ASTRAZENECA PLC
Form 6-K
August 01, 2013

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 August 2013

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
30 June 2013

Line Extensions

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced Phase | Estimated Filing US | EU | Japan | China |
|---|---|---|---|---|---|---|---|---|
| **Cardiovascular** | | | | | | | | |
| Axanum*** | proton pump inhibitor + low dose aspirin FDC | low dose aspirin associated peptic ulcer in high risk CV patients | III | | Withdrawn | Launched | | |
| Brilinta/ Brilique EUCLID | ADP receptor antagonist | outcomes study in patients with PAD | III | 4Q 2012 | 2016 | 2016 | 2016 | 2017 |
| Brilinta / Brilique PEGASUS-TIMI 54 | ADP receptor antagonist | outcomes study in patients with prior MI | III | 4Q 2010 | 2015 | 2015 | 2015 | 2017 |
| Bydureon EXSCEL# | GLP-1 receptor agonist | outcomes study | III | 2Q 2010 | 2018 | 2018 | 2018 | |
| Bydureon Dual Chamber Pen# | GLP-1 receptor agonist | diabetes | III | | 3Q 2013 | 4Q 2013 | | |
| Forxiga (dapagliflozin)/ metformin FDC# | SGLT2 inhibitor + metformin FDC | diabetes | III | 3Q 2007 | 4Q 2013 | Filed | | |
| Forxiga (dapagliflozin)# | SGLT2 inhibitor | diabetes - add on to DPP-4 | III | 1Q 2010 | | Filed | | |
| Forxiga (dapagliflozin)# | SGLT2 inhibitor | diabetes - add on to insulin and add-on to metformin long-term data | III | 2Q 2008 | | Filed | | |
| Forxiga (dapagliflozin)# | SGLT2 inhibitor | diabetes - in patients with high CV risk - Study 18 and 19 long-term data | III | 1Q 2010 | | 1H 2014 | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Forxiga (dapagliflozin)# | SGLT2 inhibitor | diabetes - triple therapy (dapa+met+ SU) | III | 1Q 2011 | | 4Q 2013 | | |
| Forxiga (dapagliflozin) DECLARE# | SGLT2 inhibitor | outcomes study | III | 2Q 2013 | 2020 | 2020 | | |
| Kombiglyze XR/ Komboglyze FDC#* | DPP-4 inhibitor + metformin FDC | diabetes | III | | Launched | Launched | | 1H 2014 |
| SaxaDapa FDC# | DPP-4 inhibitor / SGLT2 inhibitor | diabetes | III | 2Q 2012 | 2015 | 2015 | | |
| Onglyza SAVOR-TIMI 53# | DPP-4 inhibitor | outcomes study | III | 2Q 2010 | 4Q 2013 | 4Q 2013 | | 2H 2014 |

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced Phase | Estimated Filing US | EU | Japan | China |
|---|---|---|---|---|---|---|---|---|
| Gastrointestinal | | | | | | | | |
| Entocort | glucocorticoid steroid | Crohn's disease / ulcerative colitis | III | | Launched | Launched | 2015 | N/A |
| Nexium | proton pump inhibitor | peptic ulcer bleeding | III | | Filed** | Launched | N/A | Launched |
| Neuroscience | | | | | | | | |
| Diprivan# | sedative and anaesthetic | conscious sedation | III | | | Launched | 2H 2014 | Launched |
| Oncology | | | | | | | | |
| Faslodex | oestrogen receptor antagonist | 1st line advanced breast cancer | III | 4Q 2012 | 2016 | 2016 | 2016 | 2016 |
| Iressa | EGFR tyrosine kinase inhibitor | treatment beyond progression | III | 1Q 2012 | | 2015 | 2015 | 2015 |
| Respiratory, Inflammation & Autoimmunity | | | | | | | | |
| Symbicort | inhaled steroid/ long-acting 2 agonist | Breath Actuated Inhaler asthma / COPD | III | 4Q 2011 | 1H 2014 | | | |

#Partnered product
*Kombiglyze XR US; Komboglyze FDC EU

**2nd CRL received from FDA in 2011. AZ response submitted to FDA in December 2012
***Commercial support now withdrawn, no Japan launch expected

NCEs
Phase III/Registration

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced | Estimated Filing US | EU | Japan | China |
|---|---|---|---|---|---|---|---|---|
| **Cardiovascular** | | | | | | | | |
| Brilinta/ Brilique | ADP receptor antagonist | arterial thrombosis | III | | Launched | Launched | Filed | Launched |
| Epanova# | omega-3 free fatty acids | hypertri-glyceridaemia | III | | Filed | | | |
| Forxiga (dapagliflozin)# | SGLT2 inhibitor | diabetes | III | | Filed* | Launched | Filed | Filed |
| metreleptin# | leptin analogue | lipodystrophy | III | | Filed | 1H 2014 | N/A | |
| **Infection** | | | | | | | | |
| CAZ AVI# (CAZ104) | beta lactamase inhibitor/ cepha-losporin | intra abdominal infections (cIAI) & urinary tract infections (cUTI); hospital acquired pneumonia (HAP) & ventilator associated pneumonia (VAP) *** | III | 1Q 2012 | N/A | 2H 2014 | 2015 | 2016 |
| Q-LAIV Flu Vaccination** | live, attenuated, intranasal influenza virus vaccine quadrivalent | seasonal influenza | III | | Approved | Filed | | |
| Zinforo (ceftaroline) # | extended spectrum cepha-losporin with affinity to penicillin- binding proteins | pneumonia / skin infections | III | | N/A | Launched | | 1H 2014 |
| **Neuroscience** | | | | | | | | |
| naloxegol (NKTR-118)# | oral peripherally-acting mu-opioid receptor antagonist | opioid-induced constipation | III | 2Q 2011 | 3Q 2013 | 3Q 2013 | | |
| **Oncology** | | | | | | | | |
| Caprelsa | VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity | medullary thyroid cancer | III | | Launched | Launched | 2015 | Filed |
| moxetumomab pasudotox# | anti-CD22 recombinant immunotoxin | hairy cell leukaemia | III | 2Q 2013 | 2017 | 2017 | | |

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced Phase | Estimated Filing US | EU | Japan | China |
|---|---|---|---|---|---|---|---|---|
| Respiratory, Inflammation & Autoimmunity | | | | | | | | |
| brodalumab# | anti-IL-17R MAb | psoriasis | III | 3Q 2012 | 2015 | 2015 | | |
| PT003 GFF | LABA/LAMA | COPD | III | 2Q 2013 | 2015 | 2016 | | |
| lesinurad | selective uric acid reabsorption inhibitor (SURI) | chronic treatment of patients with gout | III | 4Q 2011 | 2H 2014 | 2H 2014 | 2017 | 2017 |

#Partnered product
*CRL received in January 2012, re-submission 3Q 2013
**sBLA in US, MAA in EU
***HAP/VAP is a follow up filing, EU filing expected in 2017

NCEs
Phases I and II

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced Phase | Estimated Filing US | EU | Japan | China |
|---|---|---|---|---|---|---|---|---|
| Cardiovascular | | | | | | | | |
| AZD1722# | NHE3 inhibitor | end stage renal disease / chronic kidney disorder | II | 1Q 2013 | | | | |
| MEDI6012 (ACP-501) | 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 | | | | |
| MEDI4893 | staph alpha toxin YTE MAb | hospital-acquired pneumonia / serious S. aureus infection | I | 1Q 2013 | | | | |
| MEDI-550 | pandemic influenza virus vaccine | pandemic influenza prophylaxis | I | 2Q 2006 | | | | |
| PRVV (MEDI-559) | live attenuated paediatric RSV | RSV prophylaxis | I | 4Q 2008 | | | | |

| | | | | |
|---|---|---|---|---|
| | vaccine | | | |
| Neuroscience | | | | |
| AZD3241 | myeloper-oxidase (MPO) inhibitor | Parkinson's disease | II | 2Q 2012 |
| AZD5213 | histamine-3 receptor antagonist | neuropathic pain* | II | |
| AZD6765 | NMDA receptor antagonist | major depressive disorder | II | 3Q 2007 |
| AZD3293# | beta secretase | Alzheimer's disease | I | 4Q 2012 |

#Partnered product
*Terminated in Alzheimer's Disease - neuropathic pain study due to start 3Q 2013

NCEs
Phases I and II (continued)

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced Phase | Estimated Filing US | EU | Japan | China |
|---|---|---|---|---|---|---|---|---|
| Oncology | | | | | | | | |
| 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 | gBRCAm ovarian cancer, gBRCAm breast cancer, gastric cancer | II | 1Q 2012 | | | | |
| selumetinib# (AZD6244) (ARRY-142886) | MEK inhibitor | solid tumours | II | 4Q 2006 | | | | |
| tremelimumab | anti-CTLA4 MAb | solid tumours | II | 3Q 2004 | | | | |
| AZD1208 | PIM kinase inhibitor | haematological malignancies | I | 1Q 2012 | | | | |
| AZD2014 | TOR kinase inhibitor | solid tumours | I | 1Q 2010 | | | | |
| AZD5363# | AKT inhibitor | solid tumours | I | 4Q 2010 | | | | |
| AZD8186 | PI3 kinase beta inhibitor | solid tumours | I | 2Q 2013 | | | | |
| AZD9150# | | | I | 1Q 2012 | | | | |

| | | | | |
|---|---|---|---|---|
| | STAT3 inhibitor | haematological malignancies | | |
| AZD9291 | epidermal growth factor inhibitor | solid tumours | I | 1Q 2013 |
| MEDI0639# | anti-DLL-4 MAb | solid tumours | I | 2Q 2012 |
| MEDI3617# | anti-ANG-2 MAb | solid tumours | I | 4Q 2010 |
| MEDI4736# | anti-PD-L1 MAb | solid tumours | I | 3Q 2012 |
| MEDI-565# | anti-CEA BiTE | solid tumours | I | 1Q 2011 |
| MEDI6469# | murine anti-OX40 MAb | solid tumours | I | 1Q 2006 |
| volitinib# | MET inhibitor | solid tumours | I | 1Q 2012 |

#Partnered product

NCEs
Phases I and II (continued)

| Compound | Mechanism | Area Under Investigation | Phase | Date Commenced | Estimated Filing US | EU | Japan | China |
|---|---|---|---|---|---|---|---|---|
| Respiratory, Inflammation & Autoimmunity | | | | | | | | |
| AZD2115# | MABA | COPD | II | 2Q 2012 | | | | |
| AZD5069 | CXCR2 | asthma | II | 4Q 2010 | | | | |
| AZD5423# | inhaled SGRM | COPD | II | 4Q 2010 | | | | |
| benralizumab# | anti-IL-5R MAb | asthma / COPD | II | 4Q 2008 | | | | |
| mavrilimumab# | anti-GM-CSFR MAb | rheumatoid arthritis | II | 1Q 2010 | | | | |
| MEDI2070# | anti-IL-23 MAb | Crohn's disease | II | 1Q 2013 | | | | |
| MEDI-546# | anti-IFN-alphaR MAb | SLE | II | 1Q 2012 | | | | |
| MEDI7183# | anti-a4b7 MAb | Crohn's disease / ulcerative colitis | II | 4Q 2012 | | | | |
| MEDI8968# | anti-IL-1R MAb | COPD, HS | II | 4Q 2011 | | | | |
| sifalimumab# | anti-IFN-alpha MAb | SLE | II | 3Q 2008 | | | | |
| tralokinumab | anti-IL-13 MAb | asthma / IPF / UC | II | 1Q 2008 | | | | |

| | | | | |
|---|---|---|---|---|
| AZD8848# | inhaled TLR7 | asthma | I | 2Q 2012 |
| AZD7594# | inhaled SGRM | COPD | I | 4Q 2012 |
| AZD7624 | ip38i | COPD | I | 1Q 2013 |
| 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 |
| RDEA3170 | selective uric acid reabsorption inhibitor (SURI) | chronic treatment of patients with gout | I | 3Q 2011 |

#Partnered product

Development Pipeline - Discontinued Projects between 1 January 2013 and 30 June 2013

Infection

| NCE/Line Extension | Compound | Reason for Discontinuation | Area Under Investigation |
|---|---|---|---|
| NCE | MEDI-557 | safety / efficacy | RSV prevention in high risk adults (COPD/CHF/other) |

Neuroscience

| NCE/Line Extension | Compound | Reason for Discontinuation | Area Under Investigation |
|---|---|---|---|
| NCE | AZD1446 | safety / efficacy | Alzheimer's disease |
| NCE | AZD3480 | safety / efficacy | Alzheimer's disease |
| NCE | MEDI5117 | safety / efficacy | rheumatoid arthritis |

Oncology

| NCE/Line Extension | Compound | Reason for Discontinuation | Area Under Investigation |
|---|---|---|---|
| NCE | AZD8330#(ARRY 424704) | safety / efficacy | solid tumours |
| NCE | fostamatinib | safety / efficacy | haematological malignancies |
| NCE | MEDI-575 | safety / efficacy | NSCLC |

Respiratory, Inflammation & Autoimmunity

| NCE/Line Extension | Compound | Reason for Discontinuation | Area Under Investigation |
|---|---|---|---|
| NCE | fostamatinib | safety / efficacy | rheumatoid arthritis |
| NCE | MEDI7814 | economic | COPD |
| NCE | MEDI4212 | safety / efficacy | asthma |

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.

- ENDS -

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: 01 August 2013

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