

ASTRAZENECA PLC
Form 6-K
November 06, 2014

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

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

For the month of November 2014

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

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

Form 20-F Form 40-F

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

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

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

Yes No

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

ASTRAZENECA DEVELOPMENT PIPELINE, 30 SEPTEMBER 2014

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Phase III / Pivotal / Registration

NMEs and significant additional indications

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

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Cardiovascular and Metabolism							
Brilinta/ Brilique1	ADP receptor antagonist	arterial thrombosis		Launched	Launched	Filed	Launched
Epanova#	omega-3 free fatty acids	hypertriglyceridaemia		Approved			
Farxiga / Forxiga2	SGLT-2 inhibitor	Type 2 diabetes		Launched	Launched	Launched	Filed
Myalept	leptin analogue	lipodystrophy		Launched	2015	N/A	
roxadustat#	hypoxia-inducible factor inhibitor	anaemia in CKD / ESRD	Q3 2014	2018	N/A	N/A	2016
Oncology							
AZD9291	EGFR tyrosine kinase inhibitor	advanced EGFRm T790M NSCLC	Q2 2014	2015	2015	2015	2017
Caprelsa	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer		Launched	Launched	Q4 2014	Filed
MEDI4736# PACIFIC	anti-PD-L1 MAb	stage III NSCLC	Q2 2014	2017	2020	2020	
MEDI4736# ATLANTIC¶	anti-PD-L1 MAb	3rd line NSCLC	Q1 2014	2016	2017	2017	
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2018	2018		
Lynparza (olaparib)	PARP inhibitor	BRCAm PSR ovarian cancer		Filed	Filed7#		
Lynparza (olaparib)SOLO-1	PARP inhibitor	1st line BRCAm ovarian cancer	Q3 2013	2017	2017	2017	2018
Lynparza (olaparib) SOLO-2	PARP inhibitor	BRCAm PSR ovarian cancer	Q3 2013	2016	2016	2016	2016
Lynparza (olaparib) GOLD	PARP inhibitor	2nd line gastric cancer	Q3 2013			2017	2018

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Lynparza (olaparib) OlympiA	PARP inhibitor	adjuvant breast cancer	Q2 2014	2020	2020	2020	2021
Lynparza (olaparib) OlympiAD	PARP inhibitor	metastatic breast cancer	Q2 2014	2016	2016	2016	
selumetinib# SELECT-1	MEK inhibitor	2nd line KRAS+ NSCLC	Q4 2013	2017	2017		
selumetinib# ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2017	2017		
selumetinib# SUMIT	MEK inhibitor	uveal melanoma	Q2 2014	2015	2015		
tremelimumab#	anti-CTLA-4 MAb	mesothelioma	Q2 2014	2016	2016	2016	

Phase III / Pivotal / Registration (continued)

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity							
benralizumab# CALIMA, SIROCCO, ZONDA	anti-IL-5R MAb	severe asthma	Q4 2013	2016	2016		
benralizumab# TERRANOVA, GALATHEA	anti-IL-5R MAb	COPD	Q3 2014	2018	2018		
brodalumab# AMAGINE-1,2,3	anti-IL-17R MAb	psoriasis	Q3 2012	++	++		
brodalumab# AMVISION-1,2	anti-IL-17R MAb	psoriatic arthritis	Q1 2014	++	++		
Lesinurad3 CLEAR 1,2 CRYSTAL	selective uric acid reabsorption inhibitor (SURI)	chronic treatment of patients with gout	Q4 2011	Q4 2014	Q4 2014		
PT003 GFF	LAMA / LABA	COPD	Q2 2013	2015	2016	2017	2017
PT001 GP	LAMA	COPD	Q2 2013	2016	2016	2017	2017
tralokinumab STRATOS 1-2 TROPOS	anti-IL-13 MAb	severe asthma	Q3 2014	2018	2018	2018	
Infection							
CAZ AVI#4 RECLAIM	cephalosporin / beta lactamase inhibitor	serious infections	Q1 2012	N/A	2015		2016
CAZ AVI#4 REPROVE	cephalosporin / beta lactamase inhibitor	hospital-acquired pneumonia / ventilator-associated	Q2 2013	N/A	2017		2018

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Zinforo#	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia pneumonia / skin infections	N/A	Launched	N/A	Filed
Neuroscience						
Movantik/Moventig5#	oral peripherally-acting mu-opioid receptor antagonist	opioid-induced constipation	Approved	Filed6		

Partnered product.

¶ Registrational Phase II / III study.

++ Filing is the responsibility of the partner.

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

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

3 Regulatory approval no longer being sought in China. This market will be served by RDEA3170.

4 No current plan to launch CAZ AVI in Japan.

5 Movantik in the US; Moventig in EU.

6 Positive opinion received.

7 Positive opinion announced on 24 October 2014.

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	Estimated Filing			
					US	EU	Japan	China
Cardiovascular and Metabolism								
tenapanor (AZD1722)#	NHE3 inhibitor	ESRD-Pi / CKD with T2DM1	II	Q1 2013				
AZD4901	hormone modulator	polycystic ovarian syndrome	II	Q2 2013				
AZD1979	melanin-concentrating hormone (MCH) receptor	obesity	I	Q2 2014				
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		solid tumours	II	Q1 2013				

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	mTOR serine / threonine kinase inhibitor				
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011	
MEDI-551#	anti-CD19 MAB	CLL / DLBCL	II	Q1 2012	
MEDI-573#	anti-IGF MAB	metastatic breast cancer	II	Q2 2012	
Lynparza (olaparib)	PARP inhibitor	prostate cancer	II	Q3 2014	
selumetinib#	MEK inhibitor	2nd line KRAS- NSCLC	II	Q1 2013	
AZD5363#	AKT kinase inhibitor	breast cancer	II	Q1 2014	
MEDI4736#	anti-PD-L1 MAB	solid tumours	II	Q3 2014	
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	pALL	II	Q3 2014	
volitinib#	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 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	
AZD9150#	STAT3 inhibitor	haematological malignancies	I	Q1 2012	
AZD9291 + (MEDI4736# or selumetinib# or volitinib#)	EGFR tyrosine kinase inhibitor + (anti-PD-L1 or MEK inhibitor or MET tyrosine kinase inhibitor)	advanced EGFRm NSCLC	I	Q3 2014	

Phases I and II (continued)

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	Estimated Filing			
					US	EU	Japan	China
Oncology (continued)		NSCLC	I	Q3 2014				

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MEDI4736# after (AZD9291 or Iressa or (selumetinib# +docetaxel) or tremelimumab) TATTON	anti-PD-L1 MAB + (EGFR tyrosine kinase inhibitor or MEK inhibitor or anti- CTLA-4 MAb)			
MEDI-565#	anti-CEA BiTE MAb	solid tumours	I	Q1 2011
MEDI0639#	anti-DLL-4 MAB	solid tumours	I	Q2 2012
MEDI0680	anti-PD-1 MAB	solid tumours	I	Q4 2013
MEDI3617#	anti-ANG-2 MAB	solid tumours	I	Q4 2010
MEDI4736#	anti-PD-L1 MAB	various cancers	I	Q3 2014
MEDI4736# + MEDI0680	anti-PD-L1 MAB + anti-PD- 1 MAB	solid tumours	I	Q2 2014
MEDI4736# + MEDI6469	anti-PD-L1 MAB + murine OX40 agonist	solid tumours	I	Q3 2014
MEDI4736# + dabrafenib + trametinib2	anti-PD-L1 MAB + BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
MEDI4736# + Iressa	anti-PD-L1 MAB + EGFR tyrosine kinase inhibitor	NSCLC	I	Q2 2014
MEDI4736# + tremelimumab	anti-PD-L1 MAB + anti- CTLA-4 MAB	solid tumors	I	Q4 2013
MEDI-551# + rituximab3	anti-CD19 MAB + anti-CD20 MAB	haematological malignancies	I	Q2 2014
MEDI6383	OX40 agonist	solid tumours	I	Q3 2014
MEDI6469#	murine OX40 agonist	solid tumours	I	Q1 2006
Respiratory, Inflammation and Autoimmunity				
AZD2115#	MABA	COPD	II	Q2 2012
AZD9412#	inhaled interferon	asthma / COPD	II	Q1 2010
anifrolumab#	anti-IFN- alphaR MAB	SLE	II	Q1 2012
brodalumab#	anti-IL-17R MAB	asthma	II	Q2 2013
mavrilimumab#			II	Q1 2010

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	anti-GM-CSFR MAb	rheumatoid arthritis		
MEDI2070#	anti-IL-23 MAb	Crohn's disease	II	Q1 2013
MEDI7183#	anti-a4b7 MAb	Crohn's disease / ulcerative colitis	II	Q4 2012
MEDI9929#	anti-TSLP MAb	asthma	II	Q2 2014
PT010	LAMA / LABA / ICS	COPD	II	Q2 2014
RDEA3170	selective uric acid reabsorption inhibitor (SURI)	chronic management of hyperuricaemia in patients with gout	II	Q3 2013
sifalimumab#	anti-IFN-alpha MAb	SLE	II	Q3 2008
tralokinumab	anti-IL-13 MAb	IPF	II	Q4 2012

Phases I and II (continued)

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	US	Estimated Filing		
						EU	Japan	China
Respiratory, Inflammation and Autoimmunity (continued)								
AZD1419#	TLR9 agonist	asthma	I	Q3 2013				
AZD7594	inhaled SGRM	asthma / COPD	I	Q3 2012				
AZD7624	inhaled P38 inhibitor	COPD	I	Q1 2013				
MEDI-551#	anti-CD19 MAb	multiple sclerosis	I	Q3 2012				
MEDI4920	anti-CD40L- Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014				
MEDI5872#	anti-B7RP1 MAb	SLE	I	Q4 2008				
Infection								
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis	II	Q4 2012				
CXL#	beta lactamase inhibitor / cephalosporin	MRSA	II	Q4 2010				
ATM AVI	monobactam / beta lactamase inhibitor	targeted serious bacterial infections	I	Q4 2012				
AZD0914	GyrAR		I	Q4 2013				

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		serious bacterial infections			
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	I	Q2 2006	
MEDI-559	paediatric RSV vaccine	RSV prophylaxis	I	Q4 2008	
MEDI4893	MAB binding to S. aureus toxin	hospital-acquired pneumonia / serious S. aureus infection	I	Q1 2013	
MEDI3902	anti-Psl/PcrV	pseudomonas	I	Q3 2014	
MEDI7510	RSV sF+GLA-SE	prevention of RSV disease in older adults	I	Q2 2014	
MEDI8897#	anti-RSV MAb-YTE	passive RSV prophylaxis	I	Q2 2014	
Neuroscience					
AZD3241	myeloperoxidase inhibitor	multiple system atrophy ⁵	II	Q2 2012	
AZD5213	histamine-3 receptor antagonist	Tourette's syndrome / neuropathic pain	II	Q4 2013	
AZD3293#	beta-secretase inhibitor	Alzheimer's disease	I	Q4 2012	
AZD6423	NMDA antagonist	suicidal ideation	I	Q3 2013	
MEDI1814	anti-amyloid beta MAB	Alzheimer's disease	I	Q2 2014	

Partnered product.

- 1 Fluid retention indication for tenapanor terminated in Q2.
- 2 MedImmune-sponsored study in collaboration with GSK.
- 3 MedImmune-sponsored study in collaboration with Genentech.
- 4 Original programme terminated in 2013. Programme now reinitiated.
- 5 Multiple system atrophy is now the lead indication for this molecule.

Line Extensions

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Cardiovascular and Metabolism							
Brilinta / Brilique1 EUCLID	ADP receptor antagonist	outcomes study in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018

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Brilinta / Brilique1 PEGASUS- TIMI 54	ADP receptor antagonist	outcomes study in patients with prior myocardial infarction	Q4 2010	2015	2015	2015	2017
Brilinta / Brilique1 SOCRATES	ADP receptor antagonist	outcomes study in patients with stroke or TIA	Q1 2014	2016	2016	2016	2017
Brilinta / Brilique1 THEMIS	ADP receptor antagonist	outcomes study in patients with type 2 diabetes and CAD, but without a previous history of MI or stroke	Q1 2014	2017	2017	2018	2018
Bydureon Dual Chamber Pen	GLP-1 receptor agonist	type 2 diabetes		Launched	Approved	Filed	
Bydureon EXSCEL	GLP-1 receptor agonist	type 2 diabetes outcomes study	Q2 2010	2018	2018	2018	
Bydureon weekly suspension	GLP-1 receptor agonist	type 2 diabetes	Q1 2013	2015	2015		
Farxiga / Forxiga2 DECLARE- TIMI 58	SGLT-2 inhibitor	type 2 diabetes outcomes study	Q2 2013	2020	2020		
Kombiglyze XR FDC / Komboglyze FDC3	DPP-4 inhibitor / metformin FDC	type 2 diabetes		Launched	Launched		Filed
Onglyza SAVOR- TIMI 53	DPP-4 inhibitor	type 2 diabetes outcomes study	Q2 2010	Filed	Launched		2015
saxagliptin / dapagliflozin FDC	DPP-4 inhibitor / SGLT-2 inhibitor FDC	type 2 diabetes	Q2 2012	2015	2015		
Xigduo XR FDC / Xigduo FDC4	SGLT-2 inhibitor / metformin FDC	type 2 diabetes		Filed	Approved ⁶		
Oncology Caprelsa	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	differentiated thyroid cancer	Q2 2013	2016	2016	2016	

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Faslodex FALCON	oestrogen receptor antagonist	1st line hormone receptor +ve advanced breast cancer	Q4 2012	2016	2016	2016	2016
Respiratory, Symbicort5	Inflammation and ICS / LABA	Autoimmunity Breath Actuated Inhaler asthma / COPD					

Line Extensions (continued)

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Neuroscience							
Diprivan#	sedative and anaesthetic	conscious sedation		N/A	Launched	Q4 2014	Launched
Gastrointestinal							
Entocort	glucocorticoid steroid	Crohn's disease / ulcerative colitis		Launched	Launched	2015	N/A
linaclotide#	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	2015
Nexium	proton pump inhibitor	refractory reflux esophagitis		N/A	N/A	Q4 2014	N/A
Nexium	proton pump inhibitor	stress ulcer prophylaxis		N/A	N/A	N/A	2017
Nexium	proton pump inhibitor	paediatrics		Launched	Launched	2016	TBD

Partnered product.

- 1 Brilinta in the US; Brilique in rest of world.
- 2 Farxiga in the US; Forxiga in rest of world.
- 3 Kombiglyze XR in the US; Komboglyze FDC in the EU.
- 4 Xigduo XR FDC in the US; Xigduo FDC in the EU.
- 5 Development of a new BAI device is ongoing.
- 6 Approval announced on 30 October 2014.

Completed projects

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Nexium	proton pump inhibitor	peptic ulcer bleeding		Launched	Launched	N/A	Launched

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Terminations (discontinued projects between 1 July and 30 September 2014)¹

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD1208	Safety / efficacy	haematological malignancies
NME	AZD8848#	Safety / efficacy	asthma
LCM	Iressa IMPRESS	Safety / efficacy	treatment beyond progression

Partnered product.

¹ tremelimumab+Iressa removed from table Q3 2014. Project is not terminated but is an investigator-sponsored study and, therefore, does not meet the requirement for inclusion in this table.

SIGNATURES

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

AstraZeneca PLC

Date: 06 November 2014

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