

ASTRAZENECA PLC
Form 6-K
January 12, 2009
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 December 2008

Commission File Number: 001-11960

AstraZeneca PLC

15 Stanhope Gate, London W1K 1LN, England

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 PLC

INDEX TO EXHIBITS

1. Press release entitled, “PN 400 Phase III studies show clinically meaningful benefit in reducing gastric ulcers compared to enteric-coated naproxen”, dated 3 December 2008.
 2. Press release entitled, “AstraZeneca and Bristol-Myers Squibb announce expansion of worldwide collaboration to develop and commercialise Dapagliflozin in Japan”, dated 8 December 2008.
 3. Press release entitled, “AstraZeneca and Targacept announce top-line results from Phase IIb study of AZD3480 in cognitive dysfunction in schizophrenia”, dated 8 December 2008.
 4. Press release entitled, “AstraZeneca returns worldwide rights to IPI-504 and IPI-493 development programs to infinity pharmaceuticals”, dated 11 December 2008.
 5. Press release entitled, “AstraZeneca responds to FDA Joint Advisory Committees’ recommendation on SYMBICORT”, dated 12 December 2008.
 6. Press release entitled, “AstraZeneca and MAP Pharmaceuticals announce worldwide collaboration to develop and commercialise Unit Dose Budesonide”, dated 19 December 2008.
 7. Press release entitled, “AstraZeneca receives FDA Complete Response Letter on SEROQUEL XR for Major Depressive Disorder”, dated 24 December 2008.
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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: 9 January 2009

By: /s/ Justin Hoskins

Name: Justin Hoskins

Title: Deputy Company Secretary

Item 1

PN 400 PHASE III STUDIES SHOW CLINICALLY MEANINGFUL BENEFIT IN REDUCING GASTRIC ULCERS COMPARED TO ENTERIC-COATED NAPROXEN

AstraZeneca and POZEN Inc., co-development partner for the investigational compound PN 400, have announced today results from two Phase III studies, PN 400-301 and PN 400-302 comparing PN 400 (enteric-coated naproxen 500 mg and immediate release esomeprazole 20 mg) to enteric-coated naproxen 500 mg. These studies were conducted by POZEN under an agreed Special Protocol Assessment (SPA) with the FDA.

The PN 400-301 and PN 400-302 studies both achieved the primary endpoints. Subjects taking PN 400 experienced statistically significantly fewer endoscopically confirmed gastric ulcers than those taking naproxen. In each of the trials, approximately 400 subjects received either PN 400 or enteric-coated naproxen 500 mg, twice daily, over a six-month treatment period. Subjects underwent upper endoscopies at baseline and at one, three, and six months. The primary endpoint was the cumulative incidence of gastric ulcers. Full results of the PN 400-301 and PN-400 302 will be published in a timely manner.

The Food and Drug Administration (FDA) has recently informed POZEN that they are conducting an internal review on the acceptability of using endoscopic gastric ulcers as a primary endpoint in clinical studies. The FDA has not indicated when their internal review will be completed, although the FDA has scheduled an FDA internal meeting to review this subject during the first quarter of 2009.

Two additional Phase III studies, PN-400-307 and PN 400-309, are still ongoing. Upon completion of the entire PN 400 Phase III clinical programme, AstraZeneca will make a final determination regarding regulatory filing, which is planned for mid-2009.

About PN 400

PN 400 is an investigational compound under co-development by AstraZeneca and POZEN, Inc. that combines the pain reliever naproxen (an NSAID) with esomeprazole – a proton pump inhibitor (PPI), for the treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients who are at risk of developing gastric ulcers.

Osteoarthritis is one of the most frequent causes of physical disability among adults; with an estimated 46 million adults in the US have physician-diagnosed arthritis, accounting for 21 percent of the US adult population. Two thirds of the people that have doctor-diagnosed arthritis are under the age of 65.

About AstraZeneca

AstraZeneca is a major international healthcare business engaged in research, development, manufacturing and marketing of prescription pharmaceuticals and supplier for healthcare services. AstraZeneca is one of the world's leading pharmaceutical companies with healthcare sales of US \$29.55 billion and is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infection product sales. AstraZeneca is listed in the Dow Jones Sustainability Index (Global) as well as the FTSE4Good Index. For more Information visit www.astrazeneca.com

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3 December 2008

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Item 2

ASTRAZENECA AND BRISTOL-MYERS SQUIBB ANNOUNCE EXPANSION OF WORLDWIDE COLLABORATION TO DEVELOP AND COMMERCIALISE DAPAGLIFLOZIN IN JAPAN

AstraZeneca and Bristol-Myers Squibb today announced expansion of their worldwide collaboration to include the development and commercialisation of dapagliflozin in Japan. Dapagliflozin, one of two investigational drugs under joint development by the companies, is currently being studied in Phase III clinical trials in several countries, including the U.S., to assess its efficacy and safety as a once-daily treatment for type 2 diabetes.

In January 2007, Bristol-Myers Squibb and AstraZeneca entered into a global collaboration, excluding Japan, to enable the companies to research, develop and commercialise dapagliflozin. The companies now have agreed to co-develop dapagliflozin in Japan with AstraZeneca having operational and cost responsibility for all development and regulatory activities on behalf of the collaboration. The two companies will jointly market the product in Japan, sharing all commercialisation expenses and activities and splitting profits/losses equally. Bristol-Myers Squibb will manufacture dapagliflozin and also book sales. Dapagliflozin is currently being studied in Phase II clinical trials in Japan.

“Bristol-Myers Squibb and AstraZeneca have been working together to develop dapagliflozin for type 2 diabetes for nearly two years – this inclusion of Japan was a natural progression of our collaboration and an important strategic step in our relationship,” said Lamberto Andreotti, Executive Vice President and Chief Operating Officer, Bristol-Myers Squibb. “Our companies have a shared vision for these diabetes treatments, and this agreement will help ensure we can successfully launch and maximize the potential of dapagliflozin for the more than 6 million people in Japan living with type 2 diabetes.”

“Last year, the cost of treating and preventing type 2 diabetes and its complications in Japan was more than USD 18.4 billion, which is a significant cost to Japanese society,” said Bruno Angelici, Executive Vice President, International Sales and Marketing Organisation, AstraZeneca. “We have a long-standing presence in Japan, and our agreement with Bristol-Myers Squibb to bring a potentially important type 2 diabetes treatment to market in the region will not only help reduce this cost burden, but also reduce the impact this disease has on the country’s health.”

About Dapagliflozin

Dapagliflozin was specifically designed to be a novel, selective inhibitor of sodium glucose cotransporter 2 (SGLT2), which regulates the reabsorption of glucose in the kidney. It has a C-glucoside chemical structure, which prolongs the pharmacokinetic half-life and duration of action. Dapagliflozin is metabolized through the liver and excreted in the urine. Phase IIB data for Dapagliflozin were presented at the 2008 American Diabetes Association Annual Meeting and the 2008 European Association for the Study of Diabetes Annual Meeting.

About ONGLYZA™ (saxagliptin)

In addition to the companies collaboration on dapagliflozin, Bristol-Myers Squibb and AstraZeneca have been working together to develop another potential treatment for type 2 diabetes -- ONGLYZA™ (saxagliptin) -- globally, excluding Japan.

ONGLYZA, the proposed tradename for saxagliptin, is an investigational DPP-4 inhibitor being studied in clinical trials as a once-daily therapy to determine its efficacy and safety. Saxagliptin was specifically designed to be a selective inhibitor with extended binding to the DPP-4 enzyme, with dual routes of clearance. The companies submitted a New Drug Application to the U.S. Food & Drug Administration (FDA) on June 30, which has been officially filed by the FDA, and a Marketing Authorisation Application to the European Medicines Agency (EMA) on July 1, which has been accepted for review by the Agency. The name ONGLYZA, if approved by the FDA and the EMA, will serve as the trade name for saxagliptin.

Saxagliptin Phase III data have previously been presented as a monotherapy, as well as in combination with metformin, sulfonylureas and thiazolidinediones, commonly prescribed oral anti-diabetic medications. The overall clinical development program included over 5,000 individuals -- more than 4,000 of whom were given saxagliptin. The worldwide collaboration for the development and commercialisation of saxagliptin will continue to exclude Japan. On December 27, 2006, Bristol-Myers Squibb and Otsuka Pharmaceutical Co., Ltd. announced an exclusive licensing agreement for saxagliptin in Japan.

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About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information, visit www.bms.com.

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8 December 2008

- Ends -

Item 3

ASTRAZENECA AND TARGACEPT ANNOUNCE TOP-LINE RESULTS FROM PHASE IIb STUDY OF AZD3480 IN COGNITIVE DYSFUNCTION IN SCHIZOPHRENIA

AstraZeneca and Targacept, Inc. today announced top-line results from a Phase IIb clinical trial of AZD3480 (TC-1734) conducted by AstraZeneca in cognitive dysfunction in schizophrenia (CDS), known as the HALO trial.

AZD3480 did not meet the trial's criteria for statistical significance on the primary outcome endpoints, improvement on various cognitive domains measured by the IntegNeuro computerized test battery. AZD3480 was generally well tolerated in the study. AstraZeneca and Targacept do not expect to progress AZD3480 into Phase III studies for CDS.

In addition to the HALO trial, AstraZeneca and Targacept previously announced top-line results from a Phase IIb study of AZD3480 in mild to moderate Alzheimer's disease, known as the Sirocco trial and are currently evaluating AZD3480 in a Phase II exploratory study in attention deficit/hyperactivity disorder (ADHD) in adults. A decision by AstraZeneca with respect to potential further development of AZD3480 in Alzheimer's disease or ADHD is now expected in the first half of 2009, pending completion of the adult ADHD study and other ongoing evaluations.

"While this trial outcome did not meet our objectives, we continue to pursue medicines that target neuronal nicotinic receptors (NNRs) with Targacept to treat cognitive disorders," said Bob Holland, Vice President and Head of the Neuroscience Therapy Area, AstraZeneca.

AstraZeneca and Targacept also announced that the lead compound arising out of the parties' preclinical research collaboration is poised to enter the clinic. AstraZeneca plans by the end of 2008 to initiate a Phase I trial of AZD1446 (TC-6683), a product candidate selective for the alpha4beta2 NNR. Under the terms of the parties' collaboration agreement, AstraZeneca has agreed to make a \$2.0 million milestone payment to Targacept.

"We are obviously disappointed that AZD3480 did not meet our goals in the HALO trial," commented J. Donald deBethizy, Ph.D., President and Chief Executive Officer of Targacept. "We thank AstraZeneca for its commitment to AZD3480 and its investment in this pioneering work in an emerging area considered to be critical in the treatment of patients with schizophrenia. We look forward to continuing our cognition-focused collaboration with AstraZeneca."

Study Design

The Phase IIb HALO trial was conducted by AstraZeneca under the terms of an exclusive global license and research collaboration agreement. The trial was a multi-center, randomized, double blind, placebo controlled, dose-finding study conducted at approximately 70 enrolling sites in the United States and Canada. Subjects (n = 445) between 18 and 55 years of age who were active smokers and taking medication from the class of drugs known as atypical anti-psychotics were randomly assigned to one of three dose groups of AZD3480 or to placebo and dosed over a 12-week period. The primary outcome measures of the trial were change from baseline after 12 weeks on various domains of cognition as measured by the IntegNeuro computerized test battery.

About Cognitive Dysfunction in Schizophrenia

Schizophrenia is a chronic, severe and disabling form of psychosis that, in addition to symptoms such as delusions and hallucinations, is often marked by impairments in cognitive functions such as attention, vigilance, memory and reasoning. These cognitive impairments play a primary role in the inability of schizophrenic patients to function normally. It has been estimated that there are 7.9 million schizophrenic patients in the world's seven major pharmaceutical markets and that the majority of all schizophrenic patients are cognitively impaired.

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About Targacept

Targacept is a clinical-stage biopharmaceutical company that discovers and develops NNR Therapeutics (TM), a new class of drugs for the treatment of central nervous system diseases and disorders. Targacept's product candidates selectively modulate neuronal nicotinic receptors that serve as key regulators of the nervous system to promote therapeutic effects and limit adverse side effects. Targacept has product candidates in development for Alzheimer's disease, cognitive dysfunction in schizophrenia, pain and depression, as well as multiple preclinical programs. Targacept also has a cognition-focused collaboration with AstraZeneca and a strategic alliance with GlaxoSmithKline. Targacept's news releases are available on its website at www.targacept.com

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8 December 2008

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Item 4

**ASTRAZENECA RETURNS WORLDWIDE RIGHTS TO IPI-504 AND IPI-493 DEVELOPMENT PROGRAMS
TO INFINITY PHARMACEUTICALS**

AstraZeneca today announced that it has returned worldwide rights to Infinity Pharmaceuticals for the development and commercialisation of Infinity's heat shock protein 90 (Hsp90) drug candidates IPI-504 (MEDI-561) and IPI-493, in development for the treatment of cancer and related conditions.

The collaboration, initiated in August 2006 between MedImmune and Infinity, was transferred to AstraZeneca following its acquisition of MedImmune in June 2007.

After reviewing the potential opportunity for these projects within its portfolio and considering competing R&D investment priorities, AstraZeneca has decided to return the responsibility for development and commercialisation of this program to Infinity.

Infinity is fully committed to targeting Hsp90 as a potential new treatment approach to cancer, and to developing both IPI-504 and IPI-493. In particular, Infinity initiated a late stage trial of IPI-504 in patients with refractory gastrointestinal stromal tumors (GIST), a rare tumor of the gastrointestinal tract. IPI-504 and IPI-493 are in additional late- and early-stage ongoing clinical trials.

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11 December 2008

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Item 5

ASTRAZENECA RESPONDS TO FDA JOINT ADVISORY COMMITTEES' RECOMMENDATION ON SYMBICORT

On 11 December 2008, the Joint Advisory Committees of the U.S. Food and Drug Administration (FDA) – including the Drug Safety & Risk Management Advisory Committee, the Pediatric Advisory Committee, and the Pulmonary-Allergy Drugs Advisory Committee – completed a review of the benefits and risks of asthma medications containing long-acting beta-agonists (LABAs). The committees concluded that the benefits of AstraZeneca's SYMBICORT (budesonide/formoterol fumarate dihydrate), a combination LABA/Inhaled Corticosteroid (ICS) medication, outweigh the risks in adult and adolescent asthma patients.

Howard Hutchinson, M.D., Chief Medical Officer of AstraZeneca, said: "The safety and efficacy of SYMBICORT have been demonstrated in numerous clinical trials and from extensive post-marketing use around the world. We are pleased that the joint advisory committees' recommendation confirms our view on the positive benefit-risk profile of SYMBICORT."

The FDA frequently convenes advisory committee meetings to obtain independent expert guidance and recommendations on clinical matters. While the FDA is not required to follow this guidance, the agency usually takes the advice into consideration when rendering its final decisions on pending applications and other public health matters.

About SYMBICORT outside the U.S.

SYMBICORT (budesonide/formoterol fumarate dihydrate) is a combination of two proven medications – budesonide, an inhaled corticosteroid (ICS), and formoterol, a rapid and long-acting beta2-agonist (LABA). SYMBICORT is approved in over 100 countries for the long-term maintenance treatment of asthma and is available in two different inhalers, SYMBICORT TURBUHALER and SYMBICORT pMDI.

SYMBICORT TURBUHALER is a combination therapy indicated for the long-term maintenance treatment of paediatric and adult asthma patients who cannot be adequately controlled on other medications such as inhaled corticosteroids. SYMBICORT should not be used in patients whose asthma can be successfully managed by inhaled corticosteroids along with occasional use of inhaled short-acting beta2-agonists.

SYMBICORT TURBUHALER is also indicated for use in patients with Chronic Obstructive Pulmonary Disease (COPD) in 88 countries.

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12 December 2008

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Item 6

ASTRAZENECA AND MAP PHARMACEUTICALS ANNOUNCE WORLDWIDE COLLABORATION TO DEVELOP AND COMMERCIALISE UNIT DOSE BUDESONIDE

AstraZeneca and MAP Pharmaceuticals, Inc. announced today an exclusive worldwide agreement to develop and commercialise Unit Dose Budesonide (UDB), MAP Pharmaceuticals' proprietary nebulised formulation of budesonide. UDB is being developed by MAP Pharmaceuticals as a potential treatment for paediatric asthma and is currently in Phase III clinical development. UDB has the potential to be nebulised more quickly and at a lower nominal dose than the commercially available product.

Under the terms of the agreement, AstraZeneca will pay MAP Pharmaceuticals an upfront cash payment of \$40 million and an additional \$35 million upon the successful achievement of primary endpoint and safety results in the currently ongoing Phase III clinical study. In addition, upon the occurrence of certain events and conditions, MAP Pharmaceuticals is eligible to receive up to \$240 million in other potential development and regulatory milestones. The Agreement also provides for additional progressively demanding sales performance-related milestone payments of up to \$585 million in the event the product is a considerable commercial success. This agreement is subject to review by the United States Government under the Hart-Scott-Rodino Act and becomes effective after the expiration or earlier termination of the waiting period (or any extension thereof).

AstraZeneca also will support and fund the establishment of a MAP Pharmaceuticals sales force to co-promote UDB in the United States for a certain period of time after product launch. MAP Pharmaceuticals is also eligible to receive significant double-digit royalty payments on net sales of UDB worldwide.

MAP Pharmaceuticals and AstraZeneca will develop UDB in the United States and AstraZeneca has rights to develop and commercialise UDB outside of the United States. Under the agreement, AstraZeneca will be responsible for future UDB development costs and AstraZeneca will reimburse MAP Pharmaceuticals for the costs of future UDB development activities with respect to United States registration incurred by MAP Pharmaceuticals.

David Brennan, Chief Executive Officer of AstraZeneca said, "MAP Pharmaceuticals' advancement in Unit Dose Budesonide represents an important potential new option for treating children confronting asthma. AstraZeneca's heritage in treating paediatric asthma, combined with MAP Pharmaceuticals' expertise can open new areas of opportunity for both companies and has the potential to bring significant medical benefit to the wider community."

"AstraZeneca is an ideal partner for UDB given their extensive expertise in developing and commercialising respiratory therapies, including for paediatric asthma," said Timothy S. Nelson, President and Chief Executive Officer of MAP Pharmaceuticals. "We recognise AstraZeneca's leadership position in this therapeutic area and their potential to help MAP Pharmaceuticals achieve its key objective of reaching the broadest set of children who suffer from asthma. This relationship represents an important step in the evolution of our company, as we leverage our partner's significant expertise and resources to help us build a commercial infrastructure for subsequent product launches. In addition, this transaction greatly strengthens our balance sheet and provides us with additional financial resources moving forward."

UDB is being developed utilising a license to Elan's proprietary NanoCrystal® Technology. The small size and stability of NanoCrystal® drug particles are designed to enable improved delivery efficiency of drug formulations to the lung via nebulisation.

About UDB

UDB is being studied as a novel version of nebulised budesonide. Budesonide has been used clinically for more than 20 years. UDB is designed to be nebulised more quickly at a lower nominal dose than the commercially available product. MAP Pharmaceuticals has completed enrolment and randomised approximately 360 patients in a Phase III clinical trial to evaluate UDB for the potential treatment of paediatric asthma. The last patient in this trial is expected to complete the 12-week treatment period by the end of 2008. The safety data generated to date has shown UDB to be well tolerated with no significant adverse events.

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About MAP Pharmaceuticals

MAP Pharmaceuticals, Inc. develops and plans to commercialise new therapies for children and adults who suffer from chronic conditions that it believes are not adequately treated by currently available medicines. The company applies its proprietary inhalation technologies to enhance the therapeutic benefits and commercial attractiveness of proven drugs while minimising risk by capitalising on their known safety, efficacy and commercialization history. MAP Pharmaceuticals has two drug candidates in Phase III clinical trials. Unit Dose Budesonide is being developed for the potential treatment of paediatric asthma, and MAP0004 is being developed for the potential treatment of migraine. MAP Pharmaceuticals' pipeline also includes a drug candidate in early clinical development for the treatment of asthma and chronic obstructive pulmonary disease. Additional information about MAP Pharmaceuticals can be found at <http://www.mappharma.com>.

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19 December 2009

- ENDS -

Item 7

ASTRAZENECA RECEIVES FDA COMPLETE RESPONSE LETTER ON SEROQUEL XR FOR MAJOR DEPRESSIVE DISORDER

AstraZeneca today announced the company has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) asking for additional information for the supplemental New Drug Application for SEROQUEL XR (quetiapine fumarate) Extended Release Tablets for the treatment of Major Depressive Disorder (MDD) in adult patients.

AstraZeneca is evaluating the contents of the CRL and the proposed labelling revisions. AstraZeneca will continue discussions with the FDA and will provide a response to the agency in due course.

SEROQUEL XR, a once-daily, extended release formulation of SEROQUEL (quetiapine fumarate), was approved in the U.S. in 2007 for the acute and maintenance treatment of schizophrenia in adult patients and in October 2008 for the acute treatment of the depressive episodes associated with bipolar disorder, the manic and mixed episodes associated with bipolar I disorder, and the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex. The CRL does not change the current recommendations for the treatment of patients taking SEROQUEL XR or SEROQUEL for approved indications in schizophrenia and bipolar disorder.

An update to AstraZeneca investors on progress will be provided when appropriate.

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