its US marketing partner, Amneal Pharmaceuticals (Amneal), to resolve certain issues and appeal others. Under the terms of the District Court's consent judgment, Amneal and Hanmi have conceded the validity and enforceability of AstraZeneca's US patents no. 5,714,504 and 5,877,192 that protect Nexium. The consent judgment also provides that the Hanmi product does not infringe those patents under the District Court's claim construction of December 2012. AstraZeneca believes that this claim construction is erroneous and is seeking reversal on appeal. In July 2013, AstraZeneca filed a Notice of Appeal in the Court of Appeals for the Federal Circuit (Court of Appeals). On 13 September 2013, the Court of Appeals issued a temporary injunction against Hanmi's launch of its §505(b)(2) NDA esomeprazole strontium product. On 30 September 2013, the Court of Appeals vacated the temporary injunction. AstraZeneca's Court of Appeals appeal remains ongoing, with oral argument scheduled for 18 November 2013. AstraZeneca understands that Hanmi's §505(b)(2) NDA esomeprazole strontium product is not AB-rated and is not subject to automatic substitution with Nexium.

Patent proceedings outside the US

In September 2013, AstraZeneca entered into an agreement with Hexal AG, a member of the Sandoz group of companies (Hexal/Sandoz), to resolve more than 30 European disputes between AstraZeneca and Hexal/Sandoz affiliates related to AstraZeneca's Nexium patents and Hexal/Sandoz's version of esomeprazole magnesium. The agreement resolves disputes in 20 countries.

Patent litigation is ongoing against generic companies in several countries across Europe, including in Russia and in France.

Prilosec (omeprazole capsules)

Patent proceedings in the US

As previously disclosed, AstraZeneca commenced litigation to recover patent infringement damages against Andrx Pharmaceuticals (Andrx). On 1 October 2013, the US District Court for the Southern District of New York entered a consent order and final judgment in favour of Andrx, awarding no damages to AstraZeneca.

Pulmicort Respules (budesonide inhalation suspension)

Patent proceedings in the US

As previously disclosed, on 1 April 2013, the US District Court for the District of New Jersey (District Court) ruled that AstraZeneca's US patent no. 6,598,603 (the '603 patent) is invalid and that the generic defendants involved in the

litigation do not infringe a second patent, US patent no. 7,524,834 (the '834 patent). AstraZeneca filed a notice of appeal and on 24 May 2013, the US Court of Appeals for the Federal Circuit (Court of Appeals) enjoined the generic defendants from entering the market during the pendency of AstraZeneca's appeal. On 30 October 2013, the Court of Appeals reversed and remanded for further proceedings the District Court's decision that the generic defendants do not infringe the '834 patent but upheld the District Court's decision that the '603 patent is invalid.

#### Seroquel XR (quetiapine fumarate)

##### Patent proceedings outside the US

In Spain, in October 2013, the Barcelona Court of Appeal reversed the opinion by the Commercial Court in Barcelona and found the Seroquel XR formulation patent invalid. AstraZeneca intends to appeal the decision.

As previously disclosed, in March 2013, the Federal Court of Canada dismissed AstraZeneca's application to prohibit the Canadian Minister of Health from issuing a Notice of Compliance to Teva Canada Limited (Teva) for its generic quetiapine fumarate product relating to Seroquel XR. Teva has launched its generic Seroquel XR at-risk. Also as previously disclosed, in Canada, AstraZeneca and Sandoz have been engaged in patent litigation related to Seroquel XR since November 2011. In August 2013, AstraZeneca and Sandoz entered into a settlement agreement ending the legal action and allowing Sandoz to launch generic Seroquel XR.

Generic versions of Seroquel XR have been launched in Austria, Denmark, Germany, Italy, Portugal, Romania, UK and elsewhere in Europe. While AstraZeneca continues to have confidence in the patent protecting Seroquel XR and will continue to take appropriate legal action, additional generic launches and adverse court rulings are possible.

#### Symbicort (budesonide/formoterol)

In October 2013, AstraZeneca and Accuhale LLC (Accuhale) executed a settlement agreement to resolve and dismiss a previously disclosed lawsuit that alleged sales of Symbicort infringed a patent purportedly owned by Accuhale. A provision has been taken.

#### Product liability litigation

##### Seroquel IR (quetiapine fumarate)

As previously disclosed, a putative class action was initiated in Ontario, Canada claiming that AstraZeneca failed to provide adequate warnings in connection with an alleged association between Seroquel IR and certain health risks. In October 2013, the Ontario Superior Court dismissed the action and approved a settlement in which plaintiffs agreed to abandon all further rights of appeal regarding the Court's decision to deny class certification and AstraZeneca agreed not to pursue its costs award associated with the decision.

#### Commercial litigation

##### Average Wholesale Price (AWP) Litigation

As previously disclosed, AstraZeneca successfully appealed a \$20 million jury verdict entered against it in litigation brought by the Commonwealth of Kentucky. The Commonwealth requested that the Kentucky Supreme Court hear its appeal of that decision, but the court declined. On 27 September 2013, the Kentucky trial court entered final judgment in favour of AstraZeneca.

##### Nexium (esomeprazole magnesium)

As previously disclosed, AstraZeneca was a defendant in a class action lawsuit in the Massachusetts State Court based on allegations that AstraZeneca's promotion and advertising of Nexium to physicians, consumers and third party payers was unfair, unlawful, and deceptive. In August 2013, the Court ordered final approval of the class settlement agreement and dismissal of the matter.

##### Nexium Anti-trust Litigation

As previously disclosed, AstraZeneca is one of several defendants in a now-consolidated, multi-district litigation (MDL) proposed class action lawsuit alleging that AstraZeneca's settlements of certain patent litigation in the US relating to Nexium violated US anti-trust law and various state laws.

In September 2013, after having heard oral argument in April 2013, the US District Court for the District of Massachusetts (the court which is hearing the consolidated MDL proceeding) issued a Memorandum and Order denying defendants' motion to dismiss with respect to certain of plaintiffs' claims, and granting in part and denying in part defendants' motion to dismiss regarding other claims.

Also in September 2013, the Court heard oral argument on plaintiffs' motions to certify two proposed classes. AstraZeneca vigorously opposes plaintiffs' motions to certify the proposed classes, and a ruling by the Court on class certification is pending. A ruling certifying a class would be immediately subject to appellate review. AstraZeneca firmly believes that plaintiffs' allegations are without merit, and we are confident that our settlement agreements fully comply with applicable law. AstraZeneca will continue to vigorously contest plaintiffs' factual allegations, legal theories and assertion of damages.

Plaintiffs seek damages, subject to trebling under federal law and some state laws, based on the difference between the price the alleged classes paid for Nexium and the price they claim they would have paid for generic esomeprazole beginning in April 2008 (and several other later, alternative dates) to the present. Plaintiffs have indicated that, based on certain factual assumptions, they believe the range of possible damages for the proposed classes, prior to trebling, is in the range of \$9.7 billion to \$27.1 billion.

AstraZeneca believes that the plaintiffs' damages scenarios are speculative, contrary to fact and without merit and are not a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. Further legal, procedural, evidentiary and potentially dispositive rulings by the courts could significantly impact the range of possible damages plaintiffs ultimately may be able to seek, if any. No provision has been taken in respect of this matter.

On 15 October 2013, AstraZeneca and Ranbaxy filed a Motion for Summary Judgment on the grounds that the plaintiffs' claims with respect to the 2008 settlement agreement are barred by the four-year statute of limitations. A hearing on the statute of limitations motion is currently scheduled for 26 November 2013. Other motions for summary judgment and motions challenging expert witnesses will be filed on or before 26 November 2013.

#### Government Investigations

##### Brilinta (ticagrelor)

On 21 October 2013, AstraZeneca received a civil investigative demand from the US Department of Justice, Civil Division seeking documents and information regarding PLATO, a clinical trial about Brilinta. AstraZeneca intends to co-operate with the inquiry.

##### Seroquel IR (quetiapine fumarate) and Seroquel XR (quetiapine fumarate)

On 9 September 2013, AstraZeneca received a subpoena duces tecum from the US Attorney's Office in Boston seeking documents and information related to the safety profile of Seroquel IR and Seroquel XR. AstraZeneca intends to co-operate with the inquiry.

#### India

As previously disclosed, on 23 February 2012, the Indian Central Bureau of Investigation (CBI) filed a First Information Report in the court in Delhi against AstraZeneca and public officials of the Central Procurement Agency of the Delhi Directorate of Health Services (DHS) in connection with circumstances surrounding the submission by AstraZeneca of an alleged false affidavit in relation to pricing as part of a tender for Meronem entered into by AstraZeneca with the DHS in 2009. The CBI has now concluded its investigation and a charge sheet was filed with

Edgar Filing: ASTRAZENECA PLC - Form 6-K

the court on 5 August 2013, but neither AstraZeneca, nor any AstraZeneca employee, has been charged with any offence.

10 NINE MONTHS PRODUCT REVENUE ANALYSIS

	World		US		Europe		Established ROW		Emerging Markets	
	9M		9M		9M		9M		9M	
	2013	CER	2013	CER	2013	CER	2013	CER	2013	CER
	\$m	%	\$m	%	\$m	%	\$m	%	\$m	%
Cardiovascular:										
Crestor	4,159	(9)	2,133	(7)	914	(3)	603	(29)	509	18
Atacand	477	(40)	62	(47)	171	(57)	58	(46)	186	1
Seloken/Toprol-XL	580	(12)	112	(50)	97	(3)	17	(17)	354	12
Onglyza	285	21	202	16	41	17	14	56	28	65
Plendil	194	1	-	(100)	15	(17)	7	(22)	172	7
Tenormin	151	(6)	12	50	38	(5)	58	(10)	43	(10)
Brilinta/Brilique	191	273	49	390	112	224	11	n/m	19	233
Byetta	152	n/m	116	n/m	25	n/m	7	n/m	4	n/m
Bydureon	102	n/m	91	n/m	11	n/m	-	-	-	-
Forxiga	7	n/m	-	-	7	n/m	-	-	-	-
Others	270	7	35	192	125	(2)	19	(4)	91	(1)
Total Cardiovascular	6,568	(5)	2,812	(3)	1,556	(8)	794	(26)	1,406	12
Gastrointestinal:										
Nexium	2,881	1	1,578	(6)	268	(24)	432	46	603	13
Losec/Prilosec	364	(31)	23	(8)	96	(41)	124	(40)	121	(9)
Others	176	21	136	26	33	-	5	-	2	200
Total Gastrointestinal	3,421	(3)	1,737	(4)	397	(28)	561	10	726	9
Respiratory:										
Symbicort	2,507	10	883	21	1,107	1	294	10	223	16
Pulmicort	622	1	165	(7)	127	(11)	78	1	252	15
Others	242	(7)	42	(11)	87	(13)	24	(11)	89	3
Total Respiratory	3,371	7	1,090	14	1,321	(1)	396	7	564	13
Oncology:										
Zoladex	749	(1)	18	(5)	192	(6)	276	(3)	263	6
Iressa	489	13	-	-	132	14	149	11	208	14
Faslodex	499	6	237	4	163	(1)	45	26	54	25
Arimidex	265	(33)	2	(88)	71	(38)	116	(35)	76	(7)
Casodex	281	(9)	3	n/m	40	(15)	168	(11)	70	(5)
Others	102	13	18	(5)	20	54	42	11	22	10
Total Oncology	2,385	(3)	278	-	618	(6)	796	(7)	693	7
Neuroscience:										
Seroquel XR	1,000	(11)	549	(8)	312	(20)	60	(13)	79	9
Seroquel IR	310	(73)	2	(100)	81	(61)	108	(22)	119	(4)
Local Anaesthetics	378	(2)	-	-	153	(6)	133	(3)	92	6
Vimovo	67	43	17	(11)	23	53	14	56	13	225
Others	338	(11)	24	14	86	(29)	73	(16)	155	4



Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total Neuroscience Infection & Other:	2,093	(33)	592	(56)	655	(27)	388	(12)	458	5
Synagis	545	2	317	3	228	-	-	-	-	-
Merrem	216	(24)	9	(53)	38	(43)	5	(69)	164	(11)
FluMist	195	31	177	22	16	n/m	2	-	-	-
Others	73	3	45	15	7	(43)	8	(31)	13	50
Total Infection & Other	1,029	(1)	548	7	289	(5)	15	(47)	177	(8)
Aptium Oncology	-	(100)	-	(100)	-	-	-	-	-	-
Total	18,867	(7)	7,057	(10)	4,836	(11)	2,950	(10)	4,024	9

11 THIRD QUARTER PRODUCT REVENUE ANALYSIS

	World		US		Europe		Established ROW		Emerging Markets	
	Q3		Q3		Q3		Q3		Q3	
	2013	CER	2013	CER	2013	CER	2013	CER	2013	CER
	\$m	%	\$m	%	\$m	%	\$m	%	\$m	%
Cardiovascular:										
Crestor	1,356	(11)	719	(14)	296	(4)	170	(24)	171	18
Atacand	143	(35)	11	(74)	54	(38)	14	(55)	64	2
Seloken/Toprol-XL	173	(23)	25	(68)	31	(12)	4	(29)	113	4
Onglyza	93	10	63	2	14	27	5	67	11	25
Plendil	64	14	-	(100)	5	-	1	(50)	58	21
Tenormin	51	(2)	5	150	13	9	19	-	14	(26)
Brilinta/Brilique	75	208	18	157	44	163	5	n/m	8	n/m
Byetta	57	111	38	41	12	n/m	3	n/m	4	n/m
Bydureon	43	291	37	236	6	n/m	-	-	-	-
Forxiga	3	n/m	-	-	3	n/m	-	-	-	-
Others	102	13	12	50	51	26	7	50	32	(18)
Total Cardiovascular	2,160	(7)	928	(13)	529	3	228	(21)	475	10
Gastrointestinal:										
Nexium	918	(5)	500	(15)	86	(17)	145	54	187	(4)
Losec/Prilosec	118	(34)	7	(13)	30	(46)	38	(43)	43	(12)
Others	66	27	53	33	11	(9)	1	-	1	-
Total Gastrointestinal	1,102	(8)	560	(12)	127	(26)	184	13	231	(5)
Respiratory:										
Symbicort	839	7	307	16	349	(3)	110	11	73	16
Pulmicort	176	(6)	47	(23)	33	(16)	24	4	72	11
Others	83	(4)	14	27	25	(20)	12	30	32	(9)
Total Respiratory	1,098	4	368	10	407	(5)	146	11	177	9
Oncology:										
Zoladex	246	-	6	(14)	61	(8)	90	(1)	89	8
Iressa	165	12	-	-	43	8	51	11	71	16
Faslodex	169	3	83	4	54	(4)	16	12	16	12
Arimidex	90	(26)	4	-	23	(27)	37	(35)	26	(7)
Casodex	93	(5)	2	n/m	13	(14)	55	(8)	23	(4)
Others	34	9	5	(29)	7	40	14	6	8	40

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total Oncology	797	(1)	100	3	201	(6)	263	(6)	233	8
Neuroscience:										
Seroquel XR	339	(10)	194	(4)	104	(20)	14	(38)	27	19
Seroquel IR	84	(47)	(2)	n/m	25	(29)	28	(35)	33	(19)
Local Anaesthetics	123	(1)	-	-	48	(2)	43	(4)	32	7
Vimovo	23	64	5	25	8	60	5	67	5	150
Others	117	(6)	7	(22)	28	(13)	25	(12)	57	6
Total Neuroscience	686	(14)	204	(20)	213	(15)	115	(19)	154	3
Infection & Other:										
Synagis	130	35	6	20	124	36	-	-	-	-
Merrem	67	(23)	5	(44)	11	(41)	2	-	49	(16)
FluMist	188	30	170	21	16	n/m	2	-	-	-
Others	22	(17)	19	(17)	2	-	1	(90)	-	n/m
Total Infection & Other	407	14	200	12	153	35	5	(64)	49	(5)
Aptium Oncology	-	(100)	-	(100)	-	-	-	-	-	-
Total	6,250	(4)	2,360	(8)	1,630	(4)	941	(8)	1,319	5

Shareholder Information

ANNOUNCEMENTS AND MEETINGS

Announcement of fourth quarter and full year 2013 results 6 February 2014

Announcement of first quarter 2014 results 24 April 2014

Annual General Meeting 24 April 2014

Announcement of second quarter and half year 2014 results 31 July 2014

Announcement of third quarter and nine months 2014 results 6 November 2014

DIVIDENDS

The record date for the first interim dividend payable on 16 September 2013 was 16 August 2013. Shares traded ex-dividend from 14 August 2013.

The record date for the second interim dividend for 2013, payable on 24 March 2014, will be 21 February 2014. Shares will trade ex-dividend from 19 February 2014.

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

TRADEMARKS

Trademarks of the AstraZeneca group of companies and of companies other than AstraZeneca appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

AstraZeneca group of companies. Trademarks of companies other than AstraZeneca that appear in this document include: Onglyza and Forxiga, trademarks of Bristol-Myers Squibb Company; Byetta and Bydureon, trademarks of Amylin Pharmaceuticals, LLC and AstraZeneca Pharmaceuticals LP; and Epanova, a trademark of Chrysalis Pharma AG.

### ADDRESSES FOR CORRESPONDENCE

---

Registrar and Transfer Office Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA UK	US Depository JP Morgan Chase & Co PO Box 64504 St Paul MN 55164-0504 US	Registered Office 2 Kingdom Street London W2 6BD UK	Swedish Central Securities Depository Euroclear Sweden AB PO Box 191 SE-101 23 Stockholm Sweden
Tel (freephone in UK): 0800 389 1580 Tel (outside UK): +44 (0)121 415 7033	Tel (toll free in US): 888 697 8018 Tel (outside US): +1 651 453 2128	Tel: +44 (0) 20 7604 8000	Tel: +46 (0)8 402 9000

### CONTACT INFORMATION

---

Media Enquiries: Esra Erkal-Paler (London) +44 (0) 20 7604 8030  
Vanessa Rhodes (London) +44 (0) 20 7604 8037  
Ayesha Bharmal (London) +44 (0) 20 7604 8034  
Jacob Lund (Södertälje) +46 (0) 8 553 260 20

Analyst/Investor Enquiries: Ed Seage (US) +1 302 886 4065  
Colleen Proctor (US) +1 302 886 1842  
Karl Hård (London) +44 (0) 20 7604 8123  
Anthony Brown (London) +44 (0) 20 7604 8067  
Jens Lindberg (London) +44 (0) 20 7604 8414

### 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 interim financial statements contain 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 interim financial statements 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 delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; the risk of environmental liabilities; the risks associated with conducting business in emerging markets; the risk of reputational damage; the risk of product counterfeiting; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the impact of failing to attract and retain key personnel and to successfully engage with our employees; and the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation.

- ENDS -

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 31 October 2013

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary