

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): February 19, 2009

XOMA LTD.

(Exact name of registrant as specified in its charter)

BERMUDA

(State or other jurisdiction of incorporation)

0-14710

(Commission File Number)

52-2154066

(IRS Employer Identification No.)

2910 Seventh Street, Berkeley, California

(Address of principal executive offices)

94710

(Zip code)

Registrant's telephone number, including area code

(510) 204-7200

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events

On February 19, 2009, the European Medicines Agency (the “EMA”) announced it has recommended suspension of the marketing authorisation of RAPTIVA[®] (efalizumab) in the European Union. The EMA’s press release is attached as Exhibit 1 hereto and incorporated by reference herein.

Also on February 19, 2009, the U.S. Food and Drug Administration (the “FDA”) issued a public health advisory concerning three confirmed reports, and one possible report, of progressive multifocal leukoencephalopathy, or PML, in patients using RAPTIVA[®]. The FDA’s news release is attached as Exhibit 2 hereto and incorporated by reference herein.

XOMA Ltd. currently receives royalties on worldwide sales of RAPTIVA[®], a humanized therapeutic monoclonal antibody approved for adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. RAPTIVA[®] is marketed by Genentech Inc. in the United States and by Merck Serono S.A. outside the United States.

Item 9.01. Financial Statements and Exhibits.

1. Press Release issued by the European Medicines Agency dated February 19, 2009
 2. News Release issued by the U.S. Food and Drug Administration dated February 19, 2009
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SIGNATURE

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 hereunto duly authorized.

Dated: February 19, 2009

XOMA LTD.

By: /s/ Fred Kurland
Fred Kurland
Vice President, Finance and Chief
Financial Officer

EXHIBIT INDEX

Number

Description

1. Press Release issued by the European Medicines Agency dated February 19, 2009
2. News Release issued by the U.S. Food and Drug Administration dated February 19, 2009

PRESS RELEASE

European Medicines Agency recommends suspension of the marketing authorisation of Raptiva (efalizumab)

The European Medicines Agency (EMA) has recommended the suspension of the marketing authorisation for Raptiva (efalizumab), from Serono. The EMA's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Raptiva no longer outweigh its risks, because of safety concerns, including the occurrence of progressive multifocal leukoencephalopathy (PML) in patients taking the medicine.

Raptiva has been authorised in the European Union (EU) since September 2004 to treat adult patients with moderate to severe chronic plaque psoriasis (a disease causing red, scaly patches on the skin), who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and PUVA (psoralen ultraviolet-A).

The CHMP reviewed the medicine at the request of the European Commission, following reports of serious side effects, including three confirmed cases of PML in patients who had taken Raptiva for more than three years. PML is a rare brain infection that usually leads to severe disability or death. Two of the three confirmed cases of PML reported to the CHMP resulted in the patient's death. The CHMP also received an additional report of a suspected case of PML, which could not be confirmed.

Following review of all available data on the medicine's safety and effectiveness, the CHMP concluded that:

- Raptiva's benefits are modest;
- in addition to PML, Raptiva is associated with other serious side effects, including Guillain-Barré and Miller-Fisher syndromes, encephalitis, encephalopathy, meningitis, sepsis and opportunistic infections (infections occurring in people with compromised immune systems);
- there is not enough evidence to identify a group of patients in which the benefits of Raptiva outweigh its risks, in particular there is a lack of data on effectiveness and safety in patients who have no other treatment options and who may already have a weakened immune system as result of previous treatments.

The CHMP was therefore of the opinion that the risks of Raptiva outweigh its benefits and that the marketing authorisation for this medicine should be suspended in the EU.

Prescribers should not issue any new prescriptions for Raptiva and should review the treatment of patients currently receiving the medicine to assess the most appropriate alternatives. They should make sure that patients who have been treated with Raptiva are closely monitored for neurological symptoms and symptoms of infection. Patients who are currently taking Raptiva should not stop treatment abruptly, but should make an appointment with their doctor to discuss the most appropriate replacement treatment.

The EMEA's recommendation has been sent to the European Commission for the adoption of a legally binding decision.

Notes:

1. More information is available in a question-and-answer document. (www.emea.europa.eu/humandocs/PDFs/EPAR/raptiva/RaptivaQ&A_1552509en.pdf)
2. The suspension of a marketing authorisation is a temporary measure, during which time a medicinal product is not available. The lifting of the suspension is conditional on the marketing authorisation holder being able to demonstrate a positive benefit-risk balance for certain groups of patients.
3. More information about Raptiva is available in the European public assessment report here: <http://www.emea.europa.eu/humandocs/Humans/EPAR/raptiva/raptiva.htm>
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to:

Martin Harvey Allchurch or Monika Benstetter

Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu

FDA News

FOR IMMEDIATE RELEASE

Feb. 19, 2009

Media Inquiries:

Rita Chappelle, 301-796-4672

Consumer Inquiries:

888-INFO-FDA

FDA Advises Public of Serious Adverse Event with Psoriasis Drug Raptiva

The U.S. Food and Drug Administration today issued a public health advisory concerning three confirmed, and one possible report of progressive multifocal leukoencephalopathy (PML), a rare brain infection, in patients using the psoriasis drug Raptiva (efalizumab). Three of those patients have died. All four patients were treated with the drug for more than three years. None of the patients were receiving other treatments that suppress the immune system.

The FDA is reviewing this latest information. The agency will take appropriate steps to:

- ensure that the risks of Raptiva do not outweigh its benefits;
- that patients prescribed Raptiva are clearly informed of the signs and symptoms of PML; and
- that health care professionals carefully monitor patients for the possible development of PML.

PML is caused by a virus that affects the central nervous system. PML usually occurs in people whose immune systems have been severely weakened. It leads to an irreversible decline in neurologic function and death. Symptoms may include unusual weakness, loss of coordination, changes in vision, difficulty speaking and personality changes. There is no known effective prevention or treatment.

Psoriasis is a chronic disease, for which a number of effective therapeutic options are available, including four other approved biologic agents, ultraviolet light therapy, and the drugs cyclosporine, acitretin, and methotrexate. Generally, treatment for psoriasis patients involves a rotation of therapies.

In October 2008, the product labeling for Raptiva was revised to highlight in a boxed warning the risks of life-threatening infections, including PML. At that time, the FDA directed Genentech, the manufacturer, to develop a risk evaluation and mitigation strategy (REMS) to include a medication guide to educate patients about the drug's risks.

The FDA strongly recommends that health care professionals carefully monitor patients

on Raptiva, as well as those who have discontinued the drug, for any signs or symptoms of neurologic disease, and that they periodically reassess the benefits of continued treatment. Patients should be aware of the symptoms of PML and contact their health care professionals immediately if they experience any such symptoms.

Raptiva is a once-weekly injection approved for adults with moderate to severe plaque psoriasis who are candidates for systemic (whole body) therapy or phototherapy. The drug works by suppressing T-cells (blood cells that help fight infection) in the immune system. These cells, when activated, migrate to the skin and cause inflammation which results in the red, inflamed and scaly patches of skin, which is associated with psoriasis. By suppressing T-cells, Raptiva decreases the function of the immune system which increases a patient's susceptibility to infections.

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, fax or phone.

--Online: www.fda.gov/MedWatch/report.htm

--Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

--Fax: (800) FDA-0178

--Phone: (800) FDA-1088

Read the FDA's 2009 Public Health Advisory (www.fda.gov/cder/drug/advisory/efalizumab.htm)