

ASTRAZENECA PLC
Form 6-K
February 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 February 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-_____

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Development Pipeline as at
31 December 2013

Line Extensions

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Cardiovascular							
Brilinta/ Brilique EUCLID	ADP receptor antagonist	outcomes study in patients with PAD	4Q 2012	2016	2016	2016	2017
Brilinta / Brilique PEGASUS-TIMI 54	ADP receptor antagonist	outcomes study in patients with prior MI	4Q 2010	2015	2015	2015	2017
Brilinta/ Brilique SOCRATES1	ADP receptor antagonist	outcomes study in patients with stroke or TIA	1Q 2014	2016	2016	2016	2017
Brilinta/ Brilique THEMIS	ADP receptor antagonist	outcomes study in patients with Type 2 diabetes and CAD but without previous history of MI or stroke		2017	2017	2018	2018
Bydureon Dual Chamber Pen	GLP-1 receptor agonist	diabetes		Filed	Filed	2Q 2014	
Bydureon EXSCEL	GLP-1 receptor agonist	outcomes study	2Q 2010	2018	2018	2018	
Bydureon weekly suspension	GLP-1 receptor agonist	diabetes	1Q 2013	2015	2015		
Farxiga/Forxiga2 DECLARE	SGLT2 inhibitor	outcomes study	2Q 2013	2020	2020		
Kombiglyze XR/ Komboglyze FDC3	DPP-4 inhibitor/ metformin FDC	diabetes		Launched	Launched		Filed
Onglyza SAVOR-TIMI 53	DPP-4 inhibitor	outcomes study	2Q 2010	1Q 2014	1Q 2014		2015
saxagliptin/ dapagliflozin FDC	DPP-4 inhibitor/SGLT2 inhibitor FDC	diabetes	2Q 2012	2015	2015		
Xigduo	SGLT2 inhibitor/diabetes			Filed	Approved4		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

metformin FDC

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	US	Estimated Filing EU	Japan	China
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	peptic ulcer bleeding		Filed ⁵	Launched	N/A	Launched
Neuroscience							
Diprivan#	sedative and anaesthetic	conscious sedation			Launched	2H 2014	Launched
Oncology							
Caprelsa	VEGFR/EGFR tyrosine kinase inhibitor with RET kinase activity	differentiated thyroid cancer	2Q 2013	2016	2016	2016	
Faslodex	oestrogen receptor antagonist	1st line advanced breast cancer	4Q 2012	2016	2016	2016	2016
Iressa	EGFR tyrosine kinase inhibitor	treatment beyond progression	1Q 2012		2015	2015	2015
Respiratory, Inflammation & Autoimmunity							
Symbicort ⁶	inhaled steroid/long-acting agonist	Breath Actuated Inhaler asthma / COPD	4Q 2011				

Partnered product

1 First subject dosed in January 2014 for SOCRATES

2 Farxiga US; Forxiga rest of world

3 Kombiglyze XR US; Komboglyze FDC EU

4 Approved January 2014

5 2nd CRL received from FDA in 2011. AZ response submitted to FDA in December 2012 and application remains under FDA review

6 Filing delayed pending evaluation of alternative device design

NMEs

Phase III/Registration

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Filing			
				US	EU	Japan	China
Cardiovascular							
Brilinta /Brilique	ADP receptor antagonist	arterial thrombosis		Launched	Launched	Filed	Launched
Epanova#	omega-3 free fatty acids	hypertri-glyceridaemia		Filed			
Farxiga/ Forxiga	SGLT2 inhibitor	diabetes		Approved2	Launched	Filed	Filed
metreleptin	leptin analogue	lipodystrophy		Filed	2015	N/A	
Infection							
CAZ AVI (CAZ104)#	cephalosporin/beta lactamase inhibitor	serious infections	1Q 2012	N/A	4Q 2014	2015	2016
CAZ AVI (CAZ104)#	cephalosporin/beta lactamase inhibitor	hospital-acquired pneumonia/ventilator-associated pneumonia	3Q 2013	N/A	2017	2017	
Zinforo (ceftaroline)#	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia / skin infections		N/A	Launched	N/A	1H 2014
Neuroscience							
naloxegol (NKTR-118)#	oral peripherally-acting mu-opioid receptor antagonist	opioid-induced constipation		Filed	Filed		
Oncology							
Caprelsa	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer		Launched	Launched	3Q 2014	Filed
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	2Q 2013	2018	2018		
olaparib	PARP inhibitor	gBRCAm PSR ovarian cancer		1Q 2014	Filed		
olaparib SOLO-1	PARP inhibitor	1st line gBRCAm ovarian cancer	3Q 2013	2017	2017	2017	2017
olaparib SOLO-2	PARP inhibitor	gBRCAm PSR ovarian cancer	3Q 2013	2016	2016	2016	2016
olaparib GOLD	PARP inhibitor	2nd line gastric cancer	3Q 2013			2017	2018
selumetinib (AZD6244) (ARRY-142886)#	MEK inhibitor	2nd line KRAS+ NSCLC	4Q 2013	2017	2017		
Respiratory, Inflammation & Autoimmunity							
benralizumab#	anti-IL-5R MAb	severe asthma	4Q 2013	2016	2016		
brodalumab#	anti-IL-17R MAb	psoriasis	3Q 2012	2015	2015		
lesinurad			4Q 2011	2H 2014	2H 2014		2017

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	selective inhibitor of URAT1	chronic management of hyperuricaemia in patients with gout			
PT003 GFF	LABA/LAMA	COPD	2Q 2013	2015	2016

#Partnered product
1Farxiga US; Forxiga rest of world
2Approved January 2014

NMEs
Phases I and II

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	US	Estimated Filing EU	Japan	China
Cardiovascular								
AZD1722#	NHE3 inhibitor	ESRD-Pi / CKD- with T2DM/ ESRD-Fluid Retention	II	1Q 2013				
AZD4901	NK3	polycystic ovarian syndrome	II	2Q 2013				
roxadustat (FG-4592)#	hypoxia-inducible factor inhibitor	anaemia in CKD/end-stage renal disease	III		2018	N/A	N/A	2016
MEDI6012	LCAT	ACS	I	1Q 2012				
Infection								
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis	II	4Q 2012				
CXL#	beta lactamase inhibitor/ cephalosporin	MRSA	II	4Q 2010				
ATM AVI	BL/BLI	targeted serious bacterial infections	I	4Q 2012				
AZD0914	GyrAR	serious bacterial infections	I	4Q 2013				
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	I	2Q 2006				
		RSV prophylaxis	I	4Q 2008				

Edgar Filing: ASTRAZENECA PLC - Form 6-K

MEDI-559 (PRVV)	paediatric RSV vaccine				
MEDI4893	staph alpha toxin YTE MAb	hospital-acquired pneumonia / serious S. aureus infection	I	1Q 2013	
MEDI92872	H7N9 vaccine	avian influenza	I	4Q 2013	
Neuroscience					
AZD3241	myeloper-oxidase (MPO) inhibitor	Parkinson's disease	II	2Q 2012	
AZD5213	histamine-3 receptor antagonist	Tourette's syndrome/ neuropathic pain	II	4Q 2013	
AZD3293#	beta secretase	Alzheimer's disease	I	4Q 2012	
AZD6423	NMDA	suicidal ideation	I	3Q 2013	

#Partnered product

1In-licensed asset in late-development but the Phase III AstraZeneca programme has yet to randomise its first patient
 2Vaccine in development through a CRADA with NIAID

NMEs

Phases I and II (continued)

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	US	Estimated Filing		
						EU	Japan	China
Oncology								
AZD1775#	Wee-1 inhibitor	ovarian cancer	II	4Q 2012				
AZD2014	TOR kinase inhibitor	solid tumours	II	1Q 2013				
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	4Q 2011				
MEDI-551#	anti-CD19 MAb	haematological malignancies	II	1Q 2012				
MEDI-573#	anti-IGF MAb	MBC	II	4Q 2011				
olaparib	PARP inhibitor	breast cancer	II	1Q 2012				
selumetinib (AZD6244) (ARRY-142886)#	MEK inhibitor	various cancers	II	4Q 2008				
tremelimumab	anti-CTLA4 MAb	mesothelioma	II	2Q 2013				
AZD1208	PIM kinase inhibitor	haematological malignancies	I	1Q 2012				
AZD5363#	AKT inhibitor	solid tumours	I	4Q 2010				
AZD6738	ATR	CLL/	I	4Q 2013				

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Compound	Mechanism	Area Under Investigation	Phase	Date
AZD8186	PI3 kinase beta inhibitor	head & neck solid tumours	I	2Q 2013
AZD9150#	STAT3 inhibitor	haematological malignancies	I	1Q 2012
AZD9291	epidermal growth factor inhibitor	solid tumours	I	1Q 2013
MEDI-565#	anti-CEA BiTE	solid tumours	I	1Q 2011
MEDI0639#	anti-DLL-4 MAb	solid tumours	I	2Q 2012
MEDI0680 (AMP-514)	anti-PD-1 MAb	solid tumours	I	4Q 2013
MEDI3617#	anti-ANG-2 MAb	solid tumours	I	4Q 2010
MEDI4736#	anti-PD-L1 MAb	solid tumours	I	3Q 2012
MEDI4736# + tremelimumab	anti-PD-L1 MAb + anti-CTLA4 MAb	solid tumours	I	4Q 2013
MEDI4736# + dabrafenib + trametinib3	anti-PD-L1 MAb + BRAF inhibitor + MEK inhibitor	melanoma	I	1Q 2014
MEDI6469#	anti-OX40 MAb	solid tumours	I	1Q 2006
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	pALL	I	3Q 2008
volitinib# (AZD6094)	MET inhibitor	solid tumours	I	1Q 2012

#Partnered product

3MedImmune-sponsored study in collaboration with GlaxoSmithKline. First patient dosed in January 2014

NMEs

Phases I and II (continued)

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase	US	Estimated Filing EU	Japan	China
Respiratory, Inflammation & Autoimmunity								
AZD2115#	MABA	COPD	II	2Q 2012				
AZD5069	CXCR2	asthma	II	4Q 2010				
benralizumab#	anti-IL-5R MAb	COPD	II	4Q 2010				
brodalumab#	anti-IL-17R MAb	asthma / psoriatic	II	2Q 2013				

Edgar Filing: ASTRAZENECA PLC - Form 6-K

mavrilimumab#	anti-GM-CSFR MAb	arthritis rheumatoid arthritis	II	1Q 2010
MEDI-546#	anti-IFN-alphaR MAb	SLE	II	1Q 2012
MEDI2070#	anti-IL-23 MAb	Crohn's disease Crohn's disease	II	1Q 2013
MEDI7183#	anti-a4b7 MAb	/ ulcerative colitis	II	4Q 2012
MEDI8968#	anti-IL-1R MAb	COPD, HS chronic	II	4Q 2011
RDEA3170	selective inhibitor of URAT1	management of hyperuricaemia in patients with gout	II	3Q 2013
sifalimumab#	anti-IFN-alpha MAb	SLE	II	3Q 2008
tralokinumab	anti-IL-13 MAb	asthma / IPF	II	1Q 2008
AZD1419	TLR9	asthma	I	3Q 2013
AZD4721	CXCR2	COPD	I	3Q 2013
AZD7624	ip38i	COPD	I	1Q 2013
AZD8848#	inhaled TLR7	asthma	I	2Q 2012
MEDI-551#	anti-CD19 MAb	multiple sclerosis	I	3Q 2012
MEDI5872#	anti-B7RP1 MAb	SLE	I	4Q 2008
MEDI9929#	anti-TSLP MAb	asthma	I	4Q 2008
PT010	LAMA/LABA/ICS	COPD	I	4Q 2013

#Partnered product

Development Pipeline - Discontinued Projects between 1 January 2013 and 31 December 2013

Infection

NME/Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	MEDI-557	Safety/Efficacy	RSV prevention in high risk adults (COPD/CHF/other)

Neuroscience

NME/Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD1446	Safety/Efficacy	Alzheimer's disease
NME	AZD3480#	Safety/Efficacy	Alzheimer's disease
NME	AZD5213	Hypothesis risk	Alzheimer's disease
NME	AZD6765	Safety/Efficacy	major depressive disorder
NME	MEDI5117	Safety/Efficacy	OA pain

Oncology

Edgar Filing: ASTRAZENECA PLC - Form 6-K

NME/Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD8330#(ARRY 424704)	Safety/Efficacy	solid tumours
NME	fostamatinib#	Safety/Efficacy	haematological malignancies
NME	MEDI-575#	Safety/Efficacy	NSCLC

Respiratory, Inflammation & Autoimmunity

NME/Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD5423#	Safety/Efficacy	COPD
NME	AZD7594#	Safety/Efficacy	COPD
NME	fostamatinib#	Safety/Efficacy	rheumatoid arthritis
NME	MEDI4212	Safety/Efficacy	asthma
NME	MEDI7814	Economic	COPD
LCM	tralokinumab	Safety/Efficacy	UC

#Partnered product

Completed Projects

Compound	Mechanism	Area Under Investigation	Launch Status			
			US	EU	Japan	China
Cardiovascular						
Forxiga (dapagliflozin)	SGLT2 inhibitor	diabetes - add on to DPP-4		Approved		
Forxiga (dapagliflozin)	SGLT2 inhibitor	diabetes - add on to metformin long-term data		Approved		
Forxiga (dapagliflozin) ¹	SGLT2 inhibitor	diabetes - in patients with high CV risk - study 18 and 19 long-term data				
Forxiga (dapagliflozin)	SGLT2 inhibitor	diabetes - triple therapy (dapa+met+ SU)		Approved		
Infection						
Q-LAIV Flu Vaccination	live, attenuated, intranasal influenza virus vaccine (quadrivalent)	seasonal influenza	Approved	Approved		

¹Studies 18/19 complete. No filing planned from this data

Comments

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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.

Submission dates shown for assets in Phase III and beyond.

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 February 2014

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