

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): October 16, 2008

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 October 16, 2008, the U.S. Food and Drug Administration (the "FDA") announced labeling changes, including a Boxed Warning, to highlight the risks of life-threatening infections, including progressive multifocal leukoencephalopathy, with the use of RAPTIVA[®] (efalizumab). The FDA's news release is attached as Exhibit 1 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. News Release issued by the U.S. Food and Drug Administration dated October 16, 2008
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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: October 17, 2008

XOMA LTD.

By: /s/ Christopher J. Margolin
Christopher J. Margolin
Vice President, General
Counsel and Secretary

EXHIBIT INDEX

Number

Description

1. News Release issued by the U.S. Food and Drug Administration dated October 16, 2008

FDA News

FOR IMMEDIATE RELEASE
October 16, 2008

Media Inquiries:
Rita Chappelle, 301-827-6246
Consumer Inquiries:
888-INFO-FDA

FDA Approves Updated Labeling for Psoriasis Drug Raptiva

Safety concerns drove labeling changes

The U.S. Food and Drug Administration today announced labeling changes, including a Boxed Warning, to highlight the risks of life-threatening infections, including progressive multifocal leukoencephalopathy (PML), with the use of Raptiva (efalizumab). The labeling changes are based on the FDA's post-market surveillance. The FDA is also requiring the submission of a Risk Evaluation and Mitigation Strategy (REMS), which will include a Medication Guide for patients and a timetable for assessment of the REMS.

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 to control their psoriasis.

The FDA's Office of Surveillance and Epidemiology, charged by the Agency with monitoring drugs once approved for the marketplace, has received reports of serious infections leading to hospitalizations, and deaths in some cases, in patients using Raptiva.

The now-required Boxed Warning will highlight the risk of bacterial sepsis, viral meningitis, invasive fungal disease, progressive multifocal leukoencephalopathy and other opportunistic infections.

Additionally, Raptiva's label will be updated to include data from juvenile animal studies in mice (age equivalent to a 1-14 year old human). These data indicate a potential risk for the permanent suppression of the immune system with repeat administration of Raptiva in this age group. Raptiva is not approved for children under 18 years of age.

"As part of FDA's monitoring of the life-cycle of approved products, the agency received reports of serious infections in some patients taking Raptiva. These reports led to our decision to highlight these risks in the drugs labeling," said Janet Woodcock, the FDA's director of the Center for Drug Evaluation and Research. "Doctors and other prescribers should carefully evaluate and weigh the risk/benefit profile of Raptiva for patients who would be more susceptible to these risks."

Raptiva works by suppressing the immune system to reduce psoriasis flare-ups, however by suppressing the body's natural defense system, it can also increase

the risk of serious infections and malignancies in patients.

Patients identified to begin therapy with Raptiva should have received all their age-appropriate vaccinations before starting the drug. Vaccinations should not be administered to patients taking Raptiva because immunity to the vaccination virus may not be conferred.

Patients taking Raptiva should be educated about recognizing the signs and symptoms of infection, PML (confusion, dizziness or loss of balance, difficulty talking or walking, and vision problems), anemia (dizziness upon standing, weakness or jaundice), thrombocytopenia (bruising, bleeding gums, pin-point sized red or purple dots under the skin), or the worsening of their psoriasis or arthritis. Signs of a nervous system disorder include sudden onset of numbness, tingling or weakness in the arms, legs or face.

If any of these signs appear, Raptiva patients should seek immediate medical attention. Patients with pre-existing infections or who have a compromised immune system should notify their health care professional before beginning treatment with Raptiva.

Because reports of these adverse events were received voluntarily from populations of unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the drug's use.

One report of PML in a Raptiva-treated patient came from an ongoing post-marketing epidemiological study of patients with psoriasis.

Health care professionals should monitor patients treated with Raptiva for the signs and symptoms of these adverse events and also instruct patients to report any such signs and symptoms to them without delay.

Consumers and health care professionals can report adverse events to the FDA's MedWatch program at 800-FDA-1088, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or online at www.fda.gov/medwatch/report.htm.

Raptiva was approved in 2003. It is manufactured by Genentech, Inc. of San Francisco, Calif.