

ASTRAZENECA PLC
Form 6-K
May 28, 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 May 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 ☒ 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 to acquire OMThera Pharmaceuticals INCLUDING NDA-Ready NOVEL Dyslipidemia Treatment TO complement cardiovascular portfolio

AstraZeneca today announced that it has entered into a definitive agreement to acquire Omthera Pharmaceuticals, a specialty pharmaceutical company based in Princeton, New Jersey, focused on the development and commercialisation of new therapies for abnormal levels of lipids in the blood, referred to as dyslipidemia.

Omthera's investigational product, EpanovaTM, for the potential treatment of patients with very high triglycerides, is a novel omega-3 free fatty acid composition that has been shown to bolster levels of eicosapentaenoic acid and docosahexaenoic acid significantly in the blood. In studies to date, it has been shown to reduce triglyceride levels and improve other key lipid parameters and is expected to increase convenience for patients by providing both two and four gram once-a-day doses with or without meals.

Under the terms of the agreement, AstraZeneca will acquire Omthera for \$12.70 per share, or approximately \$323 million, which has an Enterprise Value of approximately \$260 million after incorporating Omthera's cash balances of approximately \$63 million. This represents a premium of 88% on Omthera's closing price on Friday 24 May 2013. In addition to the cash payment, each Omthera shareholder will receive Contingent Value Rights (CVRs) of up to approximately \$4.70 per share, equating to approximately \$120 million in total, if specified milestones related to Epanova are achieved, or if a milestone related to global net sales is achieved. This will bring the total potential acquisition cost to approximately \$443 million.

Omthera has completed pharmacokinetic and Phase III clinical studies to investigate the safety and efficacy profile of Epanova, a coated soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids derived from fish oils. In 2012, Omthera reported positive results from two Phase III trials (EVOLVE and ESPRIT) examining the effectiveness of Epanova in lowering very high triglycerides, and in reducing non-HDL cholesterol in combination with a statin for patients with high triglycerides. Both trials were conducted under a Special Protocol Assessment with the US Food and Drug Administration.

Omthera is expected to file a new drug application (NDA) in the US for Epanova in mid-2013 for patients with severe hypertriglyceridemia (triglyceride levels greater than or equal to 500mg/dL), with regulatory filings in other markets to follow. AstraZeneca aims to file a supplemental NDA as soon as possible for Epanova as a treatment for patients with mixed dyslipidemia (triglyceride levels of 200-499mg/dl), as well as in a fixed dose combination with CRESTOR[®] (rosuvastatin calcium) for those mixed dyslipidemia patients at high risk of a cardiovascular event. AstraZeneca intends to pursue a large-scale cardiovascular outcomes trial for Epanova in combination with statins.

Pascal Soriot, Chief Executive Officer of AstraZeneca said: "The number of people with elevated triglyceride levels is rising rapidly across the world, due in part to the increasing prevalence of obesity and diabetes. There is a clear need for effective and convenient alternatives to some of the existing treatments. Epanova offers real potential both as a distinctive monotherapy for the treatment of hypertriglyceridemia and in combination with Crestor for patients at high risk of adverse cardiovascular events. This is an exciting acquisition that clearly complements our existing portfolio in cardiovascular and metabolic disease, one of our core therapy areas."

Gerald L. Wisler President & CEO, Board Member, and Co-Founder of Omthera, commented: "We are delighted to be joining AstraZeneca, a leading pharmaceutical company with a proven track record in the development and commercialisation of global brands in the area of cardiovascular disease. We believe strongly that AstraZeneca can maximise the value of Epanova not only as a monotherapy treatment for dyslipidemia but also as a treatment for cardiovascular disease in combination with Crestor."

The Board of Directors of Omthera has unanimously approved the terms of the agreement, and has recommended that its shareholders approve the transaction. AstraZeneca's Board has also approved the terms of the agreement. Subject to the approval of Omthera's shareholders as well as other conditions including customary regulatory approvals, the transaction is expected to close in the third quarter of 2013. Omthera's shareholders representing approximately 60% of the current total shares outstanding have entered into a voting agreement with AstraZeneca to vote in favour of the transaction, subject to the conditions set out in the voting agreement.

About Epanova™

Epanova is a patent protected, novel, ultra-pure mixture of the free fatty acid forms of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) that meaningfully reduces triglycerides, improves other key lipid parameters and is expected to increase patient convenience with 2-gram once-a-day dosing with or without meals. Epanova is a coated soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids derived from fish oils, including multiple long-chain omega-3 and omega-6 fatty acids, with EPA, DHA, and docosapentaenoic acid being the most abundant forms of omega-3 fatty acids. Omthera Pharmaceuticals has completed pharmacokinetic and Phase III clinical studies to investigate the safety and efficacy profile of Epanova. In 2012 Omthera reported positive results from its Phase III EVOLVE and ESPRIT trials, both of which were conducted under a Special Protocol Assessment with the U.S. Food and Drug Administration. Omthera is expected to file an NDA for Epanova in mid-2013 for patients with triglyceride levels greater than or equal to 500mg/dL or for severe hypertriglyceridemia. Other planned indications for the monotherapy are as an adjunct to statin therapy and diet in patients with mixed dyslipidemia and increased triglycerides (>200 and <500 mg/dL) and as an adjunct to statin therapy and diet in high-risk patients for the prevention and reduction of major adverse cardiovascular events. Omthera holds worldwide rights to Epanova under a license from Chrysalis Pharma AG, a privately held Swiss company that is the owner of the product.

About hypertriglyceridemia

Hypertriglyceridemia is a serum lipid disorder (dyslipidemia) defined by serum triglyceride levels of ≥ 150 mg/dL. It is associated with an increased risk of cardiovascular diseases, such as coronary artery disease, or acute risk of pancreatitis if triglyceride levels exceed 500 mg/dL. In 2011, dyslipidemia affected 352 million people aged 20 or older across the major pharmaceutical markets (United States, France, Germany, Italy, Spain, United Kingdom, and Japan), caused by genetic predisposition and various secondary/contributing factors, such as lifestyle and dietetic behaviour (e.g. obesity, malnutrition, metabolic syndrome), as well as by numerous diseases (e.g. diabetes, renal disease, autoimmune diseases). It is estimated that there are 5 million patients in the U.S. with TG levels > 500 mg/dL. A recent NHANES analysis of dyslipidemia in the US indicated that low-density lipoprotein levels have actually declined since the last analysis, but the percentage of patients with severe hypertriglyceridemia has risen sharply along with the dramatic increases in obesity.

About mixed dyslipidemia

The second most common form of dyslipidemia is mixed dyslipidemia. Physicians estimate that between 22% and 37% of patients have this form of dyslipidemia. The term mixed dyslipidemia refers to a condition in which the patient suffers from hypercholesterolemia, low high-density lipoprotein levels and hypertriglyceridemia. Due to the nature of the condition and the fact that different classes of antidyslipidemics offer different benefits in controlling lipid abnormalities, a combination therapy is often considered the most beneficial in patients with mixed dyslipidemia.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Options are a combination of a statin with either fibrate or nicotinic acid or Omega-3 fatty acids.

About Omthera Pharmaceuticals, Inc.

Founded in 2008, Omthera Pharmaceuticals, Inc. is an emerging specialty pharmaceutical company that listed on NASDAQ in April 2013 (NASDAQ: OMTH). Led by a team of experts with exceptional experience in developing new therapies for lipid disorders, Omthera is dedicated to developing innovative therapies for the millions of patients who have elevated triglyceride levels and increased risk of cardiovascular disease. Omthera currently has 14 employees based in Princeton, New Jersey. For more information please visit: www.omthera.com

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com

CONTACTS

Omthera Pharmaceuticals contacts

Chris Schade, Executive Vice President and Chief Financial Officer +1 908 741 6402 (US)

AstraZeneca contacts

Media Enquiries

Ayesha Bharmal +44 20 7604 8034 (UK/Global)

Vanessa Rhodes +44 20 7604 8037 (UK/Global)

Tony Jewell +1 (302) 885 4594 (US)

Jacob Lund +46 8 553 260 20 (Sweden)

Investor Enquiries

James Ward-Lilley +44 20 7604 8122 mob: +44 7785 432613

Karl Hård +44 20 7604 8123 mob: +44 7789 654364

Colleen Proctor +1 302 886 1842 mob: +1 302 357 4882

Ed Seage +1 302 886 4065 mob: +1 302 373 1361

28th May 2013

- 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: 28 May 2013

By: /s/ Adrian Kemp

Name: Adrian Kemp

Title: Company Secretary