

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): September 9, 2003

XOMA LTD.

(Exact name of registrant as specified in its charter)

BERMUDA

(State or other jurisdiction of incorporation)

0-14710

52-2154066

(Commission File Number)

(IRS Employer Identification No.)

2910 Seventh Street, Berkeley, California

94710

(Address of principal executive offices)

(Zip code)

Registrant's telephone number, including area code

(510) 204-7200

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

Item 5. Other Events

On September 9, 2003, XOMA Ltd. issued the announcement attached hereto as Exhibit 1, which is incorporated herein by reference.

Item 7. Exhibits

1. Press Release dated September 9, 2003.

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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: September 10, 2003

XOMA LTD.

By: /s/ Christopher J. Margolin

Christopher J. Margolin
Vice President, General
Counsel and Secretary

EXHIBIT INDEX

Number	Description
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1.	Press Release dated September 9, 2003
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SOUTH SAN FRANCISCO, Calif. & BERKELEY, Calif.--(BUSINESS WIRE)--Sept. 9, 2003--Genentech, Inc. (NYSE:DNA) and XOMA Ltd. (Nasdaq:XOMA) today announced that the U.S. Food and Drug Administration's (FDA) Dermatologic and Ophthalmic Drug Advisory Committee (DODAC) voted unanimously (11-0) to recommend that Raptiva(TM) (Efalizumab) be approved for the treatment of moderate-to-severe plaque psoriasis in adults age 18 or older.

Although the FDA is not bound by the recommendations of its advisory committees, it generally follows their advice. Genentech and XOMA will continue discussions with the FDA regarding product labeling and post-marketing commitments.

"Today's advisory committee recommendation is an important step toward providing a new therapeutic option for people with psoriasis," said Hal Barron, M.D., F.A.C.C., Genentech's vice president, Medical Affairs. "People with psoriasis are faced with a lifetime of disease management. If approved, Raptiva may offer patients a new approach to control of this chronic disease."

Raptiva is a T-cell modulator designed to selectively and reversibly block the activation of T-cells that cause psoriasis. In clinical trials, Raptiva demonstrated rapid onset of action in the reduction of symptoms associated with psoriasis, including a reduction in the thickness, scaling and redness of skin lesions, or plaques. The therapy was administered once weekly via subcutaneous injection, and in several of the trials, was self-administered by patients at home.

Jack Castello, XOMA's president and chief executive officer added, "We are pleased with the FDA advisory committee's unanimous recommendation and if Raptiva is approved, we look forward to offering an effective biologic treatment option to patients who desire to manage their disease and remove the limitations psoriasis currently imposes on their lives."

Raptiva is being developed by Genentech and XOMA in the United States. The Biologics License Application (BLA) for Raptiva was filed in December 2002, with a supplemental data amendment filing in May 2003. An FDA response on the Raptiva BLA is expected by October 27, 2003.

Genentech and XOMA are collaborating on the development and commercialization of Raptiva in the United States. Serono S.A., Genentech's marketing partner outside the United States and Japan, announced in February 2003 that it had submitted a Marketing Authorization Application (MAA) to the European Agency for the Evaluation of Medicinal Products (EMEA) for European Union Approval of Raptiva in psoriasis. Serono has also submitted Raptiva data for marketing approval in Canada, Switzerland, Australia and New Zealand and is filing in additional countries.

Raptiva Phase III Clinical Trials Results

The FDA advisory committee's recommendation was based on data from four randomized, placebo-controlled Phase III studies. The FDA submission (BLA) included data on more than 2,700 patients treated with Raptiva, representing the largest existing database of patients treated with a biologic therapy for psoriasis. The Phase III trials were designed to evaluate the safety and efficacy of Raptiva as a potential treatment for moderate-to-severe plaque psoriasis.

The studies had a primary efficacy endpoint of 75 on the Psoriasis Area and Severity Index (PASI), measuring the proportion of patients achieving a 75 percent or greater PASI score improvement. The PASI score is a rating system that incorporates thickness of psoriatic plaque, degree of scaling, level of redness, and percentage of body surface affected. Secondary endpoints for the Phase III studies included physician assessment, patient-reported outcomes and quality-of-life improvements.

Data presented at today's DODAC advisory committee hearing included efficacy data for 12 and 24 weeks of treatment.

- At week 12 of the pivotal, randomized, double blind, placebo-controlled Phase III study, 27 percent (98/369) of the patients receiving Raptiva achieved PASI 75 and 59 percent (216/369) of patients achieved a 50 percent or greater PASI improvement (PASI 50).
- At 24 weeks of the open-label, extended treatment period following the first 12 weeks of treatment, 44 percent (161/369) of patients who had received at least one dose of Raptiva during the first 12 weeks achieved PASI 75 and 66 percent (245/369) of patients achieved PASI 50.

Raptiva was well tolerated in Phase III studies. Adverse events that occurred in at least five percent of patients treated with Raptiva and one percent more frequently than in the placebo group included headache, chills, pain, flu syndrome, fever, asthenia, nausea, myalgia (muscle pain), and pharyngitis. Five of these events (headache, chills, fever, nausea and myalgia) were predominantly acute adverse events, principally seen following the first two injections of Raptiva. For the third and subsequent doses, the incidence of acute adverse events was similar between the Raptiva and placebo groups. Less than three percent of patients were discontinued from treatment due to adverse events. Infrequent serious adverse events included psoriatic recurrences (most of which occurred after treatment was stopped), thrombocytopenia and infection.

If approved, the final efficacy and safety description included in Raptiva's product labeling will be determined by the FDA.

About Psoriasis

Psoriasis occurs when new skin cell growth rapidly accelerates, resulting in thick, red, scaly, inflamed patches on the skin surface. Psoriasis affects approximately 4.5 million Americans. Plaque psoriasis, the most common form of the disease, is characterized by inflamed patches of skin ("lesions") topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the scalp, knees, elbows and trunk. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there is currently no cure.

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About Genentech

Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Sixteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes 11 biotechnology products in the United States. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit <http://www.gene.com>.

Immediately following the advisory committee meeting, Genentech will host a webcast to discuss the results of the meeting. The webcast began at 3:00 p.m. Pacific Time/6:00 p.m. Eastern Time on September 9, 2003. The live webcast can be accessed by going to Genentech's website at <http://www.gene.com> and will be archived and available for replay until 5:00 p.m. Pacific Time on September 16, 2003.

An audio replay of the webcast will be available beginning at 5:00 p.m. Pacific Time/8:00 p.m. Eastern Time on September 9, 2003 and ending at 5:00 p.m. Pacific Time/8:00 p.m. Eastern Time on September 16, 2003. Access numbers for this replay are: 1-800-642-1687 (U.S./Canada) and 1-706-645-9291 (international); passcode number is 2287750.

About XOMA

XOMA develops and manufactures antibody and other protein-based biopharmaceuticals for disease targets that include immunological and inflammatory disorders, cancer and infectious diseases. XOMA's programs include collaborations: with Genentech, Inc. on the Raptiva(TM) antibody for psoriasis (BLA submission), psoriatic arthritis (Phase II) and other indications; and with Millennium Pharmaceuticals, Inc. on two biotherapeutic agents, CAB-2 and MLN2201, for vascular inflammation indications (preclinical and phase I, respectively). Earlier-stage development programs focus on antibodies and other compounds developed by XOMA for the treatment of cancer, retinopathies and acne. For more information about XOMA's pipeline and activities, please visit XOMA's website at <http://www.xoma.com/>.

Regarding XOMA:

Statements made in this news release related to the BLA review and other aspects of the regulatory process, as well as the collaborative arrangements regarding Raptiva(TM), or that otherwise relate to future periods, are forward looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on assumptions that may not prove accurate. Actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market. These risks include those related to safety and efficacy of the product being studied (including the product's ability to remain

safe and efficacious in the long term); action, inaction or delay by the Food and Drug Administration, European regulators and/or their advisory bodies; analysis and

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interpretation by these entities and others of scientific data; failure of the FDA to follow the recommendation of the DODAC; changes in the status of existing collaborative relationships; the ability of collaborators to meet their obligations; and market demand for products. These risks are discussed in XOMA's most recent annual report on Form 10-K and in other SEC filings. Consider such risks carefully in evaluating XOMA's prospects.

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