

ASTRAZENECA PLC  
Form 6-K  
February 05, 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 February 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

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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.

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

AstraZeneca PLC  
FOURTH QUARTER AND FULL YEAR RESULTS 2014

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London, 5 February 2015

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

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

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

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

A record six product approvals in 2014.

Pipeline progress since Q3 2014 results:

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

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

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

2015 Newsflow:

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

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

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

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

### Financial Summary

Group	Q4 2014	Actual	CER	FY 2014	Actual	CER
	\$m	%	%	\$m	%	%
Revenue	6,683	(2)	2	26,095	1	3
Core*						
Operating Profit	1,184	(40)	(33)	6,937	(17)	(13)
Earnings per Share	\$0.76	(38)	(28)	\$4.28	(15)	(8)
Reported						

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Operating (Loss)/Profit	(349)	(41)	(59)	2,137	(42)	(31)
(Loss)/Earnings per Share	(\$0.25)	(40)	(69)	\$0.98	(52)	(34)

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

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

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

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

#### Research and Development Update

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

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

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

#### Symbicort SYGMA trial start

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

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

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

#### Duaklir Genuair approval

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

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

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

AstraZeneca owns the rights to develop and commercialise Duaklir Genuair in the EU following the strategic transaction with Almirall S.A. (Almirall) in respiratory disease, which was completed in October 2014. The EU approval of Duaklir Genuair marks an important further step in AstraZeneca's inhaled therapy strategy of providing physicians and patients with a choice of products uniquely available in both dry powder and pressurised metered dose devices.

#### Lesinurad

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

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

#### Brodalumab

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

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

achieved PASI 75.

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

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

Brodalumab is being developed in collaboration with Amgen.

American College of Rheumatology 2014 Annual Meeting

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

More than 15 abstracts were featured at the ACR meeting, providing evidence of the depth and continued progress of AstraZeneca's inflammation and autoimmunity pipeline. Positive Phase III data was presented on lesinurad in gout, as well as earlier stage data around a number of innovative investigational medicines including sifalimumab and anifrolumab in systemic lupus erythematosus (lupus), mavrilimumab in rheumatoid arthritis, and brodalumab in psoriatic arthritis.

MEDI4736 (PD-L1)

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

Lynparza

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

On 19 December 2014, AstraZeneca announced that the FDA had approved Lynparza capsules (400mg twice-daily) as the first monotherapy for patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer, who have been treated with three or more prior lines of chemotherapy. Lynparza was approved under the FDA's Accelerated Approval programme, based on existing objective response rate and duration of

response data. Continued approval for this indication is contingent upon verification of clinical benefit in ongoing confirmatory Phase III trials.

#### Iressa

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

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

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

#### Epanova STRENGTH trial start

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

#### Brilinta

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

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

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

#### Moventig

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

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

open label, long-term safety study.

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

Start of pivotal trial for BACE inhibitor AZD3293

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

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

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

Business Development

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

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

Collaborations to use CRISPR technology for genome editing in drug discovery

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

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

Operating and Financial Review

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

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

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

#### Fourth Quarter

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

	Reported	Amortisation	Acquisition	share of	Other	Core	Core	Q4	CER	
	Q4 2014	Restructuring	Intangible of the BMS	diabetes	Q4 2014	Q4 2014	2013	Actual	%	%
		Impairments	&	alliance						
Revenue	6,683	-	-	-	-	6,683	6,844	(2)		2
Cost of Sales	(1,667)	35	273	-	-	(1,359)	(1,289)			
Gross Profit	5,016	35	273	-	-	5,324	5,555	(4)		1
% sales	75.1%					79.7%	81.2%	-1.5		-0.6
Distribution	(88)	-	-	-	-	(88)	(72)	22		28
% sales	1.3%					1.3%	1.1%	-0.2		-0.3
R&D	(1,499)	97	42	-	-	(1,360)	(1,205)	13		17
% sales	22.5%					20.4%	17.6%	-2.8		-2.6
SG&A	(4,084)	259	211	636	25	(2,953)	(2,483)	19		23
% sales	61.1%					44.2%	36.3%	-7.9		-7.6
Other Income	306	-	53	-	(98)	261	188	39		47
% sales	4.6%									