

ASTRAZENECA PLC  
Form 6-K  
November 06, 2014

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 November 2014

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 2014

---

London, 6 November 2014

Revenue in the third quarter was \$6,542 million, up 5%\* - third consecutive quarter of revenue growth. Nine months revenue was up 4%.

- Year-to-date growth platforms up 16%, contributing 54% of total revenue.
- Brilinta: +78%, good momentum across all regions.
- Diabetes: +139%, strong US Farxiga launch and good uptake of Bydureon Pen.
- Respiratory: +11%, US Symbicort growth of 26%.
- Emerging Markets: +12%, with China growth of 22%.
- Japan: stable, impacted by mandated biennial price cuts and increased use of generics.

Core EPS in the third quarter was \$1.05, down 8%. Nine months Core EPS declined 3%; better than anticipated in previous full-year guidance.

The Company increases its revenue and Core EPS guidance for the full year 2014.

- Revenue is now expected to increase in low single digits at CER, an upgrade on our previous guidance for revenue to be in line with 2013 at CER.
- For planning purposes this guidance assumes no US Nexium generic in 2014.
- In light of the increase in revenue expectations for the year, the Company is accelerating its investments in its growth platforms and expanding pipeline. Core EPS for 2014 is now expected to decrease at around 10% at CER; better than anticipated in previous guidance. In addition, Core EPS for 2014 at actual exchange rates is expected to be impacted negatively by currency by around 5%, assuming current exchange rates.

2015 preview.

- For 2015, the Company plans to continue to selectively invest in its growth platforms and accelerating pipeline while managing overall costs. Assuming current exchange rates, the Company is targeting Core EPS for 2015 to be no less than the lower end of the range of the upgraded guidance for Core EPS for 2014 at actual exchange rates. Guidance for 2015 is expected to be provided with 2014 results on 5 February 2015.

Significant progress made towards achieving scientific leadership in core therapeutic areas.

- Xigduo XR (dapagliflozin and metformin extended release): FDA approval of once-daily tablets.
- Lynparza (olaparib): Positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for platinum sensitive relapsed BRCA-mutated high grade serous ovarian cancer.
- Movantik/Moventig (naloxegol): FDA approval and positive CHMP opinion for opioid-induced constipation.
- CAZ-AVI (ceftazidime-avibactam): Positive Phase III data for intra-abdominal infections.
- Lesinurad: Phase III data announced as a combination therapy for symptomatic gout.

Divestment of Myalept (metreleptin) to Aegerion allows for redeployment of resources.

Strategic business combination with Almirall in respiratory disease successfully completed.

Investor Day for institutional investors and analysts will be held on 18 November 2014.

\*All growth rates are at constant exchange rates (CER).

## Financial Summary

Group	3rd Quarter 2014 \$m	Actual %	CER %	Nine Months 2014 \$m	Actual %	CER %
Revenue	6,542	5	5	19,412	3	4
Core**						
Operating Profit	1,770	(13)	(9)	5,753	(10)	(6)
Earnings per Share	\$1.05	(13)	(8)	\$3.52	(8)	(3)
Reported						
Operating Profit	541	(68)	(63)	2,486	(42)	(35)
Earnings per Share	\$0.20	(80)	(74)	\$1.23	(50)	(41)

\*\* See Operating and Financial Review below for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

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

"I'm pleased to report our third consecutive quarter of revenue growth, driven by a strong contribution from our growth platforms. Brilinta, respiratory and diabetes, our three core franchises, increased sales by 38 percent in the quarter, supported by continued selective allocation of sales and marketing resources. In addition, we have chosen to invest in our rapidly developing pipeline that will continue to create value for AstraZeneca in 2015 and beyond.

"We have made important progress towards achieving scientific leadership across all core therapeutic areas, including a positive opinion by the CHMP for Lynparza (olaparib), the FDA approval for Movantik, the launch of the Bydureon Pen in the US, and the progress of our immuno-oncology pipeline presented at ESMO. This momentum is further evidenced by the successful completion of our strategic business combination with Almirall, strengthening our respiratory franchise.

"This enhanced execution of our strategy and our sustained performance gives us confidence to increase our revenue and Core earnings guidance for the year. I'm particularly proud of our teams who continue to demonstrate their focus and belief in our strategy, which is rapidly transforming our company."

## Research and Development Update

A comprehensive update of the AstraZeneca R&D pipeline is presented in conjunction with this third quarter and nine months results announcement and is available on the Company's website [www.astrazeneca.com](http://www.astrazeneca.com).

The AstraZeneca pipeline now includes 121 projects, of which 107 are in the clinical phase of development. There are 14 NME projects currently in late stage development, either in pivotal studies or under regulatory review. During Q3 2014, across the portfolio, 11 projects have successfully progressed to their next phase. This includes one first approval in a major market, and one NME progression. In addition, five projects have entered first human testing and three projects have been withdrawn.

The quarter has seen significant progress with regard to pipeline development and further detail will be shared at the upcoming Investor Day on 18 November 2014. There has been notable progress in the following areas during Q3 2014:

#### Lynparza

On 24 October 2014, AstraZeneca announced that the CHMP of the EMA has adopted a positive opinion recommending the marketing authorisation of Lynparza (olaparib) as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed (PSR) BRCA-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to platinum-based chemotherapy. Olaparib is a poly ADP-ribose polymerase (PARP) inhibitor that exploits tumour DNA repair pathway deficiencies to preferentially kill cancer cells.

The positive CHMP opinion was based on the results from Study 19, a Phase II clinical trial that evaluated the efficacy and safety of olaparib compared to placebo in PSR high grade serous ovarian cancer patients. A preplanned retrospective analysis of outcomes by BRCA status showed that olaparib maintenance therapy significantly prolonged progression free survival (PFS) compared with placebo in patients with BRCA-mutated ovarian cancer - median PFS 11.2 months versus 4.3 months (PFS HR=0.18; 95% CI 0.10-0.31; p<0.0001).

#### Iressa

On 26 September 2014, AstraZeneca announced that the CHMP of the EMA has adopted a positive opinion on a Type-II variation update to the European label for Iressa (gefitinib). The label update will help doctors to identify lung cancer patients, based on the specific genetic drivers of their tumour, who could benefit from treatment with Iressa but are unable to provide a suitable tumour sample.

Tumour samples gained through biopsy are the primary method for determining a patient's EGFR mutation status, without which patients are not eligible for treatment with an EGFR-TKI (epidermal growth factor receptor - tyrosine-kinase inhibitor) such as Iressa, which is the standard of care in Europe. However, up to 25 percent of patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC) do not have an available or evaluable tumour sample for this method of testing.

Iressa will be the first EGFR-TKI in Europe to have a label allowing the use of circulating tumour DNA obtained from a blood sample to be used for the assessment of EGFR mutation status in those patients where a tumour sample is not an option.

European Society for Medical Oncology (ESMO), 26 - 30 September 2014

AstraZeneca provided an update on the rapid development of its oncology pipeline at the ESMO meeting in Madrid with the following highlights:

- Updated data from the ongoing Phase I/II study for AZD9291 showed an unprecedented confirmed response rate of 70% and disease control rate of 95% in T790M patients at 80mg once-daily, with a promising PFS in T790M patients, but still immature. In addition, the study showed encouraging 63% response rate in 1st line EGFRm NSCLC and a Phase III study evaluating AZD9291 in first line EGFRm NSCLC is scheduled to start later this year.
- Updated Phase I data for anti-PDL1 (MEDI4736), assessing the clinical activity and safety profile of PD-L1 as a monotherapy in patients with NSCLC and a separate analysis of patients with metastatic squamous-cell carcinoma of the head and neck (SCCHN). The Phase I data are showing encouraging efficacy as measured by response rate and support the accelerated development of MEDI4736 into Phase III clinical trials in both NSCLC and SCCHN.

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

- Preliminary data was presented from the ongoing Phase I study of PD-L1 in combination with tremelimumab (anti-CTLA-4) in NSCLC patients who have already received prior cancer treatments. The data showed early signs of anti-tumour activity and encouraging activity for combination in PD-L1 negative NSCLC. Pivotal studies will start in NSCLC and SCCHN, following completion of the dose escalation phase.

### Brilinta

On 19 August 2014, AstraZeneca announced that it has received confirmation from the United States Department of Justice that it is closing its investigation into PLATO, a clinical trial with Brilinta (ticagrelor). The government is not planning any further action.

On 1 September 2014, AstraZeneca announced the results of the Phase IV ATLANTIC study, designed to evaluate pre-hospital administration versus in-hospital administration of ticagrelor in terms of pre-percutaneous coronary intervention (PCI) - or angioplasty - procedural effectiveness, bleeding at 24 hours and 30 days and the pre-specified composite endpoint of death, MI, stroke, urgent revascularisation and definite acute stent thrombosis at 30 days.

There was no statistically significant difference between the pre-hospital or in-hospital study arms in the co-primary endpoints of pre-PCI procedural effectiveness; percentage of patients not achieving ST segment elevation resolution  $\geq 70\%$  before PCI (OR 0.93; 95% CI 0.69, 1.25;  $p=0.632$ ), and percentage of patients not reaching thrombolysis in myocardial infarction (TIMI) flow grade 3 in the infarct-related, or "culprit", artery at initial angiography (OR 0.97; 95% CI 0.75, 1.25;  $p=0.821$ ). The results indicate that the profile of Brilinta/Brilique (ticagrelor) is comparable whether administered in a pre-hospital or in-hospital setting to ST segment elevation myocardial infarction (STEMI) patients.

The ATLANTIC study was not powered to look at clinical outcomes, however there was no difference between the two arms in terms of composite endpoint. The pre-hospital administration of ticagrelor indicates a risk reduction of post-PCI stent thrombosis (a secondary endpoint) both at 24 hours (0% versus 0.8%; nominal  $p=0.0078$ ) and 30 days (0.2% versus 1.2%; nominal  $p=0.023$ ). The study results also showed that there was no difference in bleeding events between the pre-hospital and in-hospital study arms, the primary safety endpoint of the study.

Separately, on 23 September 2014, the American Heart Association (AHA) and American College of Cardiology (ACC) updated their guidelines for the management of non-ST-elevation acute coronary syndrome (NSTEMI-ACS) patients. Under the new guidelines, Brilinta is now the preferred P2Y12 inhibitor for the management of NSTEMI-ACS patients who undergo an early invasive or ischemia-guided strategy, or those who receive a coronary stent. This is the first time the AHA and ACC have recommended one oral antiplatelet over another in the treatment of ACS.

### Bydureon

On 8 September 2014, AstraZeneca announced that once-weekly Bydureon (exenatide extended-release for injectable suspension) Pen 2mg, is available in pharmacies across the United States. Bydureon is approved by the FDA as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes.

On 19 September 2014, AstraZeneca announced 28 week results from DURATION-NEO-1, a Phase III study comparing an investigational formulation of exenatide once-weekly suspension for auto-injection to twice-daily exenatide (Byetta) injection in adult patients with type 2 diabetes who had inadequate glycaemic control. The study met its primary endpoint of non-inferiority, demonstrating that exenatide once-weekly suspension for auto-injection provided greater mean reductions in HbA1c (blood glucose levels) compared to Byetta at 28 weeks (-1.4% versus -1.0%, respectively;  $p=0.007$ ). The results were presented at the 50th Annual Meeting of the European Association for the Study of Diabetes (EASD) in Vienna, Austria.

### Tralokinumab

The first patient has been dosed in the Phase III programme for tralokinumab, a potential treatment for patients with severe, inadequately controlled asthma. The Phase III programme will evaluate the safety and effectiveness of tralokinumab in reducing the rate of asthma exacerbations in adults and adolescents with severe, inadequately controlled asthma despite receiving inhaled corticosteroids plus long-acting beta2-agonist. The programme will also assess the effect of tralokinumab on lung function, patient-reported asthma symptoms and quality of life, as well as investigate whether potential clinical biomarkers could identify patients who are more likely to respond to tralokinumab.

#### Lesinurad

On 13 August 2014, AstraZeneca announced top-line results from CLEAR1, CLEAR2 and CRYSTAL, the pivotal Phase III clinical trials investigating the potential of lesinurad, a selective uric acid re-absorption inhibitor (SURI), as a combination therapy for the treatment of patients with symptomatic gout. In the CLEAR1 and CLEAR2 trials, both lesinurad 200mg and 400mg in combination with allopurinol met the primary endpoint, with a statistically significant higher proportion of patients reaching the target sUA goal of <6.0mg/dL at month 6 compared to allopurinol alone ( $p < 0.0001$ ).

In the CRYSTAL trial, lesinurad 400mg in combination with febuxostat met the primary endpoint, with a statistically significant higher proportion of patients reaching the target sUA goal of <5.0mg/dL at month 6 compared to febuxostat alone ( $p < 0.0001$ ). Although lesinurad 200mg did not achieve statistical significance at month 6 ( $p = 0.13$ ), this dose in combination with febuxostat, was superior to placebo plus febuxostat at all other time points (measured at months 1 to 5, 8, 10 and 12; nominal  $p < 0.05$ ).

The three most commonly reported adverse events across the CLEAR1 and CLEAR2 trials for patients receiving lesinurad in combination with allopurinol were upper respiratory tract infection, nasopharyngitis and back pain. In CRYSTAL, the three most commonly reported adverse events for patients receiving lesinurad in combination with febuxostat were nasopharyngitis, arthralgia and upper respiratory tract infection.

The incidence of renal-related adverse events (including serious events) and incidence of kidney stones with lesinurad 200mg plus xanthine oxidase (XO) inhibitor was comparable to placebo plus XO inhibitor. The incidence of renal-related adverse events and kidney stones was higher with lesinurad 400mg plus XO inhibitor. A full assessment of the safety and tolerability findings of all three studies is ongoing.

The Company is proceeding with preparation of regulatory submissions for lesinurad (200mg) combination therapy.

#### Movantik/Moventig

On 16 September 2014, AstraZeneca announced that the FDA approved Movantik (naloxegol) tablets C-II as the first once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) medication for the treatment of opioid-induced constipation (OIC), in adult patients with chronic, non-cancer pain.

Movantik is expected to be available to patients in the first half of 2015, following review by the US Drug Enforcement Administration for the descheduling of Movantik as a schedule II controlled substance.

On 26 September 2014, AstraZeneca announced that the CHMP of the EMA has adopted a positive opinion recommending approval of Moventig (naloxegol), an investigational PAMORA, for the treatment of OIC in adult patients who have had an inadequate response to laxative(s).

The CHMP's positive opinion on Movantik will be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union. Should the EC approve Movantik, it will be the first once-daily, oral PAMORA available in these markets for the treatment of OIC in adult patients who have had an inadequate response to laxative(s).

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

#### CAZ-AVI

On 19 August 2014, AstraZeneca announced positive top-line results from RECLAIM-1 and RECLAIM-2, the pivotal Phase III studies investigating the potential of the antibiotic ceftazidime-avibactam (CAZ-AVI) as a treatment for hospitalised adult patients with complicated intra-abdominal infections (cIAI). CAZ-AVI is being developed to treat a broad range of Gram-negative bacterial infections which are becoming resistant to antibiotics and pose an increasing threat to public health. The addition of avibactam protects ceftazidime from being broken down by beta-lactamases that are produced by resistant bacteria.

In the RECLAIM-1 and RECLAIM-2 Phase III studies, CAZ-AVI met the objective of statistical non-inferiority compared to meropenem. The primary endpoint was a clinical cure rate 28 to 35 days after randomisation (the Test of Cure visit). CAZ-AVI also treated cIAI patients infected with ceftazidime-resistant bacteria as effectively as meropenem. The RECLAIM-1 and RECLAIM-2 Phase III studies could form the basis of regulatory submissions seeking approval for a broader range of indications, in line with new EMA guidelines on the evaluation of medicines to treat bacterial infections. EU filing is anticipated in the first quarter of 2015, pending a full analysis of the data from the studies. The results will also be submitted to a scientific meeting in the first half of 2015.

CAZ-AVI is being jointly developed with Forest Laboratories, a wholly-owned subsidiary of Actavis.

#### MEDI4893/MEDI3902

MedImmune, the global biologics research and development arm of AstraZeneca, has received fast track designation from the FDA for its investigational monoclonal antibody (mAb) MEDI4893 for the prevention of nosocomial pneumonia caused by the bacterium *Staphylococcus aureus* (*S. aureus*), which is often multidrug resistant. The FDA's fast track programme is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

MEDI4893, currently in Phase IIb clinical trials, is a novel mAb that attacks a key toxin released by *S. aureus*, a bacterial pathogen that can lead to life-threatening and expensive to treat staphylococcal infections in hospitalised patients.

In September 2014, the FDA also granted fast track designation to MEDI3902, MedImmune's investigational monoclonal antibody for the prevention of nosocomial pneumonia caused by another highly drug resistant bacterium, *Pseudomonas aeruginosa*.

#### Xigduo XR

On 30 October 2014, AstraZeneca announced that the FDA had approved once-daily Xigduo XR (dapagliflozin and metformin hydrochloride extended-release) for the treatment of adults with type 2 diabetes. Xigduo XR combines two anti-hyperglycaemic agents with complementary mechanisms of action, dapagliflozin (trade name in the US, Farxiga), an inhibitor of sodium-glucose cotransporter 2 (SGLT-2), and metformin hydrochloride (HCl) extended-release, a biguanide, in a once-daily oral tablet. SGLT-2 inhibitors are a relatively new class of medicines that remove glucose from the body via the kidneys. Xigduo XR is the first and only once-daily combination tablet of an SGLT-2 inhibitor

and metformin HCl extended-release to be approved in the US. Xigduo XR is indicated as an adjunct therapy to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus, when treatment with both dapagliflozin and metformin is appropriate.

Xigduo XR is already approved in Australia for the treatment of adults with type 2 diabetes, along with diet and exercise. Xigduo (dapagliflozin and metformin hydrochloride), which uses an immediate-release form of metformin, is approved in the EU.

#### Business Development and Corporate Transactions

---

##### BACE (AZD3293) agreement with Eli Lilly & Company

On 16 September 2014, AstraZeneca and Eli Lilly & Company (Lilly) announced an agreement to jointly develop and commercialise AZD3293, an oral beta secretase cleaving enzyme (BACE) inhibitor currently in development as a potential treatment for Alzheimer's disease.

The progression of Alzheimer's disease is characterised by the accumulation of amyloid plaque in the brain, which is comprised of peptides called amyloid beta. BACE is an enzyme associated with the development of amyloid beta. Inhibiting BACE is expected to prevent the formation of amyloid plaque and eventually slow the progression of the disease. AZD3293 is an oral, potent and selective small molecule inhibitor of BACE that has been shown in Phase I studies to significantly and dose-dependently reduce levels of amyloid beta in the cerebro-spinal fluid of Alzheimer's patients and healthy volunteers.

Under the terms of the agreement, Lilly will pay AstraZeneca up to \$500 million in development and regulatory milestone payments. AstraZeneca expects to receive the first milestone payment of \$50 million in the first half of 2015. The companies will share all future costs equally for the development and commercialisation of AZD3293, as well as net global revenues post-launch.

AstraZeneca and Lilly aim to progress AZD3293 rapidly into a Phase II/III clinical trial in patients with early Alzheimer's disease. Lilly will lead clinical development, working with researchers from AstraZeneca's Innovative Medicines Unit for neuroscience, while AstraZeneca will be responsible for manufacturing. The companies will take joint responsibility for commercialisation of AZD3293.

##### Partnership with Illumina

On 21 August 2014, AstraZeneca announced that it had entered into a collaboration with gene sequencing company, Illumina, Inc. (Illumina), to develop its next generation sequencing (NGS) platform for companion diagnostic tests applicable across AstraZeneca's oncology portfolio. In the first instance, AstraZeneca intends to apply Illumina's cutting-edge technology to a novel companion diagnostic test in pivotal studies for one of its investigational oncology compounds. This is expected to be one of the first NGS-based companion diagnostic tests for a novel drug in the world, and its application could speed the clinical trial process.

Illumina's NGS technology allows rapid sequencing of multiple genes in a much faster and cheaper way than traditional DNA sequencing methods. Under the collaboration, it will be used to screen a panel of several gene sequences, scanning for all possible genetic variants, known and unknown, rather than specified mutations from a single tumour sample.

##### University of Cambridge collaboration



On 16 October 2014, AstraZeneca, together with MedImmune, announced that it had entered into four new collaborations with the University of Cambridge, building further on the existing partnership. The latest collaborations reinforce AstraZeneca's commitment to creating a permeable research infrastructure in Cambridge following the Company's decision to locate one of its three global research and development centres and its global headquarters in the city that has been home to MedImmune's biologics research laboratories for 25 years.

The agreements build on the existing strategic partnership between AstraZeneca, MedImmune and the University of Cambridge, which includes a substantial oncology research programme and co-location of AstraZeneca scientists at the Cancer Research UK Cambridge Institute, the largest single facility conducting cancer research in the University of Cambridge. The four agreements involve Neuroscience research, access to AstraZeneca pipeline compounds, a PhD programme to support future leaders in science and an entrepreneur-in-residence programme.

#### Cancer Research UK collaboration

On 25 September 2014, AstraZeneca announced that MedImmune and Cancer Research UK, with its commercial arm, Cancer Research Technology (CRT), had entered into an innovative collaboration to establish a joint laboratory in Cambridge, UK. The new laboratory, representing a first of its kind partnership for both organisations, will focus on the discovery and development of novel biologic cancer treatments over an initial five-year period.

As part of the collaboration, scientists from both organisations will work side-by-side on multiple oncology projects at the new CRUK-MEDI Alliance Laboratory. Cancer Research UK, will provide set-up and operational funding for the laboratory and will contribute a portfolio of novel drug targets together with a team of scientists. MedImmune will oversee the laboratory activities and provide access to its human antibody phage display libraries and established antibody-engineering technologies. The joint team will share knowledge and expertise to discover and develop antibodies to treat cancer.

#### Shionogi global licence agreement

On 8 October 2014, MedImmune and Japanese drug discovery-based pharmaceutical company Shionogi & Co., Ltd., announced that they had entered a global licence agreement under which MedImmune will in-licence Shionogi's novel preclinical biologic programme for the potential treatment of acute coronary syndrome (ACS).

Under the terms of the agreement, MedImmune will acquire exclusive rights to Shionogi's cardiovascular biologic programme and will be responsible for all future research, development, and manufacturing. The licenced programme acts on a biological mechanism that plays a physiological role in the metabolism of high-density lipoprotein (HDL). HDL is responsible for the transport of cholesterol out of blood vessels and plaques, and raising HDL levels has the potential to decrease the persistent residual risk in cardiovascular disease. AstraZeneca will be responsible for any future commercialisation, while Shionogi retains an option to co-market in Japan.

#### Acquisition of Definiens

On 4 November 2014, AstraZeneca announced that MedImmune had entered into an agreement to acquire Definiens, a privately-held company that has pioneered a world-leading imaging and data analysis technology, known as Tissue Phenomics, which dramatically improves the identification of biomarkers in tumour tissue.

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

Under the terms of the agreement, MedImmune will acquire 100 percent of Definiens' shares for an initial consideration of \$150 million and make additional predetermined milestone payments. Definiens will continue to operate its business with third-party customers.

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

#### Immuno-oncology combination trials with IMBRUVICA for haematological cancers

On 4 November 2014, AstraZeneca, Pharmacyclics, Inc. (Pharmacyclics) and Janssen Research & Development, LLC (Janssen) announced that they had entered into a clinical trial collaboration to evaluate the efficacy and safety of AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, in combination with IMBRUVICA (ibrutinib), an oral Bruton's tyrosine kinase inhibitor, co-developed by Pharmacyclics and Janssen and commercialised outside the US by Janssen affiliates. The study will assess the combination as a treatment for patients with haematological cancers including diffuse large B-cell lymphoma and follicular lymphoma, which are investigational uses for both compounds.

MEDI4736 blocks the signals that help tumours avoid detection by the immune system, countering the tumour's immune-evading tactics. Ibrutinib blocks signals that tell malignant B cells (white blood cells that produce antibodies) to multiply and spread uncontrollably. Preclinical evidence suggests that the combination of these two agents may lead to an enhanced anti-tumour immune response.

The Phase I part of the trial is expected to establish a recommended dose regimen for the combination of MEDI4736 and ibrutinib, and the Phase IIa part of the trial will assess the safety and efficacy of the investigational combination. Under the terms of the agreement, the two-part trial will be conducted by Pharmacyclics. The financial terms of the agreement have not been disclosed.

#### Collaborations in oncology with Pharmacyclics

On 4 November 2014, AstraZeneca and Pharmacyclics announced that they had entered into clinical trial collaborations to evaluate novel combination therapies targeting solid tumours and a number of haematological cancers.

The first collaboration, focusing on solid tumours, will evaluate the efficacy and safety of IMBRUVICA in combination with AstraZeneca's anti-PD-L1 antibody, MEDI4736.

The second collaboration will focus on haematological cancers and will explore separate combinations of two different AstraZeneca investigational PI3 kinase pathway inhibitors with IMBRUVICA, for the treatment of patients with relapsed or refractory diffuse large B-cell lymphomas. Preclinical evidence suggests that the combination of IMBRUVICA with these investigational medicines may enhance their effects.

Under the terms of the agreements, AstraZeneca and Pharmacyclics will collaborate on a non-exclusive basis and multiple Phase I and Phase IIa studies may be considered and conducted. The studies focused on solid tumours will be led by Pharmacyclics, while AstraZeneca will lead those exploring haematological cancers. The Phase I element of each study is expected to establish a recommended safe and tolerable dose and schedule for the combination and the Phase IIa element will assess its safety and efficacy in an expanded patient population. The financial terms of the agreement have not been disclosed. The results of the clinical studies will be used to determine whether further

clinical development of the different combinations is warranted.

#### Divestment of Myalept

On 6 November 2014, AstraZeneca announced that it had entered into a definitive agreement with Aegerion Pharmaceuticals, Inc. (Aegerion) to divest Myalept (metreleptin for injection), an orphan product for the treatment of complications of leptin deficiency in patients with generalised lipodystrophy.

Myalept is the first and only product approved in the US for this treatment and it has orphan drug designation in the US, EU, and Japan. Myalept is a recombinant analogue of human leptin, indicated in the US as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalised lipodystrophy.

Under the terms of the agreement, Aegerion will pay AstraZeneca \$325 million upfront to acquire the global rights to develop, manufacture and commercialise Myalept, subject to an existing distributor license with Shionogi covering Japan, South Korea and Taiwan. The transaction does not include the transfer of any AstraZeneca employees or facilities.

The divestment transaction is subject to closing conditions, including the receipt of antitrust clearance from the US Federal Trade Commission. The companies expect the transaction to complete in January 2015.

#### 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:

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

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

#### Third Quarter

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

Reported 2014	Restructuring Amortisation & Impairments	Intangible Acquisition of BMS & share of diabetes	Other	Core 2014	Core 2013	Actual% CER %
------------------	---	--	-------	--------------	--------------	---------------------

Edgar Filing: ASTRAZENECA PLC - Form 6-K

				alliance					
Revenue	6,542	-	-	-	-	6,542	6,250	5	5
Cost of Sales	(1,415)	48	178	9	-	(1,180)	(1,103)		
Gross Profit	5,127	48	178	9	-	5,362	5,147	4	5
% sales	78.4%					82.0%	82.4%	-0.4	-
Distribution	(87)	-	-	-	-	(87)	(81)	6	6
% sales	1.3%					1.3%	1.3%	-	-
R&D	(1,552)	210	67	-	-	(1,275)	(1,061)	20	18
% sales	23.7%					19.5%	17.0%	-2.5	-2.1
SG&A	(3,132)	137	204	111	194**	(2,486)	(2,154)	15	15
% sales	47.9%					38.0%	34.5%	-3.5	-3.3
Other Income	185	-	71	-	-	256	176	45	46
% sales	2.8%					3.9%	2.8%	+1.1	+1.1
Operating Profit	541	395	520*	120	194**	1,770	2,027	(13)	(9)
% sales	8.3%					27.1%	32.4%	-5.3	-4.3
Net Finance Expense	(217)	-	-	93**	10**	(114)	(114)		
Joint Ventures Profit before Tax	(2)	-	-	-	-	(2)	-		
Taxation	322	395	520	213	204	1,654	1,913	(13)	(9)
Profit after Tax	(69)	(84)	(89)*	(41)	(38)	(321)	(388)		
Non-controlling Interests	253	311	431	172	166	1,333	1,525	(13)	(8)
Net Profit	1	-	-	-	-	1	(2)		
Weighted Average Shares	254	311	431	172	166	1,334	1,523	(12)	(8)
Earnings per Share	1,263	1,263	1,263	1,263	1,263	1,263	1,252		
	0.20	0.25	0.33	0.14	0.13	1.05	1.21	(13)	(8)

\* Intangible amortisation includes Merck related amortisation, of which \$101 million

\*\* carries no tax adjustment.

Contains certain items that carry no tax adjustment.

Revenue in the third quarter was up 5 percent at CER and was also up 5 percent on an actual basis as a result of the positive impact of a strengthening Euro offsetting weakness in the currencies of Japan, Australia and certain Emerging Markets. Major patent expiries have now largely annualised. Without including the additional revenue from the acquisition of BMS's share of the global diabetes alliance, revenue in the third quarter was up 1 percent at CER.

US revenues were up 7 percent. Declining sales from mature brands such as Crestor and Nexium as well as timing of seasonal shipments of Flumist were more than offset by the inclusion of 100 percent of revenue from the diabetes brands and the continued progress of our growth platforms. Symbicort grew 29 percent in the quarter driven by volume with net price broadly flat.

Revenue in Europe declined by 1 percent, with the impact of Seroquel XR declines resulting from adverse patent rulings in some markets coupled with "at risk" launches for generics and the continuing impact of loss of exclusivity for Seroquel IR, Atacand and Merrem being largely offset by the inclusion of 100 percent of the diabetes revenue and continued growth from Brilique. Revenue in Established Rest of World was down 2 percent, with the generic competition for Crestor in Canada and Australia now largely annualised and strong growth of Symbicort and Nexium

Edgar Filing: ASTRAZENECA PLC - Form 6-K

in Japan offsetting generic pressure on oncology products in that market. Revenue in Emerging Markets was up 13 percent, with a 21 percent increase in China a major driver.

Core gross margin as a percentage of revenue was 82.0 percent in the quarter, flat at CER, as the impact of including the costs associated with brands previously accounted for as alliance revenue offset the benefit of a lower Crestor royalty.

Core R&D expense was up 18 percent in the third quarter. The acceleration in our late stage pipeline and additional costs for assets acquired by business development were only partially offset by the redeployment of costs and the headroom created through restructuring initiatives.

Expenditures in Core SG&A were up 15 percent. The increase of spend in sales and marketing is dedicated to the growth platforms and represents the totality of the increase versus previous year. Our three core franchises (Brilinta, diabetes and respiratory) have increased sales by 38 percent in the third quarter. G&A has declined in the quarter creating some headroom for investment in variable S&M costs. The impact of the final regulations from the US Internal Revenue Service (IRS) on the US Branded Prescription Drug fee increased Core SG&A by \$37 million in the quarter as the fee payable in 2014 is expected to be higher than the fee related to 2013 sales, the latter being excluded from Core SG&A.

Core other income of \$256 million was up 46 percent this quarter driven by the receipt of a milestone payment of \$50 million related to the European launch of Nexium OTC.

Core operating profit was down 9 percent to \$1,770 million. Core operating margin was down 4.3 percentage points to 27.1 percent of revenue, with the growth in other income only partially offsetting the increased investment in R&D and the growth platforms.

Core earnings per share were down 8 percent to \$1.05, broadly in line with the decrease in Core operating profit, as the impact of a higher number of shares outstanding was largely offset by the slightly lower tax rate compared to the third quarter last year (see the Taxation paragraph below for details).

Reported operating profit was down 63 percent to \$541 million. Reported EPS was down 74 percent to \$0.20. Adjustments to Core financial measures were significantly higher than those in the third quarter 2013. The adjustments in 2013 included the reversal of the olaparib impairment. In addition the recent final regulations from the IRS on the US Branded Prescription Drug fee necessitated an additional year's charge to be recognised in this quarter as a Core adjustment. Core adjustments are also higher compared to Q3 in the prior year as a result of amortisation related to the acquisition of BMS's share of the global diabetes alliance.

Nine months

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

	Reported	Intangible Amortisation	Acquisition of BMS share of diabetes & diabetes alliance	Other	Core 2014	Core Actual 2013	CER %	CER %
	2014	Restructuring & Impairments						
Revenue	19,412	-	-	-	19,412	18,867	3	4
Cost of Sales	(4,175)	72	428	146	(3,529)	(3,344)		
Gross Profit	15,237	72	428	146	15,883	15,523	2	3
% sales	78.5%				81.8%	82.3%	-0.5	-0.3

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Distribution	(236)	-	-	-	-	(236)	(234)	1	1
% sales	1.2%					1.2%	1.3%	+0.1	+0.1
R&D	(4,080)	400	99	-	-	(3,581)	(3,064)	17	14
% sales	21.0%					18.4%	16.2%	-2.2	-1.7
SG&A	(8,916)	403	600	296	354**	(7,263)	(6,382)	14	14
% sales	45.9%					37.5%	33.8%	-3.7	-3.3
Other Income	481	292	177	-	-	950	564	68	69
% sales	2.4%					4.9%	3.0%	+1.9	+1.9
Operating Profit	2,486	1,167	1,304*	442	354			(10)	(6)
% sales	12.8%					29.6%	34.0%	-4.4	-3.3
Net Finance Expense	(658)	-	-	249**	28**	(381)	(321)		
Joint Ventures	(2)	-	-	-	-	(2)	-		
Profit before Tax						5,370	6,086		
Tax	1,826	1,167	1,304	691	382			(12)	(7)
Taxation	(270)	(247)	(214)*	(136)	(54)	(921)	(1,296)		
Profit after Tax	1,556	920	1,090	555	328	4,449	4,790	(7)	(2)
Non-controlling Interests	(2)	-	-	-	-	(2)	(11)		
Net Profit	1,554	920	1,090	555	328	4,447	4,779	(7)	(2)
Weighted Average Shares	1,262	1,262	1,262	1,262	1,262	1,262	1,251		
Earnings per Share	1.23	0.73	0.86	0.44	0.26	3.52	3.82	(8)	(3)

\* Intangible amortisation includes Merck related amortisation, of which \$297 million

\*\* carries no tax adjustment.

Contains certain items that carry no tax adjustment.

Revenue in the first nine months was up 4 percent at CER and 3 percent on an actual basis as a result of the negative impact of exchange rate movements. The impact of loss of exclusivity has now reduced and is more than offset by the Company's growth drivers. Without including the additional revenue from the acquisition of BMS's share of the global diabetes alliance, revenue in the first nine months was stable at CER. US revenue was up 6 percent; revenue in Rest of World (ROW) was up 3 percent.

Core gross margin was 81.8 percent, 0.3 percentage points lower than last year.

Core R&D expense in the first nine months was up 14 percent, reflecting the expansion of the late stage pipeline.

Expenditures in Core SG&A were 14 percent higher than the first nine months of last year. The increase of spend in sales and marketing is dedicated to the growth platforms and represents the totality of the increase versus previous year. Our three core franchises have increased sales by 31 percent in the first nine months. The selective investment in the growth platforms is partially funded by the decline in G&A costs year to date.

Core other income in the first nine months was up 69 percent, with milestone income related to the launch of Nexium OTC being the largest driver.

Core operating profit in the first nine months was down 6 percent to \$5,753 million. Core operating margin was 29.6 percent of revenue, down 3.3 percentage points.

Core earnings per share were \$3.52, down 3 percent compared with the first nine months of last year. The smaller decline compared with Core operating profit is largely due to a lower tax rate resulting from the inter-governmental agreement of a transfer pricing matter which was disclosed with the second quarter results. This favourable comparison arising from the tax rate was partially offset by an increase in the number of shares outstanding and higher net finance expense in the first nine months compared with last year.

Reported operating profit in the first nine months was down 35 percent to \$2,486 million; reported EPS was down 41 percent. These are much larger declines compared with the respective Core financial measures. Core operating profit adjusting items totalled \$3,267 million this year compared with \$2,104 million in 2013, the reasons for this increase are outlined in the third quarter commentary above.

#### Enhancing Productivity

The Company is making good progress in implementing the fourth phase of restructuring announced in the first quarter of 2013 and subsequently expanded in the first half of 2014. Restructuring charges of \$395 million were taken in the third quarter, bringing the year to date total to \$1,167 million.

#### Finance Income and Expense

Core net finance expense was \$114 million for the third quarter, versus \$114 million in the same period of 2013. Core net finance expense for the first nine months was \$381 million compared to \$321 million in 2013. The increase is principally due to higher net pension costs, fair value movements and the effect of discounting a long-term liability. Since this liability does not relate to a business combination, under our definition of Core financial measures, the charge is not excluded from the Core result. In the first nine months of 2014, Reported net finance expense includes a charge of \$277 million relating to the discount unwind on contingent consideration creditors recognised on business combinations, principally relating to the acquisition of the BMS share of the global diabetes alliance.

#### Taxation

Excluding a one-off benefit of \$117 million in respect of prior periods following the inter-governmental agreement of a transfer pricing matter, the reported tax rate for the nine months was 21.2 percent. Including this benefit, the reported tax rate for the nine months was 14.8 percent. The 21.2 percent tax rate is applied to the taxable Core adjustments, resulting in an effective Core tax rate for the nine months of 17.2 percent compared with 21.3 percent for 2013.

#### Cash Flow

Cash generated from operating activities was \$5,216 million in the nine months to 30 September 2014, compared with \$4,922 million in the same period of 2013, with the lower operating profit being more than offset by improvements in working capital.

Net cash outflows from investing activities were \$5,516 million in the nine months compared with \$1,885 million to 30 September 2013. The increase is primarily due to payments made in respect of the acquisition of the BMS share of the global diabetes alliance, which include \$2,703 million upfront and \$572 million in subsequent contingent consideration.

Net cash distributions to shareholders were \$3,258 million through dividends of \$3,521 million partially offset by proceeds from the issue of shares of \$263 million due to stock option exercises.

#### Debt and Capital Structure

At 30 September 2014, outstanding gross debt (interest-bearing loans and borrowings) was \$9,926 million (31 December 2013: \$10,376 million). Of the gross debt outstanding at 30 September 2014, \$2,399 million is due within one year (31 December 2013: \$1,788 million).

The Company's net debt position at 30 September 2014 was \$3,596 million.

#### Shares in Issue

In the nine months, 5.6 million shares were issued in respect of share option exercises for a consideration of \$263 million.

The total number of shares in issue at 30 September 2014 was 1,263 million.

#### Future Prospects

- Revenue is now expected to increase in low single digits at CER, an upgrade on our previous guidance for revenue to be in line with 2013 at CER.
- For planning purposes this guidance assumes no US Nexium generic in 2014.
- In light of the increase in revenue expectations for the year, the Company is accelerating its investments in its growth platforms and expanding pipeline. Core EPS for 2014 is now expected to decrease at around 10 percent at CER; better than anticipated in previous guidance. In addition, Core EPS for 2014 at actual exchange rates is expected to be impacted negatively by currency by around 5 percent, assuming current exchange rates.
- For 2015, the Company plans to continue to selectively invest in its growth platforms and accelerating pipeline while managing overall costs. Assuming current exchange rates, the Company is targeting Core EPS for 2015 to be no less than the lower end of the range of the upgraded guidance for Core EPS for 2014 at actual exchange rates. Guidance for 2015 is expected to be provided with 2014 results on 5 February 2015.
- Recently, the American Academy of Pediatrics - Committee on Infectious Disease issued new guidelines further restricting patients eligible for preventive therapy with Synagis. While these guideline changes are inconsistent with our approved label, we expect to see a significant impact on Synagis sales in the fourth quarter of 2014 and further impact in 2015 onwards. The new guidelines could potentially impact up to 55 percent of the 2013 US patient base.

#### 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 areas is shown in Notes 8 and 9.

	Third Quarter			Nine Months		
	2014	2013	CER	2014	2013	CER
	\$m	\$m	%	\$m	\$m	%
Cardiovascular and Metabolic disease						
Crestor	1,342	1,356	(1)	4,124	4,159	-
Seloken/Toprol-XL	198	173	14	584	580	3



Edgar Filing: ASTRAZENECA PLC - Form 6-K

Onglyza	220	93	139	620	285	118
Atacand	123	143	(13)	384	477	(19)
Brilinta/Brilique	127	75	68	343	191	78
Byetta	92	57	64	258	152	69
Bydureon	125	43	191	317	102	210
Oncology						
Zoladex	240	246	(2)	697	749	(4)
Iressa	157	165	(4)	473	489	(1)
Faslodex	187	169	11	538	499	8
Arimidex	74	90	(16)	230	265	(11)
Casodex	80	93	(12)	246	281	(9)
Respiratory, Inflammation and Autoimmunity						
Symbicort	967	839	15	2,823	2,507	12
Pulmicort	205	176	17	677	622	10
Infection, Neuroscience and Gastrointestinal						
Nexium	922	918	1	2,823	2,881	-
Synagis	121	130	(7)	496	545	(9)
Seroquel XR	319	339	(6)	915	1,000	(9)
Seroquel IR	51	84	(37)	206	310	(32)

Cardiovascular and Metabolic disease

- In the US, Crestor sales in the third quarter were \$682 million, down 5 percent. Crestor total prescriptions decreased 5 percent, consistent with the revenue decline. Crestor sales in the first nine months were up 1 percent, as net price realisation and prior year rebate adjustments more than offset volume declines.
- Crestor sales in the ROW were up 4 percent to \$660 million, reflecting the annualisation of the impact of generic competition in Australia. Emerging Markets were up 13 percent, with China growing by 37 percent. Crestor sales in the ROW in the first nine months were down 2 percent to \$1,966 million.
- US sales of the Toprol-XL product range, which includes sales of the authorised generic, were down 8 percent in the quarter to \$23 million, largely the result of market share loss following additional generic entrants. Seloken sales in other markets were up 18 percent to \$175 million. Global Seloken sales in the first nine months (excluding the authorised generic) were up 6 percent to \$549 million.
- Onglyza revenue was up 139 percent in the third quarter to \$220 million, of which \$130 million was in the US and \$90 million in other markets. AstraZeneca completed the acquisition of BMS's share of the global diabetes alliance on 1 February 2014 and began reflecting 100 percent ownership at that point. Total prescriptions for the Onglyza franchise in the US were flat compared with the third quarter last year; share of total prescriptions was 14.7 percent in the US in September 2014, down 0.6 percentage points since June 2014. The revenue decline in the US was primarily driven by lower net price. Revenue in the first nine months was \$620 million, up 118 percent.
- US sales of Atacand were up 18 percent in the quarter to \$13 million. Generic competition for the diuretic combination product followed the loss of exclusivity in December 2012. Atacand sales in other markets were down 16 percent to \$110 million, reflecting loss of exclusivity in many markets. Sales in the first nine months were down

19 percent to \$384 million.

- Sales of Brilinta/Brilique were \$127 million in the third quarter. Nearly half of the sales were in Europe, where third quarter sales have increased by 36 percent compared with the third quarter of 2013. Performance in Canada, Australia and Emerging Markets is also contributing to brand revenue growth.
- Brilinta sales in the US in the third quarter were \$40 million. Total prescriptions for Brilinta in the US in the third quarter of 2014 were 10 percent higher than the second quarter of 2014. New to brand share increased by 0.6 percentage points to 7.5 percent in the third quarter.
- Byetta and Bydureon revenues in the US were \$162 million, and \$55 million in ROW in the third quarter. Bydureon share of total prescriptions in the US returned to growth in September 2014 assisted by the launch of the Bydureon Pen in that month. Nine month revenue is \$575 million, up 126 percent.

#### Oncology

- Zoladex sales were \$240 million in the third quarter. Sales in Europe were down 10 percent and down 9 percent in Japan. On a nine month basis, sales were down 4 percent to \$697 million.
- Iressa sales in the third quarter were down 4 percent to \$157 million, as a decline in Japan, more than offset growth in China. Worldwide sales of Iressa in the first nine months were down 1 percent at \$473 million.
- Arimidex sales in the first nine months were \$230 million worldwide, down 11 percent as sales continue to decline as a result of loss of exclusivity.
- Sales of Casodex in the first nine months were \$246 million, down 9 percent. All but \$5 million of these sales were in markets outside the US. Sales in Japan, which account for 50 percent of global revenue, were down 18 percent in the first nine months due to generic competition.

#### Respiratory, Inflammation and Autoimmunity

- Symbicort sales in the US were \$395 million in the third quarter, a 29 percent increase over last year. Total prescriptions for Symbicort were also up 29 percent in the third quarter. Symbicort share of total prescriptions for fixed combination products reached 31.6 percent in September 2014. Symbicort sales in the US in the first nine months were up 26 percent to \$1,116 million. Price was flat for both the quarter and nine months.
- Symbicort sales in other markets in the third quarter were \$572 million, up 7 percent. Sales in Europe were down 1 percent as price pressure was offsetting a 6 percent volume growth. Sales in Established ROW were up 18 percent. Sales in Emerging Markets were up 28 percent. Symbicort sales in the ROW in the first nine months were up 5 percent to \$1,707 million.
- US sales of Pulmicort were down 6 percent to \$155 million in the first nine months. Pulmicort sales in the ROW were up 15 percent to \$522 million, with China comprising approximately half.

#### Infection, Neuroscience and Gastrointestinal

- In the US, Nexium sales in the third quarter were \$468 million, down 7 percent compared with the third quarter last year. Nexium sales in the first nine months were down 11 percent to \$1,407 million primarily driven by volume erosion.
- Nexium sales in other markets in the third quarter were up 10 percent to \$454 million. Much of the growth came from Japan and China, up 55 percent and 25 percent respectively. Nexium sales in other markets were up 13

percent in the first nine months to \$1,416 million.

- In the US, sales of Synagis in the third quarter were \$6 million with the third quarter being out of season for the US. Outside the US, sales in the third quarter were \$115 million, down 7 percent, which reflects the quarterly phasing of revenues related to shipments to AbbVie, our international distributor. Recently, the American Academy of Pediatrics - Committee on Infectious Disease issued new guidelines further restricting patients eligible for preventive therapy with Synagis. While these guideline changes are inconsistent with our approved label we expect to see a significant impact on Synagis sales in the fourth quarter of 2014 and further impact in 2015 onwards.
- Sales of Seroquel XR in the US were \$195 million in the third quarter, up 1 percent. US sales for the first nine months were down 1 percent to \$542 million.
- Sales of Seroquel XR in the ROW were down 15 percent to \$124 million in the third quarter, as a result of generic competition (including some "at risk" launches) in Europe where sales were down 22 percent. Sales in Emerging Markets were up 8 percent.
- Sales of Seroquel IR were down 32 percent in the first nine months to \$206 million. The majority of this decline is attributable to Japan, as the partner built inventory in 2013 in anticipation of a manufacturing site change.

#### Regional Revenue

	Third Quarter				Nine Months			
	2014	2013	% Change		2014	2013	% Change	
	\$m	\$m	Actual	CER	\$m	\$m	Actual	CER
US	2,528	2,360	7	7	7,479	7,057	6	6
Europe	1,648	1,630	1	(1)	4,925	4,836	2	(2)
Established	898	941	(5)	(2)	2,659	2,950	(10)	(3)
ROW1								
Japan	568	611	(7)	(3)	1,684	1,817	(7)	-
Canada	147	144	2	6	433	476	(9)	(3)
Other	183	186	(2)	(4)	542	657	(18)	(11)
Established								
ROW								
Emerging	1,468	1,319	11	13	4,349	4,024	8	12
Markets2								
China	558	467	19	21	1,666	1,363	22	22
Total	6,542	6,250	5	5	19,412	18,867	3	4

1Established ROW comprises Canada, Japan, Australia and New Zealand.

2Emerging Markets comprises all remaining ROW markets, including Brazil, China, India, Mexico, Russia, and Turkey.

- In the US, revenue was up 7 percent in the third quarter, with declines in revenue from brands such as Nexium and timing of Flumist shipments offset by the growth platforms and the impact of completing the acquisition of BMS's share of the global diabetes alliance. The diabetes products provided \$205 million of incremental revenue, with growth from Symbicort and Brilinta also contributing.
- In the third quarter, revenue in Europe was down 1 percent as the favourable impact from the acquisition of BMS's share of the global diabetes alliance and continued growth for Brilinta were offset by continuing impact from loss

Edgar Filing: ASTRAZENECA PLC - Form 6-K

of exclusivity on Seroquel XR in some markets and Atacand.

- Revenue in Established ROW was down 2 percent in the quarter, as growth of Nexium and Symbicort in Japan were more than offset by generic competition on generic competition to oncology products and Seroquel IR inventory depletion in Japan which was due to planned manufacturing site change.
- Revenue in Emerging Markets was up 13 percent in the quarter, growth was seen across the Emerging Markets business with China growing 21 percent. Ex-China emerging markets grew by 9 percent in the third quarter. Brand growth drivers were Crestor, Nexium, Symbicort, Pulmicort and the diabetes products.

Condensed Consolidated Statement of Comprehensive Income

	2014	2013
For the nine months ended 30 September	\$m	\$m
Revenue	19,412	18,867
Cost of sales	(4,175)	(3,821)
Gross profit	15,237	15,046
Distribution costs	(236)	(234)
Research and development expense	(4,080)	(3,392)
Selling, general and administrative costs	(8,916)	(7,564)
Other operating income and expense	481	447
Operating profit	2,486	4,303
Finance income	45	37
Finance expense	(703)	(358)
Share of after tax losses of joint ventures	(2)	-
Profit before tax	1,826	3,982
Taxation	(270)	(891)
Profit for the period	1,556	3,091
Other comprehensive income		
Items that will not be reclassified to profit or loss:		
Remeasurement of the defined benefit liability	(498)	(239)
Tax on items that will not be reclassified to profit or loss	127	(38)
	(371)	(277)
Items that may be reclassified subsequently to profit or loss:		
Foreign exchange arising on consolidation	(412)	(140)
Foreign exchange arising on designating borrowings in net investment hedges	(292)	(23)
Fair value movements on derivatives designated in net investment hedges	36	60
Amortisation of loss on cash flow hedge	1	1
Net available for sale gains taken to equity	73	59
Tax on items that may be reclassified subsequently to profit or loss	30	1
	(564)	(42)
Other comprehensive income for the period, net of tax	(935)	(319)
Total comprehensive income for the period	621	2,772
Profit attributable to:		
Owners of the Parent	1,554	3,080

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Non-controlling interests	2	11
	1,556	3,091
Total comprehensive income attributable to:		
Owners of the Parent	626	2,785
Non-controlling interests	(5)	(13)
	621	2,772
Basic earnings per \$0.25 Ordinary Share	\$1.23	\$2.46
Diluted earnings per \$0.25 Ordinary Share	\$1.23	\$2.46
Weighted average number of Ordinary Shares in issue (millions)	1,262	1,251
Diluted weighted average number of Ordinary Shares in issue (millions)	1,264	1,253

Condensed Consolidated Statement of Comprehensive Income

	2014	2013
	\$m	\$m
For the quarter ended 30 September		
Revenue	6,542	6,250
Cost of sales	(1,415)	(1,238)
Gross profit	5,127	5,012
Distribution costs	(87)	(81)
Research and development expense	(1,552)	(858)
Selling, general and administrative costs	(3,132)	(2,503)
Other operating income and expense	185	136
Operating profit	541	1,706
Finance income	19	14
Finance expense	(236)	(128)
Share of after tax losses of joint ventures	(2)	-
Profit before tax	322	1,592
Taxation	(69)	(344)
Profit for the period	253	1,248
Other comprehensive income		
Items that will not be reclassified to profit or loss:		
Remeasurement of the defined benefit liability	(210)	(212)
Tax on items that will not be reclassified to profit or loss	42	(48)
	(168)	(260)
Items that may be reclassified subsequently to profit or loss:		
Foreign exchange arising on consolidation	(476)	212
Foreign exchange arising on designating borrowings in net investment hedges	(170)	(68)
Fair value movements on derivatives designated in net investment hedges	47	1
Net available for sale gains/(losses) taken to equity	24	(24)
Tax on items that may be reclassified subsequently to profit or loss	25	8
	(550)	129

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other comprehensive income for the period, net of tax	(718)	(131)
Total comprehensive income for the period	(465)	1,117
Profit attributable to:		
Owners of the parent	254	1,246
Non-controlling interests	(1)	2
	253	1,248
Total comprehensive income attributable to:		
Owners of the parent	(463)	1,112
Non-controlling interests	(2)	5
	(465)	1,117
Basic earnings per \$0.25 Ordinary Share	\$0.20	\$0.99
Diluted earnings per \$0.25 Ordinary Share	\$0.20	\$0.99
Weighted average number of Ordinary Shares in issue (millions)	1,263	1,252
Diluted weighted average number of Ordinary Shares in issue (millions)	1,264	1,254

Condensed Consolidated Statement of Financial Position

	At 30 Sep 2014 \$m	At 31 Dec 2013 \$m	At 30 Sep 2013 \$m
<b>ASSETS</b>			
Non-current assets			
Property, plant and equipment	5,989	5,818	5,728
Goodwill	11,368	9,981	9,943
Intangible assets	20,351	16,047	17,256
Derivative financial instruments	390	365	328
Investments in joint ventures	66	-	-
Other investments	281	281	236
Other receivables	1,239	1,867	539
Deferred tax assets	1,408	1,205	1,299
	41,092	35,564	35,329
Current assets			
Inventories	1,957	1,909	2,075
Trade and other receivables	6,809	7,879	7,294
Other investments	804	796	864
Derivative financial instruments	7	40	25
Income tax receivable	349	494	1,081
Cash and cash equivalents	5,146	9,217	7,453
	15,072	20,335	18,792
Total assets	56,164	55,899	54,121
<b>LIABILITIES</b>			
Current liabilities			

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Interest-bearing loans and borrowings	(2,399)	(1,788)	(1,709)
Trade and other payables	(10,149)	(10,362)	(9,242)
Derivative financial instruments	(17)	(2)	(1)
Provisions	(564)	(823)	(579)
Income tax payable	(2,695)	(3,076)	(3,144)
	(15,824)	(16,051)	(14,675)
Non-current liabilities			
Interest-bearing loans and borrowings	(7,527)	(8,588)	(8,566)
Derivative financial instruments	-	(1)	-
Deferred tax liabilities	(2,151)	(2,827)	(3,143)
Retirement benefit obligations	(2,733)	(2,261)	(2,588)
Provisions	(557)	(566)	(781)
Other payables	(6,906)	(2,352)	(921)
	(19,874)	(16,595)	(15,999)
Total liabilities	(35,698)	(32,646)	(30,674)
Net assets	20,466	23,253	23,447
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	316	315	314
Share premium account	4,245	3,983	3,770
Other reserves	1,991	1,966	1,964
Retained earnings	13,893	16,960	17,200
	20,445	23,224	23,248
Non-controlling interests	21	29	199
Total equity	20,466	23,253	23,447

Condensed Consolidated Statement of Cash Flows

	2014	2013
	\$m	\$m
For the nine months ended 30 September		
Cash flows from operating activities		
Profit before tax	1,826	3,982
Finance income and expense	658	321
Share of after tax losses of joint ventures	2	-
Depreciation, amortisation and impairment	2,261	1,978
Decrease/(increase) in working capital and short-term provisions	1,752	(257)
Non-cash and other movements	208	409
Cash generated from operations	6,707	6,433
Interest paid	(446)	(416)
Tax paid	(1,045)	(1,095)
Net cash inflow from operating activities	5,216	4,922
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	(25)	20
Purchase of property, plant and equipment	(621)	(359)
Disposal of property, plant and equipment	143	55
Purchase of intangible assets	(1,662)	(913)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Purchase of non-current asset investments	(9)	(14)
Disposal of non-current asset investments	-	31
Payments to joint ventures	(70)	-
Upfront payments on acquisitions	(2,778)	(825)
Payment of contingent consideration on acquisitions	(572)	-
Interest received	88	88
Payments made by subsidiaries to non-controlling interests	(10)	(10)
Payments received by subsidiaries from non-controlling interests	-	42
Net cash outflow from investing activities	(5,516)	(1,885)
Net cash (outflow)/inflow before financing activities	(300)	3,037
Cash flows from financing activities		
Proceeds from issue of share capital	263	268
Repayment of loans	(750)	-
Dividends paid	(3,521)	(3,461)
Hedge contracts relating to dividend payments	(14)	(36)
Repayment of obligations under finance leases	(27)	(19)
Payments to acquire non-controlling interest	(102)	-
Movement in short-term borrowings	295	-
Net cash outflow from financing activities	(3,856)	(3,248)
Net decrease in cash and cash equivalents in the period	(4,156)	(211)
Cash and cash equivalents at the beginning of the period	8,995	7,596
Exchange rate effects	(30)	(62)
Cash and cash equivalents at the end of the period	4,809	7,323
Cash and cash equivalents consists of:		
Cash and cash equivalents	5,146	7,453
Overdrafts	(337)	(130)
	4,809	7,323

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 2013	312	3,504	1,960	17,955	23,731	215	23,946
Profit for the period	-	-	-	3,080	3,080	11	3,091
Other comprehensive income	-	-	-	(295)	(295)	(24)	(319)
Transfer to other reserves	-	-	4	(4)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,499)	(3,499)	-	(3,499)



Edgar Filing: ASTRAZENECA PLC - Form 6-K

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

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non-controlling interests \$m	Total equity \$m
At 1 Jan 2014	315	3,983	1,966	16,960	23,224	29	23,253
Profit for the period	-	-	-	1,554	1,554	2	1,556
Other comprehensive income	-	-	-	(928)	(928)	(7)	(935)
Transfer to other reserves	-	-	25	(25)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,532)	(3,532)	-	(3,532)
Issue of Ordinary Shares	1	262	-	-	263	-	263
Share-based payments	-	-	-	(136)	(136)	-	(136)
Transfer from non-controlling interests to payables	-	-	-	-	-	(3)	(3)
Net movement	1	262	25	(3,067)	(2,779)	(8)	(2,787)
At 30 Sep 2014	316	4,245	1,991	13,893	20,445	21	20,466

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

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 2014 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 2013. There have been no significant new or revised accounting standards applied in the nine months ended 30 September 2014.

The information contained in Note 7 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2013.

The Group has considerable financial resources available. As at 30 September 2014, the Group had \$5.7 billion in financial resources (cash balances of \$5.1 billion and undrawn committed bank facilities of \$3.0 billion that are available until April 2019, with \$2.4 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, government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully.

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

The comparative figures for the financial year ended 31 December 2013 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				At 30
	Jan	Cash	Non-cash	Exchange	Sep
	2014	Flow	Movements	Movements	2014
	\$m	\$m	\$m	\$m	\$m
Loans due after one year	(8,516)	-	1,047	9	(7,460)
Finance leases due after one year	(72)	-	5	-	(67)
Total long term debt	(8,588)	-	1,052	9	(7,527)
Current instalments of loans	(766)	750	(935)	-	(951)
	(30)	27	(45)	2	(46)

Current instalments of finance leases					
Total current debt	(796)	777	(980)	2	(997)
Other investments - current	796	21	-	(13)	804
Net derivative financial instruments	402	18	(40)	-	380
Cash and cash equivalents	9,217	(4,041)	-	(30)	5,146
Overdrafts	(222)	(115)	-	-	(337)
Short-term borrowings	(770)	(295)	-	-	(1,065)
	9,423	(4,412)	(40)	(43)	4,928
Net funds/(debt)	39	(3,635)	32	(32)	(3,596)

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 2014 is stated after charging restructuring costs of \$1,167 million (\$395 million for the third quarter 2014). These have been charged to profit as follows:

	3rd Quarter 2014 \$m	3rd Quarter 2013 \$m	9 Months 2014 \$m	9 Months 2013 \$m
Cost of sales	48	6	72	104
Research and development expense	210	53	400	406
Selling, general and administrative costs	137	126	403	526
Other income	-	-	292	-
Total	395	185	1,167	1,036

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

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

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

operations, requires that the acquisition is accounted for as a business combination in accordance with IFRS 3 Business Combinations.

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

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

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

Goodwill of \$1.6 billion is underpinned by a number of elements, which individually cannot be quantified. Most significant among these are the synergies AstraZeneca expect to be able to generate through more efficient manufacturing processes and the incremental value accessible through strategic and operational independence upon taking full control of the alliance.

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

The results from the additional acquired interests in the diabetes alliance have been consolidated into the Company's results from 1 February 2014, which have added revenue of \$646 million in the period to 30 September 2014. Due to the highly integrated nature of the diabetes alliance, and the fact that it is not operated through a separate legal entity, the incremental direct costs associated with the additional acquired interest are not separately identifiable and it is impracticable therefore to disclose the profit or loss recognised in the period since acquisition.

	Fair value \$m
Non-current assets	
Intangible assets	5,746
Property, plant and equipment	478
	6,224

Current assets	480
Current liabilities	(278)
Non-current liabilities	(106)
Total net assets	
acquired	6,320
Goodwill	1,552
Fair value of total consideration	7,872
Less: fair value of contingent consideration	(5,169)
Total upfront consideration	2,703
Less: cash and cash equivalents acquired	-
Net cash outflow	2,703

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

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

In the period between acquisition and 30 September 2014, the effect of discounting increased the contingent consideration liability by \$249 million and revaluations increased fair value by \$6 million. Cash payments in the period since acquisition totaled \$572 million.

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

## 5 STRATEGIC TRANSACTION WITH ALMIRALL IN RESPIRATORY DISEASE

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

Upfront consideration of \$875 million is subject to adjustment for working capital and certain other items, and will be paid within 10 days of closing. Further payments of up to \$1.22 billion are payable upon future development, launch, and sales-related milestones. AstraZeneca has also agreed to make various sales-related payments.

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

The combination of intangible product rights with an established work force and their associated operating processes, principally those related to the selling and marketing operations, requires that the transaction is accounted for as a business combination in accordance with IFRS 3 Business Combinations. Since completion of the transaction occurred after the balance sheet date, no amounts in respect of the acquired business have been included in the Financial Statements for the nine months ended 30 September 2014.

Due to the close proximity of completion of the transaction to the announcement of the Third Quarter and Nine Months Results, full disclosure of the initial accounting entries, including the fair value of identifiable assets and liabilities acquired, the fair value of future contingent consideration, and the level of goodwill, will be made with the Full Year Results on 5 February 2015.

## 6 FINANCIAL INSTRUMENTS

As detailed in our most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the accounting policies, including fair value measurement, for financial instruments from those disclosed on pages 139 and 140 of the Company's Annual Report and Form 20-F Information 2013. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include \$1,085 million of other investments, \$1,211 million of loans, and \$380 million of derivatives as at 30 September 2014. The total fair value of interest-bearing loans and borrowings at 30 September 2014, which have a carrying value of \$9,926 million in the Condensed Consolidated Statement of Financial Position, was \$11,013 million. Contingent consideration liabilities arising on the Company's acquisitions of business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	2014
	\$m
At 1 January	514
Acquisitions	5,169
Settlements	(572)
Revaluations	6
Discounting	277
Foreign exchange	(3)
At 30 September	5,391

For all other financial instruments which are carried at amortised cost, amortised cost approximates to fair value.

## 7 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

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

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

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

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

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

Matters disclosed in respect of the third quarter of 2014 and to 6 November 2014

#### Patent litigation

##### Byetta (exenatide)

##### Patent proceedings in the US

In October 2014, AstraZeneca received a Paragraph IV notice from Teva Pharmaceuticals USA, Inc. (Teva) alleging certain patents listed in the FDA Orange Book with reference to Byetta (exenatide) are invalid, unenforceable and/or not infringed by Teva's proposed generic product. Teva has filed an Abbreviated New Drug Application (ANDA) seeking to market 300mcg/1.2mL and 600mcg/2.4mL (250mcg/mL) exenatide for injection. AstraZeneca is reviewing Teva's notice.

##### Crestor (rosuvastatin calcium)

##### Patent proceedings outside the US

As previously disclosed, in Australia in 2011 and 2012, AstraZeneca instituted proceedings against Apotex Pty Ltd, Watson Pharma Pty Ltd. and Actavis Australia Pty Ltd. asserting infringement of various formulation and method patents for Crestor. In March 2013, the Federal Court of Australia held all three patents at issue invalid. AstraZeneca appealed in relation to two patents. On 12 August 2014, the Full Court of the Federal Court of Australia held the two patents invalid. AstraZeneca has sought leave to appeal to the High Court in relation to one method patent.

##### Faslodex (fulvestrant)

##### Patent proceedings in the US

As previously disclosed, in June 2014, AstraZeneca filed a patent infringement lawsuit against Sandoz Inc. and Sandoz International GmbH in the US District Court in New Jersey relating to four patents listed in the FDA Orange Book with reference to Faslodex. In September 2014, AstraZeneca filed two similar lawsuits against Sagent

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

Pharmaceuticals, Inc. relating to the same four patents in US District Courts in New Jersey and Illinois.

Nexium (esomeprazole magnesium)

Patent proceedings in the US

In October 2014, AstraZeneca received a Paragraph IV Notice from Actavis Laboratories FL, Inc. (Actavis) alleging certain patents listed in the FDA Orange Book with reference to Nexium 24HR are invalid, unenforceable and/or not infringed by Actavis' proposed generic product. Actavis has filed an Abbreviated New Drug Application (ANDA) seeking to market 20mg esomeprazole magnesium over the counter. AstraZeneca is reviewing Actavis' notice.

In October 2014, AstraZeneca received a Paragraph IV Notice from Aurobindo Pharma Limited (Aurobindo) alleging US Patent No. 6,143,771 is invalid, unenforceable and/or not infringed by Aurobindo's proposed generic product. Aurobindo has filed an ANDA seeking to market 20mg/vial and 40mg/vial esomeprazole sodium for injection. AstraZeneca is reviewing Aurobindo's notice.

Patent proceedings outside the US

As previously disclosed, in Canada, patent infringement proceedings against Apotex Inc. continue. On 2 July 2014, the Federal Court found Canadian Patent No. 2,139,653 invalid. AstraZeneca has appealed.

In Canada, on 14 July 2014, AstraZeneca received a Notice of Allegation from Teva Canada Limited (Teva) alleging either that Teva's esomeprazole magnesium product would not infringe the patents listed on the Canadian Patent Register in relation to Nexium or, alternatively, that certain of the patents were invalid. AstraZeneca has commenced an application in response.

Pulmicort Respules (budesonide inhalation suspension)

Patent proceedings in the US

As previously disclosed, in December 2013, the US District Court for the District of New Jersey temporarily enjoined the generic defendants from entering the market until resolution of AstraZeneca's motion for a preliminary injunction. On 6 October 2014, the Court commenced a hearing on the preliminary injunction motion as well as a trial on the merits in respect of US Patent No. 7,524,834.

Seroquel XR (quetiapine fumarate)

Patent proceedings in the US

In September 2014, AstraZeneca received a Paragraph IV Notice from Pharmadax, Inc. and Pharmadax USA, Inc. (collectively, Pharmadax) alleging that the patent listed in the FDA Orange Book with reference to Seroquel XR is invalid, unenforceable and/or is not infringed by the Pharmadax proposed generic product. Pharmadax has submitted an Abbreviated New Drug Application (ANDA) seeking to market quetiapine fumarate 150, 200, 300 and 400mg tablets. In October 2014, AstraZeneca filed a patent infringement lawsuit against Pharmadax and Pharmadax (Guangzhou) Inc. in the US District Court for the District of New Jersey. In October 2014, AstraZeneca also filed a similar patent infringement suit against the same parties in the US District Court for the Central District of California Southern Division.

Product liability litigation

Crestor (rosuvastatin calcium)

As previously disclosed, AstraZeneca is defending a number of lawsuits alleging multiple types of injuries caused by the use of Crestor, including diabetes mellitus, various cardiac injuries, rhabdomyolysis, and/or liver and kidney injuries. The claims of 571 plaintiffs, comprising 101 California residents and 470 non-California residents, were aggregated in one coordinated proceeding in Los Angeles, California. The claims of additional plaintiffs are waiting to be added to the coordination. In October 2014, the coordination judge dismissed the claims of the 470



non-California plaintiffs whose claims were in the coordinated proceeding. Those plaintiffs may or may not refile their claims in an appropriate venue. There are now a total of 729 plaintiffs remaining with claims pending in California state court.

#### Nexium (esomeprazole magnesium)

As previously disclosed, AstraZeneca has been defending federal Multi-District Litigation (MDL) against plaintiffs who allege that Nexium caused bone deterioration, loss of bone density and/or bone fractures. On 1 October 2014, the MDL court granted AstraZeneca's motion for summary judgment as to approximately 270 claims that remained pending in the MDL and entered judgment in AstraZeneca's favour. Of the more than 1,910 plaintiffs who have filed claims against AstraZeneca alleging Nexium caused bone-related injuries, fewer than 40 plaintiffs' claims remain active and the rest have been dismissed. All of the remaining active claims are pending in California state court.

#### Commercial litigation

##### Nexium settlement anti-trust litigation

As previously disclosed, AstraZeneca is one of several defendants in a Multi-District Litigation class action and individual lawsuits alleging that AstraZeneca's settlements of certain patent litigation in the US relating to Nexium violated US anti-trust law and various state laws. A trial commenced on 20 October 2014 on certain liability issues for claims that remain in the case.

On 31 July 2014, the US Court of Appeals heard oral argument on AstraZeneca's appeal of the District Court's procedural decision to certify a class action of end payers. The Appeals Court has not issued a decision.

In October 2014, the US District Court for the District of Pennsylvania granted plaintiffs' motion to remand an indirect purchaser opt-out case to the Pennsylvania Court of Common Pleas. Another indirect purchase opt-out case was transferred to the District of Massachusetts for consideration. No schedule has been set in either of the opt-out cases.

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

In October 2014, following a previously disclosed investigation by the State of Texas into AstraZeneca's sales and marketing activities involving Seroquel, the Texas Attorney General's Office intervened in a state whistleblower action pending in Travis County Court, Texas. The lawsuit alleges that AstraZeneca engaged in inappropriate promotion of Seroquel and made improper payments intended to influence the formulary status of Seroquel in violation of the Texas Medicaid Fraud Prevention Act and Texas common law.

#### Other Commercial litigation

##### Medco qui tam litigation (Schumann)

As previously disclosed, AstraZeneca had been named as a defendant in a lawsuit filed in the Federal Court in Philadelphia under the qui tam (whistleblower) provisions of the federal and certain state False Claims Acts alleging overpayments by federal and state governments resulting from alleged false pricing information reported to the government and alleged improper payments intended to influence the formulary status of Prilosec and Nexium to Medco and its customers. In January 2013, the Court granted AstraZeneca's motion and dismissed the case with prejudice. The plaintiff appealed. In October 2014, the US Court of Appeals for the Third Circuit affirmed the lower court's decision to dismiss AstraZeneca from the litigation with prejudice.

#### Government investigations

##### Brilinta (ticagrelor)

In August 2014, AstraZeneca announced that it had received confirmation from the US Department of Justice that it was closing its investigation regarding PLATO, a clinical trial. AstraZeneca understands that the US Government is not planning any further action.

## 8 NINE MONTHS PRODUCT REVENUE ANALYSIS

	World		US		Europe		Established ROW		Emerging Markets	
	9M	CER	9M	CER	9M	CER	9M	CER	9M	CER
	2014	%	2014	%	2014	%	2014	%	2014	%
Cardiovascular and Metabolic disease:										
Crestor	4,124	-	2,158	1	914	(4)	503	(10)	549	11
Seloken/Toprol-XL	584	3	76	(32)	94	(5)	15	-	399	17
Onglyza	620	118	380	88	111	161	42	214	87	221
Atacand	384	(19)	33	(47)	133	(25)	34	(36)	184	2
Brilinta/Brilique	343	78	103	110	171	47	24	136	45	142
Byetta	258	69	160	38	61	132	20	200	17	350
Bydureon	317	210	271	198	39	236	4	100	3	100
Plendil	190	(2)	-	-	14	(7)	8	14	168	(2)
Tenormin	121	(18)	6	(50)	37	(5)	42	(22)	36	(14)
Others	387	39	124	254	144	6	22	16	97	9
Total Cardiovascular and Metabolic disease	7,328	12	3,311	18	1,718	7	714	(4)	1,585	16
Oncology:										
Zoladex	697	(4)	18	-	174	(14)	239	(7)	266	5
Iressa	473	(1)	-	-	124	(9)	134	(3)	215	4
Faslodex	538	8	250	5	187	11	44	4	57	17
Arimidex	230	(11)	12	500	60	(18)	81	(25)	77	5
Casodex	246	(9)	5	67	32	(23)	129	(17)	80	16
Others	103	4	20	11	25	20	32	(19)	26	27
Total Oncology	2,287	(2)	305	10	602	(6)	659	(11)	721	8
Respiratory, Inflammation and Autoimmunity:										
Symbicort	2,823	12	1,116	26	1,115	(3)	337	23	255	21
Pulmicort	677	10	155	(6)	121	(8)	69	(5)	332	33
Others	227	(6)	22	(48)	84	(6)	21	(13)	100	14
Total Respiratory, Inflammation and Autoimmunity	3,727	11	1,293	19	1,320	(4)	427	16	687	25
Infection, Neuroscience and Gastrointestinal:										
Nexium	2,823	-	1,407	(11)	279	1	501	25	636	9
Synagis	496	(9)	265	(16)	231	1	-	-	-	-
Seroquel XR	915	(9)	542	(1)	264	(18)	34	(39)	75	3
Seroquel IR	206	(32)	20	900	69	(19)	23	(78)	94	(16)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Local Anaesthetics	371	1	-	-	152	(4)	125	-	94	11
Losec/Prilosec	312	(13)	20	(13)	99	1	80	(31)	113	(6)
Merrem	190	(9)	7	(22)	25	(37)	3	(40)	155	(1)
FluMist/Fluenz	161	(18)	143	(19)	16	(6)	2	-	-	-
Others	596	(7)	166	(25)	150	(2)	91	2	189	5
Total Infection, Neuroscience and Gastrointestinal	6,070	(6)	2,570	(11)	1,285	(7)	859	(4)	1,356	4
Total	19,412	4	7,479	6	4,925	(2)	2,659	(3)	4,349	12

9 THIRD QUARTER PRODUCT REVENUE ANALYSIS

	World		US		Europe		Established ROW		Emerging Markets	
	Q3		Q3		Q3		Q3		Q3	
	2014	CER	2014	CER	2014	CER	2014	CER	2014	CER
	\$m	%	\$m	%	\$m	%	\$m	%	\$m	%
Cardiovascular and Metabolic disease:										
Crestor	1,342	(1)	682	(5)	303	1	165	-	192	13
Seloken/Toprol-XL	198	14	23	(8)	31	-	5	50	139	22
Onglyza	220	139	130	106	42	193	15	220	33	230
Atacand	123	(13)	13	18	37	(31)	12	(14)	61	(3)
Brilinta/Brilique	127	68	40	122	61	36	10	100	16	100
Byetta	92	64	55	45	21	67	8	133	8	233
Bydureon	125	191	107	189	15	133	1	100	2	100
Plendil	68	5	-	-	4	(20)	4	300	60	2
Tenormin	40	(22)	2	(60)	12	(8)	13	(32)	13	(7)
Others	160	56	65	442	52	(4)	4	(43)	39	31
Total Cardiovascular and Metabolic disease	2,495	16	1,117	20	578	8	237	7	563	20
Oncology:										
Zoladex	240	(2)	7	17	57	(10)	83	(6)	93	6
Iressa	157	(4)	-	-	40	(7)	45	(8)	72	-
Faslodex	187	11	89	7	64	17	16	-	18	19
Arimidex	74	(16)	3	(25)	19	(17)	26	(27)	26	4
Casodex	80	(12)	2	-	10	(23)	41	(22)	27	17
Others	37	15	7	40	9	14	13	(7)	8	43
Total Oncology	775	(2)	108	8	199	(3)	224	(12)	244	7
Respiratory, Inflammation and Autoimmunity:										
Symbicort	967	15	395	29	358	(1)	126	18	88	28
Pulmicort	205	17	51	9	32	(6)	22	(4)	100	40
Others	72	(10)	5	(64)	25	-	10	(25)	32	14
Total Respiratory, Inflammation and Autoimmunity	1,244	14	451	23	415	(1)	158	11	220	30

Autoimmunity										
Infection,										
Neuroscience and										
Gastrointestinal:										
Nexium	922	1	468	(7)	85	(1)	166	17	203	10
Synagis	121	(7)	6	-	115	(7)	-	-	-	-
Seroquel XR	319	(6)	195	1	83	(22)	14	(7)	27	8
Seroquel IR	51	(37)	(6)	n/m	22	(16)	2	(93)	33	6
Local Anaesthetics	122	2	-	-	46	(6)	45	5	31	10
Losec/Prilosec	97	(17)	6	(14)	32	7	26	(32)	33	(21)
Merrem	60	(10)	1	(80)	9	(18)	1	(50)	49	-
FluMist/Fluenz	149	(21)	133	(22)	16	(6)	-	(100)	-	-
Others	187	(20)	49	(42)	48	(4)	25	(6)	65	(12)
Total Infection,										
Neuroscience and										
Gastrointestinal	2,028	(7)	852	(12)	456	(9)	279	(5)	441	2
Total	6,542	5	2,528	7	1,648	(1)	898	(2)	1,468	13

#### Shareholder Information

#### ANNOUNCEMENTS AND MEETINGS

Announcement of fourth quarter and full year 2014 results	5 February 2015
Announcement of first quarter 2015 results	24 April 2015
Annual General Meeting	24 April 2015
Announcement of second quarter and half year 2015 results	30 July 2015
Announcement of third quarter and nine months 2015 results	5 November 2015

#### DIVIDENDS

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

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

Future dividends will normally be paid as follows:

First interim	Announced with second quarter and half year results and paid in September
Second interim	Announced with fourth quarter and full year results and paid in March

The Company expects to change depository bank for its US American Depositary Receipt (ADR) Programme to Citibank, N.A. during December 2014.

#### 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 AstraZeneca group of companies. Trademarks of companies other than AstraZeneca that appear in this document include Duaklir Genuair and Eklira, trademarks of Almirall, S.A. and Imbruvica, a trademark of Pharmacyclics, Inc.

#### 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: 8030 Vanessa Rhodes (London) Ayesha Bharmal (London) Jacob Lund (Södertälje)	Esra Erkal-Paler (London)  +44 (0) 20 7604 8037 +44 (0) 20 7604 8034 +46 (0) 8 553 260 20	+44 (0) 20 7604
Analyst/Investor Enquiries: 8199 Karl Hård (London) Anthony Brown (London) Jens Lindberg (London) Eugenia Litz (London)	Thomas Kudsk Larsen (London)  +44 (0) 20 7604 8123 +44 (0) 20 7604 8067 +44 (0) 7557 319729 +44 (0) 20 7604 8233	+44 (0) 20 7604

#### 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 failure of information technology and cybercrime; 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.

#### 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: 06 November 2014

By: /s/ Adrian Kemp  
Name: Adrian Kemp  
Title: Company Secretary