

ASTRAZENECA PLC  
Form 6-K  
July 30, 2015

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 July 2015

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-\_\_\_\_\_

30 July 2015

H1 2015 Results

## Financial Summary

	\$m	H1 2015		\$m	Q2 2015	
		% change			% change	
		CER1	Actual		CER1	Actual
Total Revenue <sup>2</sup>	12,364	1	(6)	6,307	2	(7)
Core <sup>3</sup> Op. Profit	3,618	(4)	(9)	1,813	(4)	(11)
Core EPS	\$2.29	-	(7)	\$1.21	3	(8)
Reported Op. Profit	1,856	1	(5)	923	(10)	(17)
Reported EPS	\$0.99	2	(4)	\$0.55	(4)	(13)

- Total H1 Revenue up 1%; Core Gross margin over 83%, up 1% point
- Robust top-line performance, supported by externalisation, underpins accelerated investment in R&D to progress pipeline, up 24% in H1
  - Core SG&A efficiency programme - early progress: Core SG&A 35% of Q2 Total Revenue (Q4 2014: 44%)
- Sales & marketing effectiveness, centralisation of functions, process improvements, third-party spend, further efficiencies across support areas, footprint optimisation
  - Core H1 EPS stable, up 3% in Q2, enhanced by one-off tax benefit
- FY 2015 Total Revenue guidance at CER improved: Now expected to decline by low single-digit percent (prior guidance - mid single-digit). Core EPS guidance at CER is unchanged: Expected to increase by low single-digit percent, reflecting the continued accelerated investment in R&D
  - The Board recommends an unchanged first interim dividend of \$0.90

## H1 Commercial Highlights

Growth platforms grew by 11%, representing 56% of Total Revenue:

1. Brilinta/Brilique: +42%. Achieved 10% new-to-brand prescription market share in the US
2. Diabetes: +32%, including 88% sales growth in Emerging Markets
3. Respiratory: +9%, ahead of market growth. Q2 sales up 11%
4. Emerging Markets: +14%. China sales growth of +19%
5. Japan: +2%, with Q2 sales growth of +6%

Achieving Scientific Leadership: Progress since the prior results announcement

Regulatory Approvals	Iressa - lung cancer (US) Faslodex 500mg - breast cancer (China)
Regulatory Submissions* and/or Regulatory Submission Acceptances	saxagliptin/dapagliflozin - diabetes (EU) AZD9291 - lung cancer (US*, EU) cediranib - ovarian cancer (EU)
Phase III Read-outs	Ceftazidime Avibactam (CAZ AVI) - serious infections (EU) selumetinib - uveal melanoma: Primary endpoint not met
Other Key Developments	Brilinta/Brilique - post-myocardial infarction (MI): Granted FDA Priority Review

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

“We made good progress in the period, delivering a robust underlying business performance. This represents six successive quarters of top-line growth. The initiatives introduced to increase efficiency are starting to reduce SG&A costs, supporting our continued strategic investment in science and the acceleration of our pipeline which has positive momentum across all key areas.

I'm particularly pleased by the pace of progress in Oncology, with new approvals for both Iressa and Faslodex accompanied by regulatory submissions for AZD9291 and cediranib. The strong performance of the growth platforms

and the subsequent upgrade to top-line guidance, together with increased R&D productivity reaffirm the confidence we have in our ability to navigate the final impacts from the loss of exclusivity and meet our revenue targets.”

#### Notes

1. All growth rates are shown at constant exchange rates (CER) unless specified otherwise.
2. Total Revenue defined as Product Sales and Externalisation Revenue. For further details on the presentation of Total Revenue, see the announcement published by the Company on 6 March 2015.
3. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

#### Results Presentation

A presentation for investors and analysts, hosted by management, will begin at midday BST today. The accompanying live webcast can be accessed via [www.astrazeneca.com/investors](http://www.astrazeneca.com/investors).

#### Reporting Calendar

The Company intends to publish its nine months and third quarter financial results on 5 November 2015.

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

#### Media Enquiries

Esra Erkal-Paler	UK/Global	+44 20 7604 8030
Vanessa Rhodes	UK/Global	+44 20 7604 8037
Ayesha Bharmal	UK/Global	+44 20 7604 8034
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

#### Investor Enquiries

UK		
Thomas Kudsk Larsen		+44 20 7604 8199 +44 7818 524185
Eugenia Litz	RIA	+44 20 7604 8233 +44 7884 735627
Nick Stone	CVMD	+44 20 7604 8236 +44 7717 618834
Karl Hård	Oncology	+44 20 7604 8123 +44 7789 654364
Craig Marks	ING	+44 20 7604 8591 +44 7881 615764
Christer Gruvris		+44 20 7604 8126 +44 7827 836825

#### US

Dial / Toll-Free		+1 301 398 3251 +1 866 381 7277
------------------	--	---------------------------------

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

Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

### Research and Development Update

---

A comprehensive update of the AstraZeneca development pipeline is presented in conjunction with this announcement and can be found later in the document.

Progress since the prior results announcement on 24 April 2015:

Regulatory Approvals	2	<ul style="list-style-type: none"> <li>- Iressa - lung cancer (US)</li> <li>- Faslodex 500mg - breast cancer (China)</li> </ul>
Regulatory Submissions* and/or Regulatory Submission Acceptances	4	<ul style="list-style-type: none"> <li>- saxagliptin/dapagliflozin - diabetes (EU)</li> <li>- AZD9291 - lung cancer (US*, EU)</li> <li>- cediranib - ovarian cancer (EU)</li> <li>- CAZ AVI - serious infections (EU)</li> </ul>
Phase III Read-outs	1	<ul style="list-style-type: none"> <li>- selumetinib - uveal melanoma: Primary endpoint not met</li> </ul>
Other Key Developments	1	<ul style="list-style-type: none"> <li>- Brilinta/Brilique - post-MI (PEGASUS trial): Granted FDA Priority Review</li> </ul>
Forthcoming Regulatory Submissions	3	<ul style="list-style-type: none"> <li>- brodalumab - psoriasis, PT003 - COPD, AZD9291 - lung cancer (JP)</li> </ul>
Forthcoming Regulatory Decisions	5	<ul style="list-style-type: none"> <li>- lesinurad - gout, saxagliptin/dapagliflozin, Brilinta/Brilique, AZD9291, CAZ-AVI</li> </ul>
Pivotal Trial Starts	6	<ul style="list-style-type: none"> <li>- PT010 - COPD</li> <li>- anifrolumab - lupus</li> <li>- durvalumab (MEDI4736) + tremelimumab - 2nd-line SCCHN** (CONDOR trial), 2nd and 3rd-line gastric cancer, 1st-line NSCLC (MYSTIC trial)</li> <li>- AZD9291 - 2nd-line EGFRm NSCLC (CAURAL trial)</li> </ul>
New Molecular Entities (NMEs) in Pivotal Studies or under Regulatory Review	15	<ul style="list-style-type: none"> <li>RIA</li> <li>- lesinurad - gout</li> <li>- PT003 - COPD</li> <li>- PT010 - COPD (new)</li> <li>- brodalumab - psoriasis</li> <li>- benralizumab - severe asthma</li> <li>- tralokinumab - severe asthma</li> <li>- anifrolumab - lupus (new)</li> </ul>

CVMD

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

- roxadustat - anaemia

### Oncology

- AZD9291 - lung cancer
- cediranib - ovarian cancer
- selumetinib - lung cancer
- tremelimumab - mesothelioma
- durvalumab - lung cancer
- moxetumomab pasudotox - leukaemia

### ING

- CAZ AVI - serious infections

Projects in clinical pipeline 119

### \*\*Squamous Cell Carcinoma of the Head and Neck

In the period 2015-2016 AstraZeneca anticipates 12-16 Phase II starts, 14-16 NME and major line-extension regulatory submissions and 8-10 NME and major line-extension approvals.

#### 1. Respiratory, Inflammation and Autoimmunity (RIA)

Significant progress continues to be made in the RIA pipeline, which now includes seven programmes in pivotal studies or under registration. AstraZeneca holds a unique position in respiratory disease, including asthma, chronic obstructive pulmonary disease (COPD) and idiopathic pulmonary fibrosis (IPF), with a range of differentiated potential medicines in development by leveraging novel combinations, biologics and devices. The pipeline also has a number of promising assets in inflammatory and autoimmune diseases within areas such as psoriasis, psoriatic arthritis, gout, systemic lupus and rheumatoid arthritis.

AstraZeneca and Ardea Biosciences had a strong presence at the recent European League Against Rheumatism annual meeting, with 24 abstracts accepted. Data were presented on several investigational molecules including lesinurad (gout), mavrilimumab (rheumatoid arthritis) and brodalumab (psoriatic arthritis).

##### a) PT010 (COPD)

The first patient has been dosed in the Phase III programme for PT010, a combination of budesonide, glycopyrronium and formoterol fumarate (BGF) in development for patients with moderate to severe COPD. PT010 has the potential in a number of markets to be the first fixed-dose triple-combination medicine to be delivered in a pressurised metered-dose inhaler using the unique porous particle co-suspension technology developed by Pearl Therapeutics, acquired by AstraZeneca in 2013.

The Phase III ETHOS trial is assessing a twice-daily investigational formulation in more than 8,000 patients with moderate to severe COPD over the course of 52 weeks. More than 750 centres in over 25 countries are expected to participate in the trial.

ETHOS is a randomised, double-blind, multi-centre, parallel group trial assessing efficacy and safety of BGF relative to two active comparators - a fixed-dose combination of the budesonide and formoterol fumarate and a fixed-dose combination of glycopyrronium and formoterol. The primary endpoint is the rate of moderate or severe COPD exacerbations.

##### b) Anifrolumab (lupus)

The first patient has been dosed in the Phase III programme for anifrolumab, a first-in-class investigational medicine for patients with moderate to severe systemic lupus erythematosus (SLE, or lupus), and the only anti-type-I IFN receptor approach currently in development. The Phase III TULIP programme includes two clinical trials that will evaluate the efficacy and safety of anifrolumab versus placebo in subjects with moderately to severely active, autoantibody-positive SLE, while receiving standard of care (SoC) treatment. The programme will assess the effect of anifrolumab in reducing disease activity (as measured by the SRI-4), decreasing use of oral corticosteroids, improving skin manifestations (as measured by CLASI) and reducing flares.

Anifrolumab has been developed with a biomarker test based on the type-I IFN-inducible gene signature, which is also being investigated as part of the clinical programme. The Company intends to present full anifrolumab Phase IIb data at the American College of Rheumatology congress in November 2015.

c) Benralizumab (severe asthma)

The Phase III benralizumab trials CALIMA and SIROCCO have completed enrolment. These trials are designed to evaluate safety and effectiveness in actively reducing exacerbations in patients with uncontrolled asthma. The trials also assess lung function, asthma symptoms and other asthma-control measures, as well as emergency room and hospitalisation rates.

d) Tralokinumab (severe asthma)

In May 2015 AstraZeneca announced that it had entered an agreement with Abbott Laboratories, Inc. (Abbott) to develop companion diagnostic tests to identify patients with severe asthma most likely to benefit from tralokinumab. No companion diagnostic blood tests have yet been approved for use in asthma.

Under the terms of the agreement, Abbott will develop and commercialise diagnostic tests to measure serum levels of the proteins periostin and dipeptidyl peptidase-4 (DPP-4), identified as potential predictive biomarkers of up-regulated IL-13 in severe asthma. The tests will be developed in conjunction with the Phase III trials of tralokinumab as a potential treatment for patients with severe, inadequately-controlled asthma.

e) Brodalumab (psoriasis)

In May 2015 Amgen, Inc. (Amgen) announced the termination of its co-development and commercialisation agreement with AstraZeneca for brodalumab, an investigational IL-17 receptor monoclonal antibody in development for patients with moderate-to-severe plaque psoriasis, psoriatic arthritis, and axial spondyloarthritis.

AstraZeneca has conducted an initial evaluation of the data, which confirms that brodalumab demonstrated strong efficacy in psoriasis and indicates that the observations of suicidal ideation and behaviour are unlikely to be causally related to brodalumab therapy. Whilst continuing the transfer of the programme from Amgen, the Company is proceeding with a full analysis and evaluating potential partnering options in parallel. AstraZeneca will communicate its definitive decision in due course.

## 2. Cardiovascular and Metabolic Disease (CVMD)

AstraZeneca's strategy in CVMD focuses on ways to reduce morbidity, mortality and organ damage by addressing multiple risk factors across cardiovascular (CV) disease, diabetes and chronic kidney-disease indications. The patient-centric approach is reinforced by science-led life-cycle management programmes and technologies, including early research into regenerative methods.

Reporting results of the Company's research and development in diabetes, AstraZeneca presented 86 abstracts at the recent American Diabetes Association (ADA) annual meeting. These abstracts included clinical trial data evaluating Farxiga/Forxiga, Bydureon, Byetta and Onglyza, as well as the investigational combination of Onglyza and Farxiga/Forxiga.

Notable late-breaking abstracts included data from a positive Phase III trial comparing the efficacy and safety of Farxiga/Forxiga versus placebo as an add-on to Onglyza and metformin immediate release in adults with type-2 diabetes who had inadequate glycaemic control. The trial met its primary endpoint.

a) Brilinta/Brilique (CV disease)

In April 2015, AstraZeneca announced that the FDA had accepted a supplemental new-drug application (sNDA) and granted Priority Review for Brilinta for patients with a history of prior MI. The sNDA was based on the results of PEGASUS-TIMI 54, a large-scale outcomes trial in more than 21,000 patients that investigated Brilinta plus low-dose aspirin, compared to placebo plus low-dose aspirin, for the chronic secondary prevention of atherothrombotic events in patients who had experienced a heart attack one to three years prior to trial enrolment.

A Priority Review designation is granted to medicines that the FDA determines have the potential to provide significant improvements in the treatment, prevention or diagnosis of a disease.

b) Onglyza (type-2 diabetes)

AstraZeneca is working closely with regulators as part of the ongoing review of the full SAVOR dataset. The Company is currently awaiting a forthcoming decision from the FDA on a possible label update for Onglyza and Kombiglyze XR respectively.

At the recent ADA meeting AstraZeneca announced results from an observational, retrospective trial which found no evidence of increased risk of hospitalisation for heart failure (hHF) with Onglyza, compared with sitagliptin, both of which are DPP-4 inhibitors, in patients with type-2 diabetes. A similar finding was obtained when comparing the overall DPP-4 class to sulfonylureas. The analysis included patients with and without prior CV disease and concluded that, among the latter, DPP-4 treatment was associated with a statistically-significant lower risk of hHF compared to treatment with sulfonylureas.

c) SGLT2 Inhibitors (type-2 diabetes)

In May 2015, the FDA posted a Drug Safety Communication warning that sodium/glucose co-transporter-2 (SGLT2) inhibitors, the class to which Farxiga/Forxiga belongs and is used to treat type-2 diabetes, may lead to diabetic ketoacidosis (DKA), a medical condition where the body produces high levels of blood acids called ketones that may require hospitalisation.

Last month the European Medicines Agency (EMA) announced a review of SGLT2 inhibitors to evaluate the risk of DKA. The regulatory authorities will continue to investigate this safety issue and will determine whether changes are needed in the prescribing information for this class of drugs. AstraZeneca is committed to working with the FDA and EMA during their respective reviews of the data.

The DECLARE outcomes trial for Farxiga/Forxiga recently completed its global patient enrolment around one year ahead of plan. The DECLARE trial is a large CV outcomes trial designed to assess the impact of Farxiga/Forxiga on CV risk/benefit, when the medicine is added to a patient's current anti-diabetes therapy, on CV events such as heart attack, ischemic stroke and CV-related death, compared with placebo. The trial involves the enrolment of around 26,000 patients with type-2 diabetes in more than 30 countries with the aim of randomising over 17,000 patients. It is an event-driven trial and is estimated to be completed in 2019.

d) Tenapanor (chronic kidney disease)

In June 2015 Ardelyx, Inc. (Ardelyx) announced that it had entered into a termination agreement with AstraZeneca. Under the agreement all rights to Ardelyx's portfolio of NHE3-inhibitors, including Ardelyx's lead product candidate, tenapanor will be returned to Ardelyx.

### 3. Oncology

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

AstraZeneca's vision in Oncology is to help patients by redefining the cancer-treatment paradigm, with the aim of bringing six new cancer medicines to patients between 2013 and 2020. A broad pipeline of next-generation medicines is focused principally on four disease areas - breast, ovarian, lung and haematological cancers.

As well as other tumour types, these are being targeted through four key platforms - immunotherapy, the genetic drivers of cancer and resistance, DNA damage repair, and antibody drug conjugates, underpinned by personalised healthcare and biomarker technologies.

AstraZeneca hosted an investor science event during the 2015 American Society of Clinical Oncology (ASCO) meeting in Chicago. Key presentations included:

- Data presented on durvalumab (formerly MEDI4736) as monotherapy in heavily pre-treated patients with non-small cell lung cancer (NSCLC) or SCCHN were encouraging and suggested that patients with PD-L1 positive tumours may have an improved overall response rate (ORR) compared to patients with PD-L1 negative tumours, highlighting the unmet medical need for the majority of tumours that are PD-L1 negative
- Data presented on durvalumab plus tremelimumab confirmed the Phase III trial dose and schedule for this combination. The combination demonstrated an ORR of 38% at doses selected for the Phase III trials versus a 5% ORR for patients receiving durvalumab monotherapy in the 1108 trial. The combination was well tolerated with a very low 7% drug-related discontinuation rate
- In addition, durvalumab is demonstrating strong potential to combine with small molecules

AstraZeneca has an extensive development programme underway across multiple tumour types and stages of disease, assessing the potential for immunotherapy to either replace or combine with traditional targeted and chemotherapy treatment.

Today there are six AstraZeneca Oncology NMEs in pivotal studies or under regulatory review.

Highlights from the late-stage portfolio include:

Medicine	Indication	Status
Iressa	Lung cancer	Earlier this month the Company announced that the FDA had approved Iressa (gefitinib) tablets, a 250mg once-daily 1st-line treatment for patients with metastatic epidermal growth-factor receptor (EGFR) mutated NSCLC. Iressa was granted Orphan Drug Designation by the FDA in 2014.
AZD9291	Lung cancer	In June 2015, the Company submitted the rolling new-drug application (NDA) for AZD9291 as a potential medicine for the 2nd-line treatment of patients with advanced or metastatic T790M-mutated NSCLC. The EMA also accepted the regulatory submission for AZD9291.  CAURAL, a randomised Phase III trial in 2nd-line metastatic EGFR T790M-mutation positive NSCLC testing AZD9291 plus durvalumab versus AZD9291 monotherapy is being prepared for dosing. The trial has a primary endpoint of progression-free survival (PFS).



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

At the ASCO meeting, preliminary efficacy and safety data for AZD9291 in the 1st-line treatment of EGFRm-positive advanced NSCLC were presented. Data showed that 81% (95% confidence interval (CI) 68% to 89%) of patients on a once-daily dose of AZD9291 were progression-free at nine months; the ORR was 73% (95% CI 60% to 84%). The longest duration of response was ongoing at 13.8 months at the time of data cut-off. These data support the ongoing development of AZD9291 in 1st-line lung cancer, including the Phase III FLAURA trial.

Cediranib	Ovarian cancer	The Company received acceptance from the EU this month for the marketing authorisation application for cediranib with an intended indication in platinum-sensitive relapsed ovarian cancer. The application was based on the ICON6 trial. ICON6 results showed that, compared to platinum chemotherapy alone, cediranib given with platinum-based chemotherapy and continued as maintenance, significantly improves PFS in women with recurrent ovarian cancer.
-----------	----------------	---

Subsequent secondary-efficacy measures supported significant sustained efficacy, leading to a strong overall survival trend.

The Phase III SUMIT trial of selumetinib (MEK inhibitor) in combination with dacarbazine did not meet its primary endpoint of PFS. This combination therapy showed an adverse event profile generally consistent with current knowledge of the safety profiles of dacarbazine and selumetinib. A full evaluation of the data is ongoing.

Selumetinib	Uveal melanoma	Outside uveal melanoma, selumetinib is in a Phase III trial in 2nd-line KRAS-mutant advanced NSCLC in combination with docetaxel, in a Phase III trial in differentiated thyroid cancer and in a Phase II registration trial in patients with neurofibromatosis Type 1. These trials have a different scientific rationale and selumetinib is being tested in alternative combinations. The findings from SUMIT are not expected to have any impact on the other studies.
-------------	----------------	---

Lung cancer	ATLANTIC, a Phase II trial in PD-L1 positive 3rd-line metastatic NSCLC, is now fully recruited and scheduled to deliver data in the second half. This trial could potentially, if positive, support the first regulatory submission for durvalumab.
-------------	---

ARCTIC, a Phase III trial in 3rd-line metastatic NSCLC is recruiting patients and contains a randomised durvalumab monotherapy sub-study for PD-L1 positive patients versus SoC and a sub-study with a concurrent-combination treatment with

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

tremelimumab versus the contribution of components and SoC in PD-L1 negative patients.

MYSTIC, which is being prepared for dosing, is a 1st-line NSCLC durvalumab-tremelimumab trial in PD-L1 unselected, EGFR/ALK wild-type patients and includes a sub-group analysis of PD-L1 positive and PD-L1 low/negative patients. The primary endpoint is PFS and the trial includes durvalumab monotherapy and the durvalumab-tremelimumab combination versus SoC.

NEPTUNE, a further durvalumab-tremelimumab versus SoC trial with overall survival (OS) as the primary endpoint complements the MYSTIC PFS trial and will commence in due course.

A third 1st-line NSCLC trial of durvalumab plus chemotherapy in PD-L1 unselected, EGFR/ALK wild-type NSCLC will also be initiated after a lead-in phase.

PD-L1 status is being assessed by a proprietary (SP263) immunohistochemistry diagnostic test jointly developed with Ventana Medical Systems, Inc., a member of the Roche Group.

Head and Neck cancer In the CONDOR trial for patients with recurrent or metastatic SCCHN the first patient was dosed in the quarter. The CONDOR trial is a Phase II, randomised, global trial of durvalumab monotherapy, tremelimumab monotherapy and durvalumab in combination with tremelimumab in PD-L1 negative patients. It is designed to complement the HAWK trial which targets PD-L1 positive patients.

Gastric cancer A Phase II trial in 2nd and 3rd-line gastric cancer was also initiated in the period. This trial explores durvalumab-tremelimumab versus durvalumab versus tremelimumab.

Pancreatic cancer A pancreatic cancer uncontrolled Phase II trial will explore combinations of immunotherapies, in particular durvalumab plus tremelimumab, in 2nd-line metastatic pancreatic ductal adenocarcinoma (PDAC). In addition, the programme will explore combinations of immunotherapy with both chemotherapy in 1st-line PDAC and with targeted therapies in 2nd-line PDAC; the first targeted therapy included in this trial is AZD5069 (CXCR2).

Bladder cancer A 1st-line bladder cancer Phase III, randomised and controlled trial will evaluate both durvalumab monotherapy and durvalumab-tremelimumab in metastatic, urothelial bladder cancer.

Durvalumab and Ramucirumab (advanced solid tumours)

In May 2015, AstraZeneca and Eli Lilly & Company (Lilly) announced a clinical-trial collaboration to evaluate the safety and preliminary efficacy of durvalumab, in combination with ramucirumab, Lilly's VEGF receptor-2 anti-angiogenic cancer medicine. The planned trial will assess the combination as a treatment for patients with advanced solid tumours.

A Phase I trial is expected to establish the safety and a recommended dosing regimen, with the potential to open expansion cohorts in various tumours of interest for the combination of durvalumab and ramucirumab. Under the terms of the agreement, the trial will be sponsored by Lilly.

4. Infection, Neuroscience and Gastrointestinal (ING)

a) CAZ-AVI (serious infections)

In May 2015 the EU submission for CAZ-AVI was validated and accepted by the EMA.

CAZ-AVI is being developed to treat adult hospitalised patients with complicated intra-abdominal infections, complicated urinary tract infections or nosocomial pneumonia (including hospital acquired pneumonia and ventilated patients). Full Phase III results evaluating the safety and efficacy of CAZ-AVI for the global RECLAIM-1 and RECLAIM-2 studies and the global REPRISE trial were presented at the 25th European Congress of Clinical Microbiology and Infectious Diseases.

CAZ-AVI is anticipated as the first choice for the treatment of Gram-negative pathogens that are increasingly becoming resistant to prevailing standards of care, leading to greater numbers of life-threatening infections and additional healthcare costs.

b) AZD3293 (Alzheimer's disease)

AZD3293 is an oral, potent and selective small-molecule inhibitor designed as a novel treatment for patients suffering from early Alzheimer's disease. A global co-development and co-commercialisation agreement was established with Lilly in 2014 for this important potential medicine.

Under the terms of the agreement, Lilly will pay AstraZeneca up to \$500m in development and regulatory milestone payments. The first progress milestone was met in July 2015 and, as such, \$50m of Externalisation Revenue from Lilly to AstraZeneca will be recognised in the third quarter.

Scientific Collaborations

---

Montreal Heart Institute

AstraZeneca announced in May 2015 a collaboration with the Montreal Heart Institute in Quebec, Canada, to search the genomes of up to 80,000 patients for genes associated with cardiovascular diseases and diabetes, their complications and treatment outcomes. This is one of the largest such screens of its type to date and will drive understanding of the biological mechanisms underlying these conditions and their complications. The analysis will also uncover which genetic traits are linked to better treatment outcomes.

Corporate and Business Development Update

---

a) Haematology Collaboration with Celgene

In April 2015 AstraZeneca announced an exclusive collaboration agreement with Celgene Corporation (Celgene), a global leader in haematological cancers, for the development and commercialisation of durvalumab across a range of

blood cancers including non-Hodgkin's lymphoma, myelodysplastic syndrome and multiple myeloma.

Under the terms of the agreement, Celgene made an upfront payment of \$450m in the second quarter to AstraZeneca. Celgene will lead on development across all clinical trials within the collaboration and will take on all research and development costs until the end of 2016, after which it will take on 75% of these costs. Celgene will also be responsible for global commercialisation of approved treatments. AstraZeneca will continue to manufacture and book all sales of durvalumab and will pay a royalty to Celgene on worldwide sales in haematological indications. The royalty rate will start at 70% and will decrease to approximately half of the sales of durvalumab in haematological indications over a period of four years. AstraZeneca may elect to opt out of funding part of any clinical study prior to its initiation, resulting in an increase of future royalty rates or a subsequent re-opt in payment.

Within the collaboration, durvalumab will be assessed both as monotherapy and in combination with other AstraZeneca and Celgene potential and existing cancer medicines. Over time, the collaboration has the potential to expand and include other assets.

#### b) NKG2A Antibody Collaboration with Innate

AstraZeneca entered into a collaboration in the second quarter with Innate Pharma SA (Innate) to accelerate and broaden the development of Innate's proprietary NKG2A antibody, IPH2201, including in combination with durvalumab. Currently in Phase II development, IPH2201 is a potential first-in-class humanised IgG4 antibody against NKG2A. NKG2A is a checkpoint receptor that inhibits the anti-cancer functions of Natural Killer and cytotoxic T-cells.

Under the terms of the agreement, AstraZeneca made an initial payment to Innate of \$250m, which included the consideration for exclusive global rights to co-develop and commercialise IPH2201 in combination with durvalumab, as well as access to IPH2201 in monotherapy and other combinations in certain treatment areas for which AstraZeneca has the option to pay a further \$100m prior to initiation of Phase III development. The agreement also includes additional regulatory and sales-related milestones. AstraZeneca will book all sales and will pay Innate double-digit royalties on net sales. The arrangement includes the right for Innate to co-promote in Europe for a 50% profit share.

#### c) Joint Venture with Fujifilm Kyowa Kirin Biologics

In July 2015 AstraZeneca entered into an agreement with Fujifilm Kyowa Kirin Biologics Co., Ltd to establish a joint venture for the development and commercialisation of FKB238, a biosimilar version of bevacizumab, currently in Phase I development for the treatment of multiple solid tumours. The Company plans to use the biosimilar in combination with its portfolio of innovative oncology investigational and on-market medicines, across a range of cancers and at different stages of disease.

By developing an interchangeable biosimilar to support the Company's combination-focused oncology strategy, AstraZeneca will explore potential new treatment options for patients, while at the same time keep the cost of those combination therapies low enough to enable access for the majority of patients.

#### d) Entocort Divestment

In July 2015 AstraZeneca completed an agreement entered into with Tillotts, part of the Zeria Group, for the divestment of global rights, outside the US, to Entocort (budesonide), a gastroenterology medicine for patients with mild-moderate Crohn's disease and ulcerative colitis.

Entocort is currently available in over 40 countries, with total product sales of \$53m outside the US in 2014. A regulatory submission for Entocort in Japan is anticipated in the coming months. Under the terms of the agreement, Tillotts made an upfront payment to AstraZeneca of \$215m upon completion of the transaction to acquire the rights to sell and develop Entocort capsules and enema formulations outside the US. The payment will be shown within Other Operating Income in the Company's financial statements in the third quarter.

e) Benralizumab: Japan

The Company recently announced an agreement with Kyowa Hakko Kirin Co. Ltd (Kyowa Hakko Kirin) for an exclusive option to commercialise benralizumab for asthma and COPD in Japan.

Benralizumab is a monoclonal antibody in Phase III development for the treatment of severe uncontrolled asthma and COPD. The results for benralizumab in severe asthma are expected to read out in 2016, with regulatory submissions anticipated later that year. Phase III results and regulatory filing in COPD are expected in 2018.

Under the terms of the agreement, the Company will make a \$45m up-front option payment and may make subsequent payments for regulatory filing, approval and commercial milestones, and sales royalties should the option be exercised. Kyowa Hakko Kirin will continue to be responsible for the research and development of benralizumab in Japan. On exercising the option, AstraZeneca will be responsible for all sales and marketing in asthma and COPD in Japan. Kyowa Hakko Kirin will retain the rights to participate in certain commercial activities alongside AstraZeneca.

f) Caprelsa Divestment

This month AstraZeneca announced that it had entered into a definitive agreement with Genzyme Corporation (Genzyme), part of Sanofi S.A., to divest Caprelsa (vandetanib), a rare-disease medicine. Caprelsa was granted Orphan Drug Designation by the US FDA in 2005 and is currently available in 28 countries for the treatment of aggressive and symptomatic medullary thyroid carcinoma, with global product sales of \$48m in 2014.

Under the terms of the agreement, Genzyme will pay AstraZeneca up to \$300m, including an upfront payment of \$165m to acquire the global rights to sell and develop Caprelsa, and further development and sales milestone payments of up to \$135m. The transaction does not include the transfer of any AstraZeneca employees or facilities. As an asset divestment, the upfront receipt and any subsequent payments will be reported in Other Operating Income in the Company's financial statements.

g) Creation of Antibiotics Business Unit

The Company recently announced the intention to create a new antibiotics business unit focused on the development of the late-stage pipeline of small molecules (CAZ-AVI, ATM-AVI and CXL) and on maximising the commercial potential of the portfolio of small molecule antibiotics (Merrem and Zinforo) across a number of prioritised markets.

The creation of a new, focused business unit is the best way to enable these important medicines to reach patients while further increasing the focus on the Company's three main therapy areas. The creation of this new internal structure will have no impact on either the presentation of the Company's financial statements or the Company's biologics Infection business.

h) Change In Senior Executive Team

Briggs Morrison, formerly Executive Vice President, Global Medicines Development and Chief Medical Officer, left the Company in June having accepted offers to become the Chief Executive Officer of Syndax Pharmaceuticals, Inc., a privately-held oncology company, and a Managing Director of venture capital firm, MPM Capital, Inc.

Pending the appointment of Dr Morrison's successor, Elisabeth Björk, Vice President and Head of Development, Cardiovascular, Metabolism and Diabetes was appointed Interim Chief Medical Officer and took over operational leadership of Global Medicines Development, and Pascal Soriot became temporary Co-Chairman of the Late Stage Product Committee, the governance body accountable for post-Phase II investment decisions.

i) Future Infrastructure

In the half the Company continued both with the construction of its new Global R&D Centre and Corporate Headquarters on the Cambridge Biomedical Campus and the move of employees to Cambridge from other UK locations.

AstraZeneca announced in the half that it will invest approximately \$285m in a new high-tech facility for the manufacture of biological medicines in Södertälje, Sweden. The new plant will be focused on the filling and packaging of protein therapeutics. It is anticipated that the new facility will supply medicines for clinical-trial programmes from the end of 2018 and will deliver finished products for commercial use once fully operational by 2019.

Södertälje is home to AstraZeneca's largest global tablets and capsules manufacturing facility and is also a launch-platform site for the Company, with specialist capabilities on-site that allow large-scale production of new medicines, working closely with the research and development organisation. By locating the new manufacturing plant in Södertälje, the Company will combine its expertise in biologics with the well-established culture of operational excellence that exists within the Sweden Operations unit.

## Operating and Financial Review

---

All narrative on growth and results in this section relates to Core performance, based on constant exchange rates (CER) unless stated otherwise. Financial figures are in \$millions (\$m). The performance shown below covers the six and three month periods to 30 June 2015 (the half and the quarter respectively) compared to the six and three months to 30 June 2014 (the half and the quarter respectively). Core measures, which are presented in addition to Reported financial information, are non-GAAP measures provided to enhance understanding of the Company's underlying financial performance. 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 acquisition-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 72 of the 2014 Annual Report and Form 20-F Information.

### Total Revenue

Total Revenue grew by 1% in the half to \$12,364m. Based on actual exchange rates, Total Revenue declined by 6% reflecting the particular weakness of key trading currencies against the US dollar.

### Product Sales

Product Sales declined by 2% in the half (Q2 2015: down by 1%) reflecting the US market entry of a Nexium generic product from February 2015 as well as an adverse impact from the change in accounting for the US Branded Pharmaceutical Fee following issuance of final regulations in Q3 2014.

### Externalisation Revenue

Externalisation Revenue of \$780m in the half (H1 2014: \$352m) primarily reflected income from completion of the collaboration agreement in haematology with Celgene (\$450m), together with income from the co-commercialisation agreement with Daiichi Sankyo Co, Ltd. (Daiichi Sankyo) for Movantik in the US (\$200m), plus the co-commercialisation of Nexium in Japan (\$55m), also with Daiichi Sankyo.

### Product Sales

---

Edgar Filing: ASTRAZENECA PLC - Form 6-K

The performance of a selection of key medicines is shown below. A geographical split of the performance is shown in Notes 6 and 7.

	H1 2015			Q2 2015		
	\$m	% Change CER	Actual	\$m	% Change CER	Actual
Respiratory, Inflammation and Autoimmunity						
Symbicort	1,687	-	(9)	842	-	(9)
Pulmicort	518	18	10	232	19	11
Tudorza/Eklira	85	n/m	n/m	55	n/m	n/m
Daliresp	39	n/m	n/m	32	n/m	n/m
Duaklir	7	n/m	n/m	5	n/m	n/m
Cardiovascular and Metabolic Disease						
Brilinta/Brilique	275	42	27	144	38	23
Onglyza	391	4	(2)	208	(7)	(13)
Bydureon	263	41	37	140	29	25
Byetta	172	8	4	82	(1)	(7)
Farxiga/Forxiga	205	n/m	n/m	129	n/m	n/m
Legacy:						
Crestor	2,477	(5)	(11)	1,310	(3)	(10)
Seloken/Toprol-XL	378	7	(2)	184	6	(5)
Atacand	194	(11)	(26)	99	(13)	(29)
Oncology						
Iressa	273	(3)	(14)	129	(1)	(12)
Lynparza	30	n/m	n/m	21	n/m	n/m
Legacy:						
Zoladex	409	9	(11)	215	14	(9)
Faslodex	333	5	(5)	172	9	(4)
Casodex	139	(5)	(16)	69	(5)	(17)
Arimidex	126	(9)	(19)	64	(6)	(18)
Infection, Neuroscience and Gastrointestinal						
Nexium	1,291	(27)	(32)	647	(27)	(33)
Seroquel XR	526	(7)	(12)	264	(8)	(13)
Synagis	270	(28)	(28)	66	40	40
Losec/Prilosec	181	(6)	(16)	85	(9)	(19)
FluMist/Fluenz	21	75	75	14	180	180
Movantik/Moventig	4	n/m	n/m	1	n/m	n/m

H1 Product Sales Summary

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

During 2014, final regulations relating to the US Branded Pharmaceutical Fee were issued, affecting how the fee is recognised; AstraZeneca consequently accrues for the obligation as each sale occurs. As the fee is based on actual Product Sales in the current year, the fee is recognised as a deduction from Product Sales rather than a charge to SG&A, impacting individual brand sales by an average of 2%.

### RIA

#### Symbicort

Product Sales in the half were stable at \$1,687m. The brand continues to demonstrate strong differentiation in asthma reinforced by guidelines and ongoing lifecycle management in milder conditions.

In the US, the decline in the half to \$717m was limited to 1% with continued lower net prices reflecting additional access and co-pay assistance. Symbicort's share of total prescriptions for fixed-combination medicines increased in the half, growing by 0.7% points.

In Europe, Product Sales declined by 8% to \$582m, reflecting increased competition from recently-launched analogue medicines. This performance contrasted with growth of 28% in Emerging Markets to \$187m, notably with 64% growth in China where Product Sales reached \$63m.

#### Pulmicort

Product Sales of Pulmicort in the first half were \$518m, up 18%. Growth was driven primarily by the performance of Pulmicort Respules in Emerging Markets, which were up 37% at \$303m. China Product Sales increased by 43% to \$240m, reflecting sustained investment in supporting asthma and COPD patients for several years, both in hospitals and more recently at home.

In February 2015, the US District Court for the District of New Jersey ruled the patent protecting Pulmicort Respules in the US was invalid. The US Court of Appeals for the Federal Circuit subsequently affirmed the decision (see Note 5). Consequently a reduced level of sales-related receipts was realised in the second quarter (within Other Operating Income) from Teva Pharmaceutical Industries, Ltd.

#### Tudorza/Eklira

Product Sales in the half were \$85m. This included \$45m in the US, where the brand name is Tudorza, following the completion of the acquisition of the Actavis plc product rights in March 2015.

Rights were also acquired at that time for Daliresp, for which sales amounted to \$39m in the half.

### CVMD

#### Brilinta/Brilique

Product Sales in the half were \$275m, up 42%, with consistent strong growth in each quarter.

Brilinta Product Sales in the US were \$101m, up 60%. The brand's weekly new-to-brand prescription market share achieved a new high of 10% in June 2015.

In Europe, Brilique continued to perform well, with an increase in Product Sales of 21% to \$110m, reflecting indication leadership across a number of European markets. Emerging Market sales grew by 80% to \$47m as the medicine remains in launch phase.

#### Onglyza

Product Sales were up 4% in the half to \$391m. Growth of 19% in Q1 was offset by a 7% decline in Q2, reflecting a reallocation of promotional activities to Farxiga/Forxiga.



In the US, H1 Product Sales were down 16% at \$211m driven primarily by destocking and competition in the DPP-4 class, as well as the aforementioned changes in promotional activities. Product Sales in the Rest of World (ROW) were \$180m, with growth in all key markets, notably in Europe where sales were \$71m, up 23%. Product Sales in the half in Emerging Markets grew by 56% to \$77m.

#### Bydureon/Byetta

Combined sales were \$435m in the half, up 26%, with Bydureon representing 60% of total Bydureon/Byetta sales.

Product Sales in the US were \$343m, up 28%. Bydureon total prescriptions grew 22% in the second quarter, reflecting the launch of the Bydureon Pen in September 2014. Most of the remaining sales of Bydureon/Byetta reside in Europe, where sales growth of 19% in the half reflected the ongoing successful Pen launch.

#### Farxiga/Forxiga

Product Sales were \$205m in the half following the recent launch of the brand.

In the US, Product Sales of \$115m compared to \$26m in the comparative period. Additional promotional activity underpinned the growth of Farxiga, which continued to face market share pressures in the period, due to formulary-access changes.

Product Sales in Europe, at \$53m in the half, more than doubled while Emerging Markets sales stood at \$26m.

#### Crestor

Product Sales declined by 5% in the half to \$2,477m. The performance reflected ongoing generic competition and price pressures.

In the US, Crestor's H1 Product Sales declined by 7% to \$1,374m, with price pressures exacerbated by lower volumes that were in line with total prescription share; inventory movements also impacted the performance. Market share was maintained in the second quarter however, with a 1% point growth in new-to-brand share since the start of the year. In Europe, Product Sales declined by 7% to \$469m, reflecting prevailing competitive trends.

Crestor consolidated its position as the leading statin in Japan, growing its sales by 6% in the half. Emerging Markets delivered sales growth of 5% at \$352m, including 21% in China.

#### Oncology

##### Iressa

H1 Product Sales declined by 3% to \$273m, primarily a function of the competitive environment in Europe where sales were down by 5%, and in Japan down by 14%. The latter territory saw a material swing in performance from quarter to quarter, with year-on-year growth of 9% in Q2.

Emerging Markets grew by 3% with Product Sales of \$139m, with particular growth in China, up 5% and Russia, up 23%.

##### Lynparza

Product Sales reached \$30m following the launch in the US at the end of 2014. Growth has been driven by the pool of eligible patients awaiting treatment as well as patients newly-tested for BRCA mutation. Over 1,000 patients have already been treated with Lynparza in the US for germline BRCA-advanced ovarian cancer with three or more lines of chemotherapy.

##### Zoladex

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

Product Sales in the half were up 9% to \$409m. Notable performances included growth of 36% in China where Product Sales reached \$60m.

### Faslodex

Product Sales for the half were up 5% to \$333m. A 1% rise in European sales to \$101m was complemented by 2% growth in the US where Product Sales reached \$165m.

The notable performance was in Emerging Markets, where sales of \$42m represented a growth rate of 32%, an encouraging result alongside the approval of 500mg Faslodex in China in May 2015.

### ING

#### Nexium

Overall H1 Product Sales fell 27% to \$1,291m, with Q2 sales similarly down 27% at \$647m. The decline was particularly felt in the US, where sales in the half fell 49% to \$479m, reflecting the loss of exclusivity in February 2015 which directly impacted both pricing and volumes. In Q2 this resulted in an increase to the estimate for pipeline inventory returns, although the value of the level of business and volume maintained remains at a high level. Sales in Europe fell 10% in the half to \$143m.

Product Sales in markets outside the US delivered a positive result, with H1 Latin American sales up 17%, Japan sales up 16% and China sales up 3%. Emerging Markets represent a key opportunity for Nexium, with the brand's sales totalling \$397m in the half.

#### Seroquel XR

Product Sales declined by 7% in the half to \$526m, with similar falls in each quarter. In the US H1 sales were up 2% to \$353m where the performance was mainly driven by a higher underlying net price.

The majority of the remainder of the brand's sales are in Europe, where a H1 sales decline of 25% to \$113m was driven primarily by competition from generic products.

#### Synagis

Product Sales fell 28% in the half to \$270m, reflecting the 38% decline in the US where the majority of sales are made. A significant factor was lower demand related to the American Academy of Pediatrics Committee on Infectious Disease guidelines issued in mid-2014. These further restricted patients eligible for preventative therapy with Synagis. While these guidelines were inconsistent with the approved label, demand was significantly impacted; this is anticipated to continue in the second half. Product Sales in Europe fell 6% to \$110m.

### Regional Product Sales

---

	H1 2015			Q2 2015		
	\$m	% Change CER	Actual	\$m	% Change CER	Actual
US	4,525	(9)	(9)	2,356	(3)	(3)
Europe	2,601	(5)	(20)	1,261	(5)	(23)
Established ROW1	1,491	(2)	(15)	785	-	(14)
Japan	977	2	(12)	522	6	(10)
Canada	273	6	(5)	138	5	(6)
	241	(23)	(33)	125	(22)	(34)

Other Established  
ROW

Emerging Markets <sup>2</sup>	2,967	14	2	1,434	9	(2)
China	1,309	19	18	583	10	11
Ex.China	1,658	10	(7)	851	8	(10)
Total	11,584	(2)	(10)	5,836	(1)	(10)

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

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

## US

Product Sales in the half were down 9% to \$4,525m, with an encouraging trend in sales illustrated by only a 3% fall in the second quarter. Excluding the impact of the change in accounting related to the Branded Pharmaceutical Fee, Product Sales in the quarter were down 1% versus the comparative period.

The headline decline in sales however reflected the loss of Nexium patent exclusivity, competition facing Crestor from therapeutic substitution by generic statins, the adverse impact of the Synagis guideline changes and the aforementioned change in accounting related to the Branded Pharmaceutical Fee. Onglyza sales also declined in the second quarter due to ongoing competition in the diabetes market.

These declines were partly offset by growth in Brilinta, Bydureon, Farxiga, Lynparza and the inclusion of Tudorza and Daliresp. Brilinta growth was driven by strong consecutive quarters of growth in total and new-to-brand prescription market share gains. Bydureon continues to benefit from the launch of the Bydureon Pen as well as growth in demand in the overall GLP-1 class. A strong acceleration in Farxiga sales reflected continued growth in demand underpinned by additional promotional activity. With Lynparza exceeding the 1,000 patient milestone, it was encouraging to see the early benefit to patients from a pipeline due to launch a number of important medicines in the US in the near term.

## Europe

Product Sales in the half were down 5% to \$2,601m. Strong growth from Forxiga and Onglyza was more than offset by continued generic competition facing Crestor and Seroquel XR. An 8% decline in Symbicort sales reflected adverse pricing movements driven by competition from analogues in key markets.

## Established ROW

Product Sales were down 2% in the first half to \$1,491m. Following a decline in the first quarter, Japan Q2 sales increased by 6%, reflecting the passing of the anniversary of the mandated April 2014 biennial price cut.

Nexium and Crestor continue to grow strongly in Japan, growing by 16% and 6% in the half, respectively. Crestor's growth reflected a continued increase in the usage of the 5mg dosage.

Canada Product Sales grew by 6% to \$273m in the half, driven by the performances of Onglyza and Symbicort.

## Emerging Markets

The Company continues to focus on delivering innovative medicines by accelerating investment in its Emerging Markets' capabilities, with a focus on China and other leading markets, such as Russia and Brazil.

Product Sales were up 14% to \$2,967m in the half with growth across the region. China sales in the half increased by 19% to \$1,309m, more in line with recent trends, with the Company's medicines for respiratory, cardiovascular and

Edgar Filing: ASTRAZENECA PLC - Form 6-K

diabetes diseases delivering particularly strong results. Russia sales were up 30% to \$116m, while Brazil sales were up 15% to \$206m.

Q2 Product Sales were up 9% to \$1,434m. China sales were up 10% to \$583m, with slower growth after a 28% growth in Product Sales in the first quarter.

Financial Performance

H1 2015	Reported	Restructuring	Intangible			Core		% Change	
			Amortisation & Impairments	Diabetes Alliance	Other <sup>1</sup>	H1 2015	H1 2014 <sup>2</sup>	CER	Actual
Product Sales	11,584	-	-	-	-	11,584	12,870	(2)	(10)
Externalisation Revenue	780	-	-	-	-	780	352	124	122
Total Revenue	12,364	-	-	-	-	12,364	13,222	1	(6)
Cost of Sales	(2,336)	101	317	-	-	(1,918)	(2,349)	(7)	(18)
Gross Profit	10,028	101	317	-	-	10,446	10,873	3	(4)
Gross Margin <sup>3</sup>	79.8%					83.4%	81.7%	+1.0	+1.7
Distribution	(161)	-	-	-	-	(161)	(149)	23	8
% Total Revenue	1.3%					1.3%	1.1%	-0.2	-0.2
R&D	(2,822)	124	62	-	-	(2,636)	(2,306)	24	14
% Total Revenue	22.8%					21.3%	17.4%	-3.8	-3.9
SG&A	(5,765)	223	444	216	298	(4,584)	(4,777)	4	(4)
% Total Revenue	46.6%					37.1%	36.1%	-0.9	-1.0
Other Operating Income	576	-	135	-	(158)	553	342	77	62
% Total Revenue	4.7%					4.5%	2.6%	+1.9	+1.9
Operating Profit	1,856	448	958	216	140	3,618	3,983	(4)	(9)
% Total Revenue	15.0%					29.3%	30.1%	-1.5	-0.8
Net Finance Expense	(513)	-	-	204	59	(250)	(267)		
Joint Ventures	(7)	-	-	-	-	(7)	-		
	1,336	448	958	420	199	3,361	3,716	(3)	(10)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Profit Before Tax									
Taxation	(88)	(94)	(193)	(95)	(2)	(472)	(600)		
Tax Rate	6.6%					14.0%	16.1%		
Profit After Tax	1,248	354	765	325	197	2,889	3,116	-	(7)
Non-controlling Interests	(1)	-	-	-	-	(1)	(3)		
Net Profit	1,247	354	765	325	197	2,888	3,113	-	(7)
Weighted Average Shares	1,263	1,263	1,263	1,263	1,263	1,263	1,261		
Earnings Per Share	0.99	0.28	0.60	0.26	0.16	2.29	2.47	-	(7)

1 Other adjustments include provision charges and settlement income related to certain legal matters (see Note 5) and fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 4).

2 2014 comparatives have been restated to reflect the reclassification of Externalisation Revenue from Other Operating Income.

3 Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales.

Q2 2015	Reported	Restructuring	Intangible			Core	Q2 2014	% Change	
			Amortisation & Impairments	Diabetes Alliance	Other <sup>1</sup>			CER	Actual
Product Sales	5,836	-	-	-	-	5,836	6,454	(1)	(10)
Externalisation Revenue	471	-	-	-	-	471	308	54	53
Total Revenue	6,307	-	-	-	-	6,307	6,762	2	(7)
Cost of Sales	(1,067)	58	44	-	-	(965)	(1,156)	(7)	(16)
Gross Profit	5,240	58	44	-	-	5,342	5,606	4	(5)
Gross Margin <sup>3</sup>	81.7%					83.5%	82.1%	+1.1	+1.4
Distribution	(84)	-	-	-	-	(84)	(77)	27	10
% Total Revenue	1.3%					1.3%	1.1%	-0.3	-0.2
R&D	(1,466)	62	48	-	-	(1,356)	(1,208)	23	12
% Total Revenue	23.2%					21.5%	17.9%	-3.7	-3.6
SG&A	(2,966)	115	242	108	285	(2,216)	(2,460)	(1)	(10)
% Total Revenue	47.0%					35.1%	36.4%	+1.2	+1.3
	199	-	86	-	(158)	127	170	(12)	(25)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other Operating Income % Total Revenue	3.2%					2.0%	2.5%	-0.3	-0.5
Operating Profit % Total Revenue	923	235	420	108	127	1,813	2,031	(4)	(11)
	14.6%					28.7%	30.0%	-1.7	-1.3
Net Finance Expense	(263)	-	-	100	31	(132)	(141)		
Joint Ventures	(2)	-	-	-	-	(2)	-		
Profit Before Tax	658	235	420	208	158	1,679	1,890	(2)	(11)
Taxation	38	(49)	(104)	(47)	2	(160)	(247)		
Tax Rate	-5.8%					9.5%	13.1%		
Profit After Tax	696	186	316	161	160	1,519	1,643	3	(8)
Non-controlling Interests	1	-	-	-	-	1	(1)		
Net Profit	697	186	316	161	160	1,520	1,642	3	(8)
Weighted Average Shares	1,264	1,264	1,264	1,264	1,264	1,264	1,262		
Earnings Per Share	0.55	0.15	0.25	0.13	0.13	1.21	1.30	3	(8)

1 Other adjustments include provision charges and settlement income related to certain legal matters (see Note 5) and fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 4).

2 2014 comparatives have been restated to reflect the reclassification of Externalisation Revenue from Other Operating Income.

3 Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales.

#### Gross Profit

Core gross profit increased by 3% in the half to \$10,446m. Excluding the impact of externalisation, the Core gross profit margin increased by 1% point. Drivers of the margin increase included the mix of Product Sales, the contribution from the growth platforms and additional manufacturing efficiencies.

#### Operating Expenses

Core R&D costs were up 24% in the half to \$2,636m as the Company continued its accelerated investment in the pipeline. The Company anticipates a lower growth rate in the second half of the year.

Core SG&A costs were up 4% to \$4,584m in the half as the Company continued to invest in the product launch programme and the growth platforms; costs declined by 1% in the second quarter, reflecting the third successive quarter of falling Core SG&A costs as a proportion of Total Revenue. In the second quarter, Core SG&A costs

represented 35% of Total Revenue, compared to 39% in Q1 2015 and 44% in Q4 2014.

The Company is committed to reducing Core SG&A costs in 2015 versus the prior year, both in terms of absolute value and, importantly, relative to Total Revenue. A number of programmes designed to meet this target are in progress. These initiatives are centred on:

- Sales, marketing and medical-cost effectiveness
- Centralisation of selected functions and process improvements
  - Reduced third-party spend
- Additional efficiencies gained across support functions and IT
- Continued footprint optimisation, including presence in the UK and US

Resources are being deployed more opportunistically to meet changing customer needs and the evolving portfolio, while driving top-line growth more efficiently.

#### Other Operating Income

Core Other Operating Income of \$553m in the half included gains on the disposal of Myalept (\$193m) and other disposals amounting to \$120m, including the US rights to Tenormin.

#### Operating Profit

Core Operating Profit was down 4% to \$3,618m in the half. Core Operating Margin declined by 1.5% points to 29.3% of Total Revenue as the Company continued to invest in the pipeline and the growth platforms.

#### Finance Expense

Core net finance expense was \$250m versus \$267m in the first half of 2014. Reported net finance expense of \$513m included a charge of \$263m relating to the discount unwind on contingent consideration creditors recognised on business combinations, principally relating to the acquisition of BMS's share of the global diabetes alliance last year.

#### Taxation

Excluding the one-off tax benefit of \$186m following settlement of past years' US federal tax liabilities, both the Core and Reported tax rates for the half year were around 20%. Including the impact of this benefit, the Core and Reported tax rates for the half year were 14% and 7% respectively. The cash tax paid for the half year was \$782m, which is 59% of Reported Profit Before Tax and 23% of Core Profit Before Tax.

The Core and Reported tax rates for the first half of 2014 were 19% and 21% respectively when excluding the impact of a one-off tax benefit of \$117m in respect of prior periods following the inter-governmental agreement of a transfer pricing matter. Including the impact of this benefit, the Core and Reported tax rates for the first half of 2014 were 16% and 13% respectively. The cash tax paid for the first half of 2014 was \$736m, which was 49% of Reported Profit Before Tax and 20% of Core Profit Before Tax.

#### Earnings Per Share (EPS)

Core EPS in the half was stable at \$2.29, a favourable performance versus Core Operating Profit due to a one-off tax benefit in the second quarter. Reported Operating Profit of \$1,856m was 1% higher than the first half of 2014. Reported EPS was up by 2% at \$0.99.

#### Productivity

Restructuring charges of \$448m were taken in the first half of 2015, including \$101m incurred on initiatives identified since the announcement of the fourth wave of restructuring.

The Company continues to make good progress in implementing the fourth wave of restructuring that was announced in 2013 and expanded in 2014. It remains on track to incur \$3.2bn in one-time restructuring costs and to deliver annualised benefits of \$1.1bn by the end of 2016. In addition to the fourth wave of restructuring an additional \$600m of costs are estimated to be incurred by the end of 2016 (of which \$362m has been incurred to date) associated with previously-announced site exits (including Avlon in the UK) and the integration of businesses acquired since the beginning of 2014.

It is anticipated that, once completed, the total annualised benefits of these additional actions will be \$200m, bringing the total annualised benefit of all ongoing restructuring activities to \$1.3bn by the end of 2016.

#### Cash Flow

The Company generated a cash inflow from operating activities of \$1,008m in the half, compared with an inflow of \$3,266m in the first half of 2014, reflecting the operational performance of the business. Net cash outflows from investing activities were \$1,234m compared with \$4,955m in the first half of 2014, primarily reflecting the acquisition of the BMS share of the global diabetes alliance last year. The Company has embarked upon an initiative to further improve cash generation from the business including standardisation of global processes and payment terms.

Net cash distributions to shareholders were \$2,337m through dividends of \$2,357m, offset by proceeds from the issue of shares of \$20m due to the exercise of stock options.

#### Debt and Capital Structure

At 30 June 2015, outstanding gross debt (interest-bearing loans and borrowings) was \$11,008m (30 June 2014: \$10,074m). Of the gross debt outstanding at 30 June 2015, \$2,705m was due within one year (30 June 2014: \$2,500m).

The Company's net debt position at 30 June 2015 was \$5,994m (30 June 2014: \$3,959m).

#### Shares in Issue

During the half, 0.5 million shares were issued in respect of share option exercises for a consideration of \$20m. The total number of shares in issue at 30 June 2015 was 1,264 million.

#### Dividends

The Board has recommended an unchanged first interim dividend of \$0.90 (57.5 pence, 7.71 SEK) per Ordinary Share.

For holders of the Company's American Depositary Shares (ADSs) this equates to \$0.45 per ADS. Following the ratio change to the Company's NYSE-listed sponsored Level 2 American Depositary Receipt programme on 27 July 2015, two ADSs equal one Ordinary Share.

The level of the dividend per share reflects the Board's aim of setting the first interim dividend at around a third of the prior-year dividend, which for FY 2014 was \$2.80 per Ordinary Share.

The Board has adopted a progressive dividend policy, by which the Board intends to maintain or grow the dividend per share each year. In adopting this policy, the Board recognises that some earnings fluctuations are to be expected as the Company's revenue base transitions through a period of exclusivity losses and new-product launches.

In setting the distribution policy and the overall financial strategy, the Board's aim is to continue to strike a balance between the interests of the business, financial creditors and the Company's shareholders. After providing for business



investment, funding the progressive dividend policy and meeting debt-service obligations, the Board will keep under review the opportunity to return cash in excess of these requirements to shareholders through periodic share repurchases. However, the Board has decided that no share repurchases will take place in 2015 in order to maintain the strategic flexibility to invest in the business.

#### FY 2015 Guidance

The Company today revises its Total Revenue guidance at CER from that provided on 24 April 2015. Total Revenue in the full year is now expected to decline by low single-digit percent versus the prior guidance of a mid single-digit decline. Core EPS guidance at CER for the year is unchanged and Core EPS is expected to increase by low single-digit percent, reflecting the continued accelerated investment in R&D.

The Company also provides the following non-guidance information related to currency sensitivity: Based on current exchange rates<sup>1</sup>, Total Revenue is expected to decline by high single-digit percent with Core EPS expected to be broadly in line with FY 2014. For additional currency sensitivity information, please see below:

Currency	Primary Relevance	Average Exchange Rates Versus USD			Impact Of 5% Weakening In Exchange Rate Versus USD (\$m) <sup>2</sup>	
		FY 2014	H1 2015 <sup>1</sup>	Change %	Total Revenue	Core Operating Profit
EUR	Product Sales	0.75	0.89	(16)	(225)	(138)
JPY	Product Sales	105.87	120.25	(12)	(119)	(84)
CNY	Product Sales	6.16	6.22	(1)	(115)	(49)
SEK	Costs	6.86	8.37	(18)	(6)	114
GBP	Costs	0.61	0.66	(7)	(37)	112
Other <sup>3</sup>					(242)	(139)

<sup>1</sup> Based on average daily spot rates YTD to the end of June 2015

<sup>2</sup> Based on 2014 actual average exchange rates and group currency exposures

<sup>3</sup> Other important currencies include AUD, BRL, CAD, KRW and RUB

#### Related Party Transactions

There have been no significant related party transactions in the period.

#### Principal Risks and Uncertainties

It is not anticipated that the nature of the principal risks and uncertainties that affect the business, and which are set out on pages 205 to 219 of the Annual Report and Form 20-F Information 2014, will change in respect of the second six months of the financial year.

In summary, the principal risks and uncertainties listed in the Annual Report and 20-F Information 2014 are:

##### a) Product pipeline risks

Failure to meet development targets; difficulties of obtaining and maintaining regulatory approvals for new products; failure to obtain and enforce effective intellectual property protection; delay to new product launches; strategic alliances and acquisitions may be unsuccessful.

b) Commercialisation and business execution risks

Challenges to achieving commercial success of new products; illegal trade in our products; developing our business in Emerging Markets; expiry or loss of, or limitations on, intellectual property rights; pressures resulting from generic competition; effects of patent litigation in respect of intellectual property rights; price controls and price reductions; economic, regulatory and political pressures; biosimilars; increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; any expected gains from productivity initiatives are uncertain; changes in senior management, failure to attract and retain key personnel and failure to successfully engage with our employees; failure of information technology; failure of outsourcing.

c) Supply chain and delivery risks

Manufacturing biologics; difficulties and delays in the manufacturing, distribution and sale of our products; reliance on third parties for goods.

d) Legal, regulatory and compliance risks

Adverse outcome of litigation and/or governmental investigations; substantial product liability claims; failure to adhere to applicable laws, rules and regulations; failure to adhere to laws, rules and regulations relating to anti-competitive behaviour; environmental and occupational health and safety liabilities; misuse of social media platforms and new technology.

e) Economic and financial risks

Adverse impact of a sustained economic downturn; political and socio-economic conditions; impact of fluctuations in exchange rates; limited third party insurance coverage; taxation; pensions.

Condensed Consolidated Statement of Comprehensive Income

	2015	Restated 2014*
	\$m	\$m
For the half year ended 30 June		
Product sales	11,584	12,870
Externalisation revenue	780	352
Total revenue	12,364	13,222
Cost of sales	(2,336)	(2,760)
Gross profit	10,028	10,462
Distribution costs	(161)	(149)
Research and development expense	(2,822)	(2,528)
Selling, general and administrative costs	(5,765)	(5,784)
Other operating income and expense	576	(56)
Operating profit	1,856	1,945
Finance income	24	26
Finance expense	(537)	(467)
Share of after tax losses in joint ventures	(7)	-
Profit before tax	1,336	1,504
Taxation	(88)	(201)
Profit for the period	1,248	1,303
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	242	(288)
Tax on items that will not be reclassified to profit or loss	(57)	85
	185	(203)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(11)	64
Foreign exchange arising on designating borrowings in net investment hedges	(217)	(122)
Fair value movements on derivatives designated in net investment hedges	20	(11)
Amortisation of loss on cash flow hedge	1	1
Net available for sale (losses)/gains taken to equity	(29)	49
Tax on items that may be reclassified subsequently to profit or loss	43	5
	(193)	(14)
Other comprehensive income for the period, net of tax	(8)	(217)
Total comprehensive income for the period	1,240	1,086
Profit attributable to:		
Owners of the Parent	1,247	1,300
Non-controlling interests	1	3
	1,248	1,303
Total comprehensive income attributable to:		
Owners of the Parent	1,239	1,089
Non-controlling interests	1	(3)
	1,240	1,086
Basic earnings per \$0.25 Ordinary Share	\$0.99	\$1.03
Diluted earnings per \$0.25 Ordinary Share	\$0.99	\$1.03
Weighted average number of Ordinary Shares in issue (millions)	1,263	1,261
Diluted weighted average number of Ordinary Shares in issue (millions)	1,265	1,263

\* 2014 comparatives restated for reclassification of Externalisation revenue (see Note 1)

Condensed Consolidated Statement of Comprehensive Income

	2015	Restated 2014*
For the quarter ended 30 June	\$m	\$m
Product sales	5,836	6,454
Externalisation revenue	471	308
Total revenue	6,307	6,762
Cost of sales	(1,067)	(1,307)
Gross profit	5,240	5,455
Distribution costs	(84)	(77)
Research and development expense	(1,466)	(1,328)
Selling, general and administrative costs	(2,966)	(3,058)
Other operating income and expense	199	117
Operating profit	923	1,109
Finance income	13	10
Finance expense	(276)	(253)
Share of after tax losses of joint ventures	(2)	-

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Profit before tax	658	866
Taxation	38	(69)
Profit for the period	696	797
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	259	(263)
Tax on items that will not be reclassified to profit or loss	(61)	79
	198	(184)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	438	9
Foreign exchange arising on designating borrowings in net investment hedges	191	(121)
Fair value movements on derivatives designated in net investment hedges	(1)	(2)
Amortisation of loss on cash flow hedge	1	1
Net available for sale (losses)/gains taken to equity	(48)	47
Tax on items that may be reclassified subsequently to profit or loss	(57)	12
	524	(54)
Other comprehensive income for the period, net of tax	722	(238)
Total comprehensive income for the period	1,418	559
Profit attributable to:		
Owners of the Parent	697	796
Non-controlling interests	(1)	1
	696	797
Total comprehensive income attributable to:		
Owners of the Parent	1,418	558
Non-controlling interests	-	1
	1,418	559
Basic earnings per \$0.25 Ordinary Share	\$0.55	\$0.63
Diluted earnings per \$0.25 Ordinary Share	\$0.55	\$0.63
Weighted average number of Ordinary Shares in issue (millions)	1,264	1,262
Diluted weighted average number of Ordinary Shares in issue (millions)	1,265	1,264

\* 2014 comparatives restated for reclassification of Externalisation revenue (see Note 1)

Condensed Consolidated Statement of Financial Position

	At 30 Jun 2015 \$m	At 31 Dec 2014 \$m	At 30 Jun 2014 \$m
<b>ASSETS</b>			
Non-current assets			
Property, plant and equipment	6,134	6,010	6,150

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Goodwill	11,467	11,550	11,560
Intangible assets	20,486	20,981	21,150
Derivative financial instruments	471	465	349
Investments in joint ventures	52	59	70
Other investments	448	502	289
Other receivables	957	1,112	1,380
Deferred tax assets	1,342	1,219	1,387
	41,357	41,898	42,335
Current assets			
Inventories	2,198	1,960	2,249
Trade and other receivables	6,615	7,232	7,817
Other investments	531	795	819
Derivative financial instruments	51	21	1
Income tax receivable	450	329	360
Cash and cash equivalents	3,967	6,360	4,958
	13,812	16,697	16,204
Total assets	55,169	58,595	58,539
LIABILITIES			
Current liabilities			
Interest-bearing loans and borrowings	(2,705)	(2,446)	(2,500)
Trade and other payables	(10,659)	(11,886)	(10,304)
Derivative financial instruments	(6)	(21)	(12)
Provisions	(731)	(623)	(679)
Income tax payable	(2,049)	(2,354)	(2,827)
	(16,150)	(17,330)	(16,322)
Non-current liabilities			
Interest-bearing loans and borrowings	(8,303)	(8,397)	(7,574)
Deferred tax liabilities	(1,582)	(1,796)	(2,427)
Retirement benefit obligations	(2,377)	(2,951)	(2,634)
Provisions	(479)	(484)	(580)
Other payables	(7,979)	(7,991)	(6,950)
	(20,720)	(21,619)	(20,165)
Total liabilities	(36,870)	(38,949)	(36,487)
Net assets	18,299	19,646	22,052
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	316	316	316
Share premium account	4,281	4,261	4,236
Other reserves	2,033	2,021	1,973
Retained earnings	11,649	13,029	15,504
	18,279	19,627	22,029
Non-controlling interests	20	19	23
Total equity	18,299	19,646	22,052

Condensed Consolidated Statement of Cash Flows

	2015	2014
	\$m	\$m
For the half year ended 30 June		
Cash flows from operating activities		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Profit before tax	1,336	1,504
Finance income and expense	513	441
Share of after tax losses in joint ventures	7	-
Depreciation, amortisation and impairment	1,565	1,410
(Increase)/decrease in working capital and short-term provisions	(767)	703
Non-cash and other movements	(612)	216
Cash generated from operations	2,042	4,274
Interest paid	(252)	(272)
Tax paid	(782)	(736)
Net cash inflow from operating activities	1,008	3,266
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	273	34
Purchase of property, plant and equipment	(497)	(378)
Disposal of property, plant and equipment	16	133
Purchase of intangible assets	(1,222)	(1,490)
Disposal of intangible assets	350	-
Purchase of non-current asset investments	(30)	(5)
Disposal of non-current asset investments	56	-
Payments to joint ventures	-	(70)
Upfront payments on business acquisitions	-	(2,778)
Payment of contingent consideration on business acquisitions	(239)	(449)
Interest received	59	58
Payments made by subsidiaries to non-controlling interests	-	(10)
Net cash outflow from investing activities	(1,234)	(4,955)
Net cash outflow before financing activities	(226)	(1,689)
Cash flows from financing activities		
Proceeds from issue of share capital	20	254
Repayment of loans	(884)	(750)
Dividends paid	(2,357)	(2,425)
Hedge contracts relating to dividend payments	(43)	25
Repayment of obligations under finance leases	(34)	(17)
Payments to acquire non-controlling interest	-	(102)
Movement in short-term borrowings	910	445
Net cash outflow from financing activities	(2,388)	(2,570)
Net decrease in cash and cash equivalents in the period	(2,614)	(4,259)
Cash and cash equivalents at the beginning of the period	6,164	8,995
Exchange rate effects	(29)	3
Cash and cash equivalents at the end of the period	3,521	4,739
Cash and cash equivalents consists of:		
Cash and cash equivalents	3,967	4,958
Overdrafts	(446)	(219)
	3,521	4,739

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

Edgar Filing: ASTRAZENECA PLC - Form 6-K

At 1 Jan 2014	315	3,983	1,966	16,960	23,224	29	23,253
Profit for the period	-	-	-	1,300	1,300	3	1,303
Other comprehensive income	-	-	-	(211)	(211)	(6)	(217)
Transfer to other reserves	-	-	7	(7)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,395)	(2,395)	-	(2,395)
Issue of Ordinary Shares	1	253	-	-	254	-	254
Share-based payments	-	-	-	(143)	(143)	-	(143)
Transfer from non-controlling interests to payables	-	-	-	-	-	(3)	(3)
Net movement	1	253	7	(1,456)	(1,195)	(6)	(1,201)
At 30 Jun 2014	316	4,236	1,973	15,504	22,029	23	22,052

	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 2015	316	4,261	2,021	13,029	19,627	19	19,646
Profit for the period	-	-	-	1,247	1,247	1	1,248
Other comprehensive income	-	-	-	(8)	(8)	-	(8)
Transfer to other reserves	-	-	12	(12)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,400)	(2,400)	-	(2,400)
Issue of Ordinary Shares	-	20	-	-	20	-	20
Share-based payments	-	-	-	(207)	(207)	-	(207)
Net movement	-	20	12	(1,380)	(1,348)	1	(1,347)
At 30 Jun 2015	316	4,281	2,033	11,649	18,279	20	18,299

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

Responsibility Statement of the Directors in Respect of the Half-Yearly Financial Report

We confirm that to the best of our knowledge:

- the condensed set of financial statements has been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union and as issued by the International Accounting Standards Board;
  - the half-yearly management report includes a fair review of the information required by:
    - (a) DTR 4.2.7R of the Disclosure and Transparency Rules, being an indication of important events that have occurred during the first six months of the financial year and their impact on the condensed set of financial statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and
    - (b) DTR 4.2.8R of the Disclosure and Transparency Rules, being related party transactions that have taken place in the first six months of the current financial year and that have materially affected the financial position or performance of the enterprise during that period; and any changes in the related party transactions described in the last annual report that could do so.

#### The Board

The Board of Directors that served during all or part of the six-month period to 30 June 2015 and their respective responsibilities can be found on pages 28 and 29 of the AstraZeneca Annual Report and Form 20-F Information 2014, with the exception of Cori Bargmann who was elected as Non-Executive Director and appointed as a member of the Science Committee on 24 April 2015. Also on 24 April 2015, Rudy Markham became Senior independent Non-Executive Director, Graham Chipchase became Chairman of the Remuneration Committee and a member of the Nomination and Governance Committee, Bruce Burlington became Chairman of the Science Committee and a member of the Nomination and Governance Committee and Geneviève Berger took on the oversight of sustainability matters on behalf of the Board.

Approved by the Board and signed on its behalf by  
Pascal Soriot  
Chief Executive Officer  
30 July 2015

#### Independent Review Report to AstraZeneca PLC

##### Introduction

We have been engaged by the Company to review the condensed set of Interim Financial Statements in the half-yearly financial report for the six months ended 30 June 2015 (but not for the quarter ended 30 June 2015 as presented in the Condensed Consolidated Statement of Comprehensive Income for the quarter ended 30 June 2015) which comprises Condensed Consolidated Statement of Comprehensive Income, Condensed Consolidated Statement of Financial Position, Condensed Consolidated Statement of Cash Flows, Condensed Consolidated Statement of Changes in Equity and Notes 1 to 6. We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

This report is made solely to the Company in accordance with the terms of our engagement to assist the Company in meeting the requirements of the Disclosure and Transparency Rules ("the DTR") of the UK's Financial Conduct Authority ('the UK FCA'). Our review has been undertaken so that we might state to the Company those matters we are required to state to it in this report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company for our review work, for this report, or for the



conclusions we have reached.

#### Directors' responsibilities

The half-yearly financial report is the responsibility of, and has been approved by, the Directors. The Directors are responsible for preparing the half-yearly financial report in accordance with the DTR of the UK FCA.

As disclosed in Note 1, the annual financial statements of the Group are prepared in accordance with International Financial Reporting Standards ("IFRSs") as adopted by the European Union ("EU") and as issued by the International Accounting Standards Board ("IASB"). The condensed set of financial statements included in this half-yearly financial report has been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the EU and as issued by the IASB.

#### Our responsibility

Our responsibility is to express to the Company a conclusion on the condensed set of financial statements in the half-yearly financial report based on our review.

#### Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity issued by the Auditing Practices Board for use in the UK. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit.

Accordingly, we do not express an audit opinion.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2015 is not prepared, in all material respects, in accordance with IAS 34 as adopted by the EU and as issued by the IASB, and the DTR of the UK FCA.

Antony Cates

for and on behalf of KPMG LLP  
Chartered Accountants  
15 Canada Square  
London E14 5GL

30 July 2015

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 six months ended 30 June 2015 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. Except as detailed below, the interim financial statements have been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2014.

#### Externalisation revenue

As announced on 6 March 2015, the Group updated its revenue accounting policy with effect from 1 January 2015. The Group's business model now includes an increasing level of externalisation activity to create value from the strong science that exists in the pipeline. Historically, reported revenue reflected only product sales, with externalisation revenue forming part of other operating income presented below gross profit. From 1 January 2015 externalisation revenue, alongside product sales, are included in total revenue. Externalisation revenue includes development, commercialisation, partnership and out-licence revenue, such as royalties and milestone receipts, together with income from services or repeatable licences. Income is recorded as externalisation revenue when the Group has a significant ongoing interest in the product and/or it is repeatable business and there is no derecognition of an intangible asset. Disposals of assets and businesses, where the Group does not retain an interest, will continue to be recorded in other operating income. The updated financial presentation reflects the Group's entrepreneurial approach and provides a clearer picture of this additional revenue stream. The updated revenue accounting policy results in a presentational change to the Statement of Comprehensive Income only, and has no impact on the Group's net results or net assets. The prior period Condensed Consolidated Statement of Comprehensive Income has been restated accordingly, resulting in \$352m of income being reclassified from other operating income to externalisation revenue for the half year ended 30 June 2014, and \$308m for the quarter ended 30 June 2014.

#### New accounting standards

The Group has adopted the amendments to IAS 19 Employee Benefits, issued by IASB in November 2013 and effective for periods beginning on or after 1 July 2014. The adoption has not had a significant impact on the Group's profit for the period, net assets or cash flows. There have been no other significant new or revised accounting standards applied in the half year ended 30 June 2015.

#### Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2014.

#### Going concern

The Group has considerable financial resources available. As at 30 June 2015 the Group has \$4.3bn in financial resources (cash balances of \$4.0bn and undrawn committed bank facilities of \$3.0bn which are available until April 2020, with only \$2.7bn 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 a period of at least 12 months. Accordingly, the interim financial statements have been prepared on a going concern basis.

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

The comparative figures for the financial year ended 31 December 2014 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 RESTRUCTURING COSTS

Profit before tax for the half year ended 30 June 2015 is stated after charging restructuring costs of \$448m (\$235m for the second quarter of 2015). These have been charged to profit as follows:

	HY 2015	HY 2014	Q2 2015	Q2 2014
	\$m	\$m	\$m	\$m
Cost of sales	101	24	58	13
Research and development expense	124	190	62	105
Selling, general and administrative costs	223	266	115	175
Other operating income and expense	-	292	-	-
Total	448	772	235	293

### 3 NET DEBT

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

	At 1 Jan 2015 \$m	Cash Flow \$m	Non-cash Movements \$m	Exchange Movements \$m	At 30 Jun 2015 \$m
Loans due after one year	(8,337)	-	19	62	(8,256)
Finance leases due after one year	(60)	-	12	1	(47)
Total long-term debt	(8,397)	-	31	63	(8,303)
Current instalments of loans	(912)	884	-	28	-
Current instalments of finance leases	(48)	34	(47)	1	(60)
Total current debt	(960)	918	(47)	29	(60)
Other investments – current	795	(286)	28	(6)	531
Net derivative financial instruments	465	56	(5)	-	516
Cash and cash equivalents	6,360	(2,363)	-	(30)	3,967
Overdrafts	(196)	(251)	-	1	(446)
Short-term borrowings	(1,290)	(910)	1	-	(2,199)
	6,134	(3,754)	24	(35)	2,369
Net debt	(3,223)	(2,836)	8	57	(5,994)

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

## 4 FINANCIAL INSTRUMENTS

As detailed in the Group's 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 140 and 141 of the Company's Annual Report and Form 20-F Information 2014. 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 \$979m of other investments, \$1,176m of loans, and \$516m of derivatives as at 30 June 2015. The total fair value of interest-bearing loans and borrowings at 30 June 2015, which have a carrying value of \$11,008m in the Condensed Consolidated Statement of Financial Position, was \$12,039m. Contingent consideration liabilities arising on business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	Diabetes Alliance 2015 \$m	Other 2015 \$m	Total 2015 \$m	Total 2014 \$m
At 1 January	5,386	1,513	6,899	514
Additions through business combinations	-	-	-	5,249*
Settlements	(103)	(136)	(239)	(449)
Revaluations	-	82	82	6
Discount unwind	204	59	263	174
Foreign exchange	-	-	-	6
At 30 June	5,487	1,518	7,005	5,500

\*The preliminary estimate of the fair value of contingent consideration of \$5,249m was subsequently revised, in the third quarter of 2014, to \$5,169m.

## 5 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 2014 (the 2014 Disclosures). Unless noted otherwise below or in the 2014 Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the 2014 Disclosures, 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 2014 Disclosures and herein.

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

Matters disclosed in respect of the first quarter of 2015 and to 24 April 2015.

#### Patent litigation

##### Crestor (rosuvastatin)

###### Patent proceedings outside the US

As previously disclosed, in Australia, in 2011 and 2012, AstraZeneca instituted proceedings against Actavis Australia Pty Ltd, Apotex Pty Ltd and Watson Pharma Pty Ltd asserting infringement of three 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. In August 2014, the Full Court of the Federal Court of Australia held the two patents invalid. In March 2015, the High Court granted AstraZeneca leave to appeal in relation to one method patent.

##### Daliresp (roflumilast)

###### Patent proceedings in the US

In April 2015, AstraZeneca received several Paragraph IV Notices challenging certain patents listed in the FDA Orange Book with reference to Daliresp. AstraZeneca is reviewing the Notices.

##### Faslodex (fulvestrant)

###### Patent proceedings outside the US

In March 2015, AstraZeneca was served with a writ of summons by which Actavis Group PTC ehf. and Actavis Italy S.p.A (together, Actavis) commenced invalidity and non-infringement proceedings before a court in Turin, Italy relating to two Faslodex formulation patents, European Patent EP 1250138 and Italian Patent IT 1333490.

##### Losec/Prilosec (omeprazole)

###### Patent proceedings in the US

As previously disclosed, in 2008, Apotex Inc. (Apotex) was found to infringe AstraZeneca's US Patent Nos. 4,786,505 and 4,853,230. In 2013, the US District Court for the Southern District of New York ordered Apotex to pay \$76m in damages with an additional sum of \$28m in pre-judgment interest, and an unspecified amount of post-judgment interest. Apotex appealed. In April 2015, the US Court of Appeals for the Federal Circuit affirmed the bulk of the damages award, with the exception of a small portion of the award which related to sales post patent expiration during a portion of the paediatric exclusivity period.

###### Patent proceedings outside the US

As previously disclosed, in Canada, in 2004, AstraZeneca brought proceedings against Apotex Inc. (Apotex) for infringement of several patents related to Losec. In February 2015, the Federal Court of Canada found that Apotex had infringed AstraZeneca's Canadian Patent No. 1,292,693. Apotex have appealed.

##### Pulmicort Respules (budesonide inhalation suspension)

###### Patent proceedings in the US

As previously disclosed, in October 2014, the US District Court for the District of New Jersey (the District Court) held a trial on the merits in respect of US Patent No. 7,524,834 (the '834 Patent) and to determine whether AstraZeneca's request for permanent injunctive relief against Breath Limited, Apotex, Inc. and Apotex Corp., Sandoz, Inc. and Watson Laboratories, Inc. (together, the Generic Challengers) should be granted. On 13 February 2015, the District Court determined that the '834 Patent is invalid and denied the injunction request. Also on 13 February 2015,

AstraZeneca filed a motion for an injunction pending an appeal of the District Court's decision, which was denied on the same day. On 16 February 2015, AstraZeneca appealed the District Court's decision to the US Court of Appeals for the Federal Circuit (the Court of Appeals) and filed an Emergency Motion for an Injunction Pending Appeal. On 17 February 2015, the Court of Appeals issued an injunction against the Generic Challengers pending submissions by the parties. On 12 March 2015, the Court of Appeals issued an injunction pending appeal. Oral argument in the appeal is scheduled for 4 May 2015.

#### Seroquel XR (quetiapine fumarate)

##### Patent proceedings in the US

As previously disclosed, in October and November 2014, AstraZeneca filed patent infringement proceedings against Pharmadax, Inc. and Pharmadax USA, Inc. (together, Pharmadax) in the US District Court for the District of New Jersey. In February 2015, AstraZeneca settled the patent infringement litigation by granting Pharmadax a licence to the Seroquel XR product patent effective from 1 November 2016, or earlier in certain circumstances.

In February 2015, AstraZeneca received a Paragraph IV Notice from AB Pharmaceuticals, LLC, the US agent of Macleods Pharmaceuticals, Ltd., (together, Macleods) alleging that the patent listed in the FDA Orange Book with reference to Seroquel XR is invalid, unenforceable and/or is not infringed by Macleods' proposed generic product. Macleods submitted an Abbreviated New Drug Application (ANDA) seeking to market quetiapine fumarate tablets. In February 2015, AstraZeneca filed a patent infringement lawsuit against Macleods and Macleods Pharma USA, Inc. in the US District Court for the District of New Jersey.

##### Patent proceedings outside the US

As previously reported, in March 2013, the Federal Court of Canada dismissed AstraZeneca's application to prohibit the Canadian Minister of Health from issuing a notice of compliance to Teva Canada Limited (Teva) for its generic quetiapine fumarate product relating to Seroquel XR. Teva subsequently launched its generic Seroquel XR at risk and filed an action seeking section 8 damages arising from these proceedings. In April 2015, AstraZeneca and Teva entered into a settlement agreement ending the ongoing patent litigation between the parties, as well as the section 8 damages action, and allowing Teva to continue selling generic Seroquel XR.

#### Vimovo (esomeprazole magnesium/naproxen)

##### Patent proceedings outside the US

In Canada, in January 2015, AstraZeneca received two Notices of Allegation from Mylan Pharmaceuticals ULC. In response, AstraZeneca and Pozen Inc. (the licensee and patent holder, respectively), commenced proceedings in relation to Canadian Patent No. 2,449,098.

#### Commercial litigation

##### Seroquel IR (quetiapine fumarate)

As previously disclosed, with regard to insurance coverage for the substantial legal defence costs and settlements that have been incurred in connection with the Seroquel IR product liability claims in the US, related to alleged diabetes and/or other related alleged injuries (which now exceed the total amount of insurance coverage available), an arbitration is ongoing against an insurer in respect of the availability of coverage under an insurance policy. The policy has a coverage limit of \$50m. AstraZeneca has not recognised an insurance receivable in respect of this legal action.

##### Synagis (palivizumab)

As previously disclosed, in September 2011, MedImmune filed an action against AbbVie, Inc. (AbbVie) (formerly Abbott International, LLC) in the Circuit Court for Montgomery County, Maryland, seeking a declaratory judgment in a contract dispute. AbbVie's motion to dismiss was granted. In September 2011, AbbVie filed a parallel action against MedImmune in the Illinois State Court, where the case is currently pending. A trial date has been set for 31 August 2015.

Toprol-XL (metoprolol succinate)

On 30 March 2015, AstraZeneca was served with a state court complaint filed by the Attorney General for the State of Louisiana alleging that, in connection with enforcement of its patents for Toprol-XL, it had engaged in unlawful monopolisation and unfair trade practices, causing the state government to pay increased prices for Toprol-XL. The complaint is very similar to prior class action complaints filed by private parties against AstraZeneca relating to Toprol-XL in 2006 and resolved by settlement in 2012. The State seeks an unspecified amount of trebled damages and pre-judgment interest. AstraZeneca denies these allegations.

Matters disclosed in respect of the second quarter of 2015 and to 30 July 2015.

Patent litigation

Crestor (rosuvastatin)

Patent proceedings outside the US

As previously disclosed, in 2014, in Japan, Shionogi & Co., Ltd. the licensor of the Crestor patent, received confirmation of a request for trial for patent invalidation in the Japanese Patent Office (JPO). The request was initiated by Teva Pharma Japan Inc. (Teva) and relates to the Crestor substance patent. On 29 June 2015, the JPO dismissed Teva's claim. A second invalidation action relating to the same patent has been filed by an individual.

As previously disclosed, in 2014, in the Netherlands, AstraZeneca received a letter from Resolution Chemicals Ltd. (Resolution) indicating that it had sought marketing authorisation for a rosuvastatin zinc product in the Netherlands. In April 2014, AstraZeneca received a writ of summons from Resolution alleging partial invalidity and non-infringement of the supplementary protection certificate (SPC) related to the Crestor substance patent. On 15 July 2015, the District Court of the Hague determined that the SPC does not extend to zinc salts of rosuvastatin and that Resolution's product does not infringe the SPC. AstraZeneca is considering its response.

Daliresp (roflumilast)

Patent proceedings in the US

As previously disclosed, in April 2015, AstraZeneca received Paragraph IV Notices challenging certain patents listed in the FDA Orange Book with reference to Daliresp. AstraZeneca has received notice from ten companies that each has submitted an Abbreviated New Drug Application (ANDA) seeking to market roflumilast. In May 2015, AstraZeneca filed a patent infringement lawsuit against each of the ten companies in the US District Court for the District of New Jersey.

Faslodex (fulvestrant)

Patent proceedings in the US

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

Patent proceedings outside the US

In July 2015, AstraZeneca was served with two nullity complaints, one filed by Hexal AG and the other by ratiopharm GmbH, commencing invalidity proceedings before the Federal Patent Court in Germany, and requesting the revocation of the German part of the Faslodex formulation use patent, EP 1,250,138.

Losec/Prilosec (omeprazole)

Patent proceedings in the US

As previously disclosed, in 2008, Apotex Inc. (Apotex) was found to infringe AstraZeneca's US Patent Nos. 4,786,505 and 4,853,230 and in 2013, the US District Court for the Southern District of New York (the District Court) ordered Apotex to pay \$76m in damages with an additional sum of \$28m in pre-judgment interest, and an unspecified amount of post-judgment interest. Apotex appealed. In April 2015, the US Court of Appeals for the Federal Circuit affirmed the bulk of the damages award, with the exception of a small portion of the award which related to sales post patent expiration during a portion of the paediatric exclusivity period. In July 2015, the District Court ordered Apotex to pay \$99m to AstraZeneca. The proceeding is now closed and AstraZeneca has recognised the settlement income.

Nexium (esomeprazole)

Patent proceedings in the US

In June 2015, AstraZeneca received a Paragraph IV Notice from HEC Pharm Co., Ltd (HEC) challenging certain patents listed in the FDA Orange Book with reference to Nexium. HEC submitted an Abbreviated New Drug Application (ANDA) seeking to market esomeprazole magnesium capsules. AstraZeneca is reviewing HEC's notice.

In June 2015, AstraZeneca received a Paragraph IV Notice from Lupin Ltd (Lupin) challenging certain patents listed in the FDA Orange Book with reference to Nexium 24HR (OTC). Lupin submitted an ANDA seeking to market OTC esomeprazole magnesium capsules. AstraZeneca is reviewing Lupin's notice.

As previously disclosed, in March 2012, AstraZeneca filed a patent infringement lawsuit against Mylan Laboratories Limited and Mylan Inc. (together, Mylan) in the US District Court for the District of New Jersey. In July 2015, AstraZeneca filed a motion for preliminary injunction against Mylan's launch of its ANDA version of esomeprazole magnesium capsules. The patents-at-issue are US Patent Nos. 6,369,085 and 7,411,070. Both patents have a date of expiry of 25 May 2018.

Patent proceedings outside the US

As previously disclosed, in July 2014, in Canada, the Federal Court found Canadian Patent No. 2,139,653 invalid and not infringed by Apotex Inc. On 6 July 2015, AstraZeneca's appeal was dismissed.

As previously disclosed, in July 2014, in Canada, 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 commenced a proceeding in 2014, but has now discontinued its application pursuant to a settlement agreement.

Onglyza (saxagliptin) and Kombiglyze XR (saxagliptin and metformin)

Patent proceedings in the US

In June 2015, Mylan Pharmaceuticals, Inc. filed a petition for an Inter Parties Review with the US Patent Office challenging the validity of the saxagliptin compound patent, US RE44,186, that is listed in the FDA Orange Book for both Onglyza and Kombiglyze XR.

Pulmicort Respules (budesonide inhalation suspension)

Patent proceedings in the US

As previously disclosed, in February 2015, the US District Court for the District of New Jersey (the District Court) determined that the asserted claims of US Patent No. 7,524,834 was invalid. AstraZeneca appealed that decision and on 7 May 2015, the US Court of Appeals for the Federal Circuit affirmed the District Court's decision and lifted the injunction that was issued pending the appeal. Since 2009, various injunctions were issued in this matter. Damages claims based on those injunctions are expected and a provision has been taken in the first half of 2015.

Seroquel XR (quetiapine fumarate)

Patent proceedings in the US



Edgar Filing: ASTRAZENECA PLC - Form 6-K

As previously disclosed, in February 2015, AstraZeneca filed a patent infringement lawsuit against Macleods Pharmaceuticals, Ltd. Macleods Pharma USA, Inc. and AB Pharmaceuticals, LLC. (together, Macleods) in the US District Court for the District of New Jersey. In June 2015, AstraZeneca settled the patent infringement litigation by granting Macleods a license to the Seroquel XR product patent effective from 1 November 2016, or earlier in certain circumstances.

Patent proceedings outside the US

In Italy, in June 2015, following a challenge to the validity of the formulation patent covering Seroquel XR by Sandoz S.p.A. and Sandoz A/S, the Court of Turin found the Seroquel XR formulation patent invalid.

Product liability litigation

Nexium (esomeprazole magnesium)

As previously disclosed, of the approximately 1,900 plaintiffs who alleged that Nexium caused osteoporotic injuries, such as bone deterioration, loss of bone density and/or bone fractures, approximately 40 claims remained active in California state court and the rest of the claims were dismissed. In June 2015, the California state court granted AstraZeneca's motion for summary judgment and dismissed the approximately 40 remaining plaintiffs' claims. In addition, as previously disclosed, approximately 270 plaintiffs have appealed the dismissals of their claims and those appeals remain pending.

Commercial litigation

Average Manufacturer's Price qui tam litigation (Streck)

AstraZeneca was one of several manufacturers named as a defendant in a lawsuit filed in the US Federal Court in Philadelphia under the qui tam (whistleblower) provisions of the federal and certain state False Claims Acts alleging inaccurate reporting of Average Manufacturer's prices to the Centers for Medicare and Medicaid Services. The action was initially filed in October 2008 but remained under seal until May 2011. In July 2015, AstraZeneca agreed upon a negotiated settlement to resolve the dispute. A provision for this amount was previously taken.

6. PRODUCT SALES ANALYSIS – H1 2015

	World		US		Europe		Established ROW		Emerging Markets	
	H1		H1		H1		H1		H1	
	2015	CER	2015	CER	2015	CER	2015	CER	2015	CER
	\$m	%	\$m	%	\$m	%	\$m	%	\$m	%
Respiratory, Inflammation and Autoimmunity:										
Symbicort	1,687	-	717	(1)	582	(8)	201	9	187	28
Pulmicort	518	18	108	4	66	(7)	41	(2)	303	37
Tudorza/Eklira	85	n/m	45	n/m	36	n/m	4	n/m	-	-
Duaklir	7	n/m	-	n/m	6	n/m	1	n/m	-	-
Others	171	20	49	188	46	(7)	10	-	66	4
Total Respiratory, Inflammation and Autoimmunity	2,468	9	919	9	736	(3)	257	9	556	30
Cardiovascular and Metabolic disease:										
Brilinta/Brilique	275	42	101	60	110	21	17	36	47	80
Onglyza	391	4	211	(16)	71	23	32	30	77	56

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Bydureon	263	41	222	35	35	71	3	33	3	200
Byetta	172	8	121	15	30	(13)	10	-	11	33
Farxiga/Forxiga	205	n/m	115	n/m	53	n/m	11	44	26	n/m
Legacy:										
Crestor	2,477	(5)	1,374	(7)	469	(7)	282	(3)	352	5
Seloken/Toprol-XL	378	7	48	(9)	49	(3)	7	(20)	274	14
Atacand	194	(11)	18	(10)	53	(33)	15	(23)	108	8
Others	327	(4)	35	(5)	75	(13)	30	(21)	187	6
Total Cardiovascular and Metabolic Disease	4,682	4	2,245	2	945	-	407	(2)	1,085	16
Oncology:										
Iressa	273	(3)	-	-	66	(5)	68	(11)	139	3
Lynparza	30	n/m	26	n/m	4	n/m	-	n/m	-	n/m
Legacy:										
Zoladex	409	9	14	27	85	(15)	133	(2)	177	32
Faslodex	333	5	165	2	101	1	25	4	42	32
Casodex	139	(5)	1	(67)	15	(18)	66	(14)	57	17
Arimidex	126	(9)	7	(22)	25	(27)	40	(15)	54	14
Others	71	23	13	-	15	13	29	79	14	(11)
Total Oncology	1,381	5	226	15	311	(7)	361	(4)	483	18
Infection, Neuroscience and Gastrointestinal:										
Nexium	1,291	(27)	479	(49)	143	(10)	272	(6)	397	(1)
Seroquel XR	526	(7)	353	2	113	(25)	14	(30)	46	10
Synagis	270	(28)	160	(38)	110	(6)	-	-	-	n/m
Losec/Prilosec	181	(6)	12	(7)	48	(12)	39	(17)	82	6
FluMist/Fluenz	21	75	21	110	-	-	-	n/m	-	-
Movantik/Moventig	4	n/m	4	n/m	-	n/m	-	n/m	-	n/m
Others	760	(8)	106	(28)	195	(13)	141	1	318	(1)
Total Infection, Neuroscience and Gastrointestinal	3,053	(18)	1,135	(34)	609	(14)	466	(7)	843	-
TOTAL PRODUCT SALES	11,584	(2)	4,525	(9)	2,601	(5)	1,491	(2)	2,967	14

7. PRODUCT SALES ANALYSIS – Q2 2015

	World		US		Europe		Established ROW		Emerging Markets	
	Q2	CER	Q2	CER	Q2	CER	Q2	CER	Q2	CER
	2015	%	2015	%	2015	%	2015	%	2015	%
	\$m		\$m		\$m		\$m		\$m	
Respiratory, Inflammation and Autoimmunity:										
Symbicort	842	-	375	(1)	276	(9)	102	24	89	16
Pulmicort	232	19	56	8	28	(15)	21	5	127	44
Tudorza/Eklira	55	n/m	35	n/m	18	n/m	2	n/m	-	n/m
Duaklir	5	n/m	-	-	4	n/m	1	n/m	-	-

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Others	91	32	37	n/m	21	(16)	7	60	26	(18)
Total Respiratory, Inflammation and Autoimmunity	1,225	11	503	16	347	(3)	133	23	242	20
Cardiovascular and Metabolic disease:										
Brilinta/Brilique	144	38	55	57	56	21	9	38	24	59
Onglyza	208	(7)	113	(22)	34	(5)	18	25	43	38
Bydureon	140	29	116	22	19	53	2	50	3	-
Byetta	82	(1)	53	-	15	(22)	6	14	8	60
Farxiga/Forxiga	129	n/m	78	n/m	29	n/m	8	n/m	14	n/m
Legacy:										
Crestor	1,310	(3)	760	(1)	226	(9)	150	(4)	174	(1)
Seloken/Toprol-XL	184	6	21	(28)	24	(3)	4	-	135	16
Atacand	99	(13)	7	(22)	23	(38)	8	(9)	61	4
Others	156	(4)	15	(25)	36	(13)	15	(26)	90	12
Total Cardiovascular and Metabolic Disease	2,452	4	1,218	3	462	(3)	220	(1)	552	14
Oncology:										
Iressa	129	(1)	-	-	31	(5)	36	10	62	(4)
Lynparza	21	n/m	18	n/m	3	n/m	-	n/m	-	n/m
Legacy:										
Zoladex	215	14	8	60	41	(17)	71	2	95	41
Faslodex	172	9	82	(4)	52	10	13	15	25	50
Casodex	69	(5)	1	(50)	7	(18)	34	(13)	27	20
Arimidex	64	(6)	4	-	12	(25)	21	(7)	27	8
Others	37	20	7	-	7	13	16	90	7	(30)
Total Oncology	707	9	120	17	153	(4)	191	4	243	20
Infection, Neuroscience and Gastrointestinal:										
Nexium	647	(27)	254	(44)	69	(14)	144	(9)	180	(16)
Seroquel XR	264	(8)	184	2	50	(30)	7	(18)	23	4
Synagis	66	40	(2)	n/m	68	51	-	-	-	n/m
Losec/Prilosec	85	(9)	5	(17)	22	(15)	20	(14)	38	3
FluMist/Fluenz	14	180	14	180	-	-	-	-	-	-
Movantik/Moventig	1	n/m	1	n/m	-	-	-	-	-	-
Others	375	(11)	59	(19)	90	(18)	70	(13)	156	(2)
Total Infection, Neuroscience and Gastrointestinal	1,452	(17)	515	(28)	299	(12)	241	(10)	397	(8)
TOTAL PRODUCT SALES	5,836	(1)	2,356	(3)	1,261	(5)	785	-	1,434	9

ASTRAZENECA DEVELOPMENT PIPELINE 30 JUNE 2015

Phase III / Pivotal Phase II / Registration

Edgar Filing: ASTRAZENECA PLC - Form 6-K

NMEs and significant additional indications

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

† US and EU dates correspond to anticipated acceptance of the regulatory filing.

# Partnered product.

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing†			
				US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity							
anifrolumab#	IFN-alphaR mAb	SLE	Q3 20151	2019	2019	2019	
benralizumab#	IL-5R mAb	severe asthma	Q4 2013	H2 2016	H2 2016	N/A	N/A
CALIMA							
SIROCCO							
ZONDA BISE							
BORA							
GREGALE							
benralizumab#	IL-5R mAb	COPD	Q3 2014	2018	2018	N/A	N/A
TERRANOVA							
GALATHEA							
brodalumab	IL-17R mAb	psoriasis	Q3 2012	2015++	2015++		
AMAGINE-1,2,3							
brodalumab	IL-17R mAb	psoriatic arthritis	Q1 2014	++	++		
AMVISION-1,2							
lesinurad	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of patients with gout	Q4 2011	Filed	Filed		
CLEAR 1,2							
CRYSTAL							
PT003 GFF	LABA / LAMA	COPD	Q2 2013	Q3 2015	H1 2016	2017	2017
PINACLE							
PT010	LABA / LAMA / ICS	COPD	Q3 20151	2018	2018	2018	2019
tralokinumab	IL-13 mAb	severe asthma	Q3 2014	2018	2018	2018	
STRATOS 1,2							
TROPOS							
Cardiovascular and Metabolic Disease							
Brilinta/Brilique2	P2Y12 receptor antagonist	arterial thrombosis		Launched	Launched	Filed	Launched
Epanova#	omega-3 carboxylic acids	severe hypertriglyceridaemia		Approved		2017	2019
Farxiga/Forxiga3	SGLT-2 inhibitor	type-2 diabetes		Launched	Launched	Launched	Filed
roxadustat#	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in CKD/ESRD	Q3 2014	2018	N/A	N/A	H2 2016
OLYMPUS							
ROCKIES							
Oncology							
AZD9291	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M	Q2 2014	Filed 4	Filed	Q3 2015	2017
AURA 2,3							

Edgar Filing: ASTRAZENECA PLC - Form 6-K

		NSCLC		(Breakthrough designation)			
AZD9291 FLAURA Caprelsa	EGFR tyrosine kinase inhibitor VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	1st-line advanced EGFRm NSCLC medullary thyroid cancer	Q1 2015	2017	2017	2017	2020
				Launched	Launched	Filed	Filed
cediranib ICON 6	VEGFR tyrosine kinase inhibitor	PSR ovarian cancer	Q2 2007		Filed5 (Orphan Drug) 2020		
durvalumab (MEDI4736)# PACIFIC	PD-L1 mAb	stage III NSCLC	Q2 2014	2017		2020	
durvalumab (MEDI4736)# ATLANTIC¶	PD-L1 mAb	3rd-line NSCLC	Q1 2014	H1 2016 (Fast Track)	2017	2017	
durvalumab (MEDI4736)# + tremelimumab ARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	2017	2017	2017	
durvalumab (MEDI4736)# HAWK¶	PD-L1 mAb	2nd-line SCCHN (PD-L1 positive)	Q1 2015	H2 2016	H2 2016	H2 2016	
durvalumab (MEDI4736)# + tremelimumab CONDOR¶	PD-L1 mAb + CTLA-4 mAb	2nd-line SCCHN (PD-L1 negative)	Q2 2015	2017	2017	2017	
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2018	2018		
selumetinib# SELECT-1	MEK inhibitor	2nd-line KRASm NSCLC	Q4 2013	2017	2017		
selumetinib# ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2018	2018		
tremelimumab¶ DETERMINE	CTLA-4 mAb	mesothelioma	Q2 2014	H1 2016 (Orphan Drug)	H2 2016	H2 2016	
Infection, Neuroscience and Gastrointestinal							
CAZ AVI# RECLAIM	cephalosporin/ beta lactamase inhibitor	serious infections	Q1 2012	N/A	Filed		2017
CAZ AVI# REPROVE	cephalosporin/ lactamase inhibitor	betahospital-acquired pneumonia/ ventilator-associated pneumonia	Q2 2013	N/A	Filed		2017
Zinforo#	extended spectrum cephalosporin with affinity to penicillin-binding	pneumonia/skin infections		N/A	Launched	N/A	Filed

proteins

# Partnered product.

¶ Registrational Phase II/III study.

++ Amgen recently announced the termination of its co-development and commercialisation agreement with AstraZeneca for brodalumab; AstraZeneca is proceeding with the transfer of the programme from Amgen and will communicate additional decisions in due course.

1 First patient dosed July 2015.

2 Brilinta in the US; Brilique in rest of world.

3 Farxiga in the US; Forxiga in rest of world.

4 AZD9291 filed in Q2. US regulatory submission acceptance anticipated in Q3 2015.

5 Cediranib regulatory submission accepted in Q3 2015.

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	Estimated Filing			
					US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity								
abediterol (AZD0548)	LABA	asthma/COPD	II	Q4 2007				
AZD7624	inhaled P38 inhibitor	COPD	II	Q4 2014				
AZD9412#	inhaled interferon beta	asthma/COPD	II	Q1 2010				
mavrilimumab#	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010				
MEDI-551#	CD19 mAb	neuromyelitis optica <sup>2</sup>	II	Q1 2015				
MEDI2070#	IL-23 mAb	Crohn's disease	II	Q1 2013				
abrilimumab (MEDI7183)#	alpha(4)beta(7) mAb	Crohn's disease / ulcerative colitis	II	Q4 2012				
MEDI9929#	TSLP mAb	asthma	II	Q2 2014				
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014				
RDEA3170	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of patients with hyperuricaemia or gout	II	Q3 2013				
sifalimumab#	IFN-alpha mAb	SLE3	II	Q3 2008				
tralokinumab	IL-13 mAb	IPF	II	Q4 2012				
tralokinumab	IL-13 mAb	atopic dermatitis	II	Q1 2015				
AZD1419#	TLR9 agonist	asthma	I	Q3 2013				
AZD7594	inhaled SGRM	asthma/COPD	I	Q3 2012				
AZD7986	DPP1	COPD	I	Q4 2014				
AZD8999	MABA	COPD	I	Q4 2013				
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014				
MEDI5872#	B7RP1 mAb	SLE	I	Q4 2008				

Edgar Filing: ASTRAZENECA PLC - Form 6-K

MEDI7836	IL-13 mAb-YTE	asthma	I	Q1 2015				
	Cardiovascular and Metabolism							
AZD4901	NK3 receptor antagonist	polycystic ovarian syndrome	II	Q2 2013				
MEDI0382	GLP-1/ glucagon dual agonist	diabetes / obesity	I	Q1 2015				
MEDI6012	LCAT	ACS	I	Q1 2012				
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014				
	Oncology							
AZD1775#	WEE-1 inhibitor	ovarian cancer	II	Q4 2012				
AZD2014	mTOR serine/ threonine kinase inhibitor	solid tumours	II	Q1 2013				
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011				
MEDI-551#	CD19 mAb	CLL / DLBCL	II	Q1 2012				
MEDI-573#	IGF mAb	metastatic breast cancer	II	Q2 2012				
selumetinib#	MEK inhibitor	2nd-line KRAS wt NSCLC	II	Q1 2013				
AZD5363#	AKT kinase inhibitor	breast cancer	II	Q1 2014				
Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	US	Estimated Filing		
						EU	Japan	China
durvalumab (MEDI4736)#	PD-L1 mAb	solid tumours	II	Q3 2014				
durvalumab (MEDI4736)# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015				
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	pALL	II	Q3 2014				
savolitinib/ volitinib (AZD6094)#	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 2014				
AZD3759	EGFR tyrosine kinase inhibitor	advanced EGFRm NSCLC	I	Q4 2014				
AZD5312#	androgen receptor inhibitor	solid tumours	I	Q2 2014				
AZD6738	ATR serine / threonine kinase inhibitor	solid tumours	I	Q4 2013				
AZD8186	PI3 kinase beta inhibitor	solid tumours	I	Q2 2013				
AZD8835	PI3 kinase alpha inhibitor	solid tumours	I	Q4 2014				
AZD9150#	STAT3 inhibitor	haematological malignancies	I	Q1 2012				

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AZD9291 + (durvalumab (MEDI4736)# or selumetinib# or volitinib#) TATTON AZD9496	EGFR tyrosine kinase inhibitor + (PD-L1 mAb or MEK inhibitor or MET tyrosine kinase inhibitor) selective oestrogen receptor downregulator (SERD)	advanced EGFRm NSCLC ER+ breast cancer	I	Q3 2014
durvalumab (MEDI4736)# after (AZD9291 or Iressa or (selumetinib# +docetaxel) or tremelimumab)	PD-L1 mAb + (EGFR tyrosine kinase inhibitor or MEK inhibitor or CTLA-4 mAb)	NSCLC	I	Q3 2014
durvalumab (MEDI4736)#	PD-L1 mAb	solid tumours	I	Q3 2014
durvalumab (MEDI4736)# + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	I	Q2 2014
durvalumab (MEDI4736)# + MEDI6383#	OX40 agonist + PD-L1 mAb	solid tumours	I	Q2 2015
durvalumab (MEDI4736)# + MEDI6469#	PD-L1 mAb + murine OX40 agonist	solid tumours	I	Q3 2014
durvalumab (MEDI4736)# + dabrafenib + trametinib1 Iressa +	PD-L1 mAb+ EGFR tyrosine kinase inhibitor PD-L1 mAb + CTLA-4 mAb	melanoma	I	Q1 2014
durvalumab (MEDI4736)# durvalumab (MEDI4736)# + tremelimumab MEDI0562#	PD-L1 mAb+ EGFR tyrosine kinase inhibitor PD-L1 mAb + CTLA-4 mAb humanised OX40 agonist	NSCLC	I	Q2 2014
MEDI-565#	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0639#	DLL-4 mAb	solid tumours	I	Q2 2012
MEDI0680	PD-1 mAb	solid tumours	I	Q4 2013
MEDI3617#	ANG-2 mAb	solid tumours	I	Q4 2010
MEDI-551# + MEDI0680	CD19 mAb + PD-1 mAb	DLBCL	I	Q4 2014
MEDI-551# + rituximab	CD19 mAb + CD20 mAb	haematological malignancies	I	Q2 2014
MEDI6383#	OX40 agonist	solid tumours	I	Q3 2014
MEDI6469#	murine OX40 agonist	solid tumours	I	Q1 2006



Edgar Filing: ASTRAZENECA PLC - Form 6-K

MEDI6469# + rituximab	murine OX40 agonist + CD20 mAb	solid tumours	I	Q1 2015	
MEDI6469# + tremelimumab	murine OX40 agonist + CTLA-4 mAb	solid tumours	I	Q4 2014	
Infection, Neuroscience and Gastrointestinal					
AZD3241	myeloperoxidase inhibitor	multiple system atrophy	II	Q2 2012	
AZD3293#	beta-secretase inhibitor	Alzheimer's disease	II	Q4 2014	
AZD5213	histamine-3 receptor antagonist	Tourette's syndrome / neuropathic pain	II	Q4 2013	
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis	II	Q4 2012	
AZD8108	NMDA antagonist	suicidal ideation	I	Q4 2014	
CXL#	beta lactamase inhibitor / cephalosporin	MRSA	II	Q4 2010	
MEDI1814	amyloid beta mAb	Alzheimer's disease	I	Q2 2014	
MEDI4893	MAB binding to S. aureus toxin	hospital-acquired pneumonia / serious S. aureus infection	II	Q4 2014	(Fast Track)
MEDI8897#	RSV mAb-YTE	passive RSV prophylaxis	II	Q1 2015	(Fast Track)
ATM AVI#	monobactam/ beta lactamase inhibitor	targeted serious bacterial infections	I	Q1 2015	
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	I	Q2 2006	
MEDI3902	anti-Psl/PcrV	prevention of nosocomial pseudomonas pneumonia	I	Q3 2014	(Fast Track)
MEDI7510	RSV sF+GLA-SE	prevention of RSV disease in older adults	I	Q2 2014	
MEDI8852	influenza A mAb	influenza A treatment	I	Q1 2015	

# Partnered product.

1 MedImmune-sponsored study in collaboration with Novartis.

2 Neuromyelitis optica now lead indication. Multiple sclerosis Phase I study continuing.

3 SLE project stopped but molecule under evaluation for alternative indications.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Significant Life-Cycle Management

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing†			
				US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity							
Duaklir Genuair#	LAMA/LABA	COPD		2018	Launched	2018	2018
Symbicort	ICS/LABA	as needed use in mild asthma	Q4 2014	N/A	2018		2019
SYGMA							
Symbicort1	ICS/LABA	breath actuated Inhaler asthma/COPD		2018			
Cardiovascular and Metabolism							
Brilinta/Brilique2 EUCLID	P2Y12 receptor antagonist	outcomes study in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018
Brilinta/Brilique2 HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q4 2014	2020	2020		
Brilinta/Brilique2 PEGASUS-TIMI 54	P2Y12 receptor antagonist	outcomes study in patients with prior myocardial infarction	Q4 2010	Filed (Priority Review)	Filed	Q4 2015	2017
Brilinta/Brilique2 SOCRATES	P2Y12 receptor antagonist	outcomes study in patients with stroke or TIA	Q1 2014	H1 2016	H1 2016	H2 2016	2017
Brilinta/Brilique2 THEMIS	P2Y12 receptor antagonist	outcomes study in patients with type-2 diabetes and CAD, but without a previous history of MI or stroke	Q1 2014	2018	2018	2018	2018
Bydureon Dual Chamber Pen	GLP-1 receptor agonist	type-2 diabetes		Launched	Launched	Approved	
Bydureon EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes study	Q2 2010	2018	2018	2018	
Bydureon weekly suspension	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	Q4 2015	Q4 2015		
Epanova STRENGTH	omega-3 carboxylic acids	outcomes study in statin-treated patients at high CV risk, with persistent hypertriglyceridemia plus low HDL-cholesterol	Q4 2014	2020	2020	2020	2020
Epanova/Farxiga/Forxiga3	omega-3 carboxylic acids/ SGLT-2 inhibitor	Non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	Q1 2015				
Farxiga/Forxiga3			Q2 2013	2020	2020		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

DECLARE-TIMI 58	SGLT-2 inhibitor	type-2 diabetes outcomes study					
Farxiga/Forxiga3	SGLT-2 inhibitor	type-1 diabetes	Q4 2014	2018	2017	2018	
Kombiglyze XR/Komboglyze4	DPP-4 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		Filed
Onglyza SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes study	Q2 2010	Filed	Launched		Q4 2015
saxagliptin/ dapagliflozin FDC	DPP-4 inhibitor/ SGLT-2 inhibitor FDC	type-2 diabetes	Q2 2012	Filed	Filed		
Xigduo XR/ Xigduo5	SGLT-2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		
Oncology Caprelsa	VEGFR/EGFR tyrosine kinase inhibitor with RET kinase activity	differentiated thyroid cancer	Q2 2013	H1 2016	H1 2016	H1 2016	
Faslodex FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer	Q4 2012	H2 2016	H2 2016	H2 2016	2017
Iressa	EGFR tyrosine kinase inhibitor	EGFRm NSCLC		Approved6	Launched	Launched	Launched
Lynparza (olaparib) SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	2017	2017	2017	
Lynparza (olaparib) SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	H1 2016	H1 2016	H2 2016	
Lynparza (olaparib) SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	2018			
Lynparza (olaparib) GOLD	PARP inhibitor	2nd-line gastric cancer	Q3 2013			2017	
Lynparza (olaparib) OlympiA	PARP inhibitor	gBRCA adjuvant triple negative breast cancer	Q2 2014	2020	2020	2020	
Lynparza (olaparib) OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	H2 2016	H2 2016	H2 2016	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Lynparza (olaparib) POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2017	2017	2017	
Lynparza (olaparib)	PARP inhibitor	prostate cancer	Q3 2014				
Infection, Neuroscience and Gastrointestinal							
Diprivan#	sedative and anaesthetic	conscious sedation		N/A	Launched	Filed	Launched
Entocort	glucocorticoid steroid	Crohn's disease / ulcerative colitis		Launched	Launched	Q3 2015	N/A
linaclotide#	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	Q4 2015
Nexium	proton pump inhibitor	stress ulcer prophylaxis					2017
Nexium	proton pump inhibitor	paediatrics		Launched	Launched	H2 2016	

# Partnered product.

- 1 Development of a new BAI device is ongoing.
- 2 Brilinta in the US; Brilique in rest of world.
- 3 Farxiga in the US; Forxiga in rest of world.
- 4 Kombiglyze XR in the US; Komboglyze in the EU.
- 5 Xigduo XR in the US; Xigduo in the EU.
- 6 Approved by FDA in July 2015.

Faslodex 500 mg approved in China in Q2 for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer (replaces 250mg dose).

Terminations (discontinued projects between 1 April and 30 June 2015)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	selumetinib# SUMIT	Safety/efficacy	uveal melanoma
NME	tenapanor (AZD1722)#	Safety/efficacy	ESRD-Pi/CKD with T2DM
LCM	Nexium	Regulatory	refractory reflux oesophagitis (JP)

Completed Projects / Divestitures

Compound	Mechanism	Area Under Investigation	Phase	Estimated Filing			
				US	EU	Japan	China
Neuroscience Movantik/ Moventig#1	oral peripherally-acting	opioid-induced constipation		Launched	Launched		

mu-opioid receptor  
antagonist

# Partnered product.

1 Movantik in the US; Moventig in EU.

#### Shareholder Information

##### Announcements and Meetings

Announcement of nine months and third  
quarter results 5 November 2015

Announcement of full year and fourth  
quarter results 4 February 2016

##### Dividends

Future dividends will normally be paid as follows:

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

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

The record date for the first interim dividend for 2015, payable on 14 September 2015, will be 14 August 2015. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 13 August 2015. American Depositary Shares listed in New York will trade ex-dividend from 12 August 2015.

##### ADR Programme

AstraZeneca announced an intended ratio change to its NYSE-listed sponsored Level 2 American Depositary Receipt (ADR) programme on 26 June 2015. The prior ratio was one American Depositary Share (ADS) per one Ordinary Share. Effective from 27 July 2015 the new ratio became two ADSs per one Ordinary Share. There was no change to the underlying Ordinary Shares.

ADS holders at the close of business New York time on the record date, 22 July 2015, received a distribution of one additional ADS for every ADS held. The new ADSs were distributed on 24 July 2015. No action was required by ADS holders to effect this change.

##### 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 Daliresp, a trademark of Takeda GmbH; Duaklir Genuair, Duaklir, Eklira, Tudorza and Tudorza Pressair, trademarks of Almirall, S.A.; Epanova, a trademark of Chrysalis Pharma AG; Imbruvica, a trademark of Pharmacyclics, Inc.; Zinforo, a trademark of Forest Laboratories; Zydelig, a trademark of GILEAD SCIENCES IRELAND UC; and Zytiga, a trademark of Johnson & Johnson.

##### Addresses for Correspondence

Registrar and Transfer Office Equiniti Limited Aspect House Spencer Road Lancing West Sussex	US Depositary Citibank Shareholder Services PO Box 43077 Providence RI 02940-3077 USA	Registered Office 2 Kingdom Street London W2 6BD UK	Swedish Central Securities Depository Euroclear Sweden AB PO Box 191
--	---	---	---

BN99 6DA  
UK

SE-101 23  
Stockholm  
Sweden

Tel (freephone in UK): 0800 389 1580  
Tel (outside UK): +44 (0)121 415 7033  
Tel: +44 (0)207 500 2030  
or +1 877 248 4237  
(1 877-CITI-ADR)/  
E-mail: citiadr@citi.com  
Tel: +44 (0)20 7604 8000  
Tel: +46 (0)8 402 9000

#### Cautionary Statements 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: This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. 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 this document 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, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; effects of patent litigation in respect of IP rights; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions, including licensing and collaborations, 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 of outsourcing; the risks associated with manufacturing biologics; the risk of delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to adhere to applicable laws, rules and regulations; the risk of failure to adhere to applicable laws, rules and regulations relating to anti-competitive behaviour; the risk that new products do not perform as we expect; failure to achieve strategic priorities or to meet targets or expectations; the risk of an adverse impact of a sustained economic downturn; political and socio-economic conditions; the risk of environmental liabilities; the risk of occupational health and safety liabilities; the risk associated with pensions liabilities; the risk of misuse of social media platforms and new technology; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the risks from pressures resulting from generic competition; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; economic, regulatory and political pressures to limit or reduce the cost of our products; 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; the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; and the risk of failure of information technology and cybercrime. Nothing in this presentation / webcast should be construed as a profit forecast.

SIGNATURES

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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: 30 July 2015

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