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 X 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 X

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

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 | | |

metformin FDC

| Compound | Mechanism | Area Under Investigation | Date Commenced Phase | Estimated Filing US | 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 | | Filed5 | 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 | | | | | | | |
| Symbicort6 | inhaled steroid/ long-acting $2$ 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

| 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/ Forxiga1 | 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 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 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 | Estimated Filing | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | US | 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 | II1 | | 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 | | | | |

| | | | | |
|---|---|---|---|---|
| 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 | Estimated Filing | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | US | 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 | | | | |

| | | | | |
|---|---|---|---|---|
| | | head & neck | | |
| AZD8186 | PI3 kinase beta inhibitor | 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-1MAb | 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# | murine 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 | Estimated Filing US | 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 | | | | |

| | | | | |
|---|---|---|---|---|
| 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 | II | 1Q 2013 |
| MEDI7183# | anti-a4b7 MAb | Crohn's disease / ulcerative colitis | II | 4Q 2012 |
| MEDI8968# | anti-IL-1R MAb | COPD, HS | II | 4Q 2011 |
| RDEA3170 | selective inhibitor of URAT1 | chronic 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

| 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

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