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XOMA LTD /DE/
Form 8-K
December 18, 2003

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): December 18, 2003

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

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

As announced on December 18, 2003, Alexion Pharmaceuticals, Inc. and XOMA Ltd. agreed to collaborate for the development and commercialization of an antibody to treat chemotherapy-induced thrombocytopenia.

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A copy of the press release is attached hereto as Exhibit 1 and is incorporated herein by reference.

Item 7. Exhibits

1. Press Release dated December 18, 2003.

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: December 18, 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 December 18, 2003. |
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Exhibit 1

Alexion Pharmaceuticals Investor/Media Contacts:
Stephen P. Squinto, Ph.D.
Executive Vice President and Head of Research
(203) 272-2596

Rhonda Chiger (Investors)
Rx Communications Group
(917) 322-2569

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Ernie Knewitz (Media)
Euro RSCG Life NRP
(212) 845-4253

XOMA Investor/Media Contacts:
Laura Zobkiw
Corporate Communications/Investor Relations
(510) 204-7273

ALEXION PHARMACEUTICALS AND XOMA FORM COLLABORATION *****

-- Product Development Efforts To Focus On TPO Mimetic Antibody --

CHESHIRE, CT and BERKELEY, CA, December 18, 2003 - Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) and XOMA Ltd. (Nasdaq: XOMA) today announced a collaborative agreement for the development and commercialization of a rationally designed human c-MPL agonist antibody to treat chemotherapy-induced thrombocytopenia. The compound was discovered at Alexion Antibody Technologies (AAT), a wholly owned subsidiary of Alexion, and is in preclinical development. The c-MPL antibody was designed to mimic the activity of human thrombopoietin (TPO), a naturally occurring protein responsible for platelet production. Thrombocytopenia is an abnormal blood condition in which the number of platelets is reduced, potentially leading to bleeding complications.

"This collaboration combines XOMA's bacterial cell expression technology and its strong process development and manufacturing capabilities with Alexion's expertise in antibody engineering, providing the best development means for this compound," said Stephen P. Squinto, Ph.D., Executive Vice President and Head of Research. "This also marks a milestone for AAT and demonstrates the progression of our pipeline; we are pleased to be moving this antibody forward jointly with XOMA."

"We're enthusiastic about working with Alexion. By collaborating with them, we gain access to a promising product candidate and Alexion's antibody engineering and development expertise," John L. Castello, XOMA's Chief Executive Officer, President and Chairman said. "The c-MPL agonist antibody is particularly well suited to our process development capabilities, including our bacterial cell expression system. By combining the strengths of our two companies, we hope to accelerate getting this product into the clinic and ultimately potential marketing approval."

Under the terms of the agreement, Alexion and XOMA will jointly develop and commercialize the c-MPL agonist antibody for chemotherapy-induced thrombocytopenia. The parties will share development and commercialization expenses, including preclinical and clinical development, manufacturing and marketing costs world-wide, as well as revenues, generally on a 70-30 basis, with Alexion retaining the larger portion. In addition, Alexion will receive payments tied to initiation of the collaboration and achievement of a regulatory milestone. XOMA will be entitled to royalty payments and milestones related to its bacterial expression technology. Specific financial terms were not disclosed. The collaboration will initially focus on preclinical, process development and scale-up work, with initial clinical testing anticipated in 2005.

About the TPO Mimetic Antibodies

The rationally designed human c-MPL agonist antibody is part of a new class of

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therapeutic antibodies that function as receptor agonists that can stimulate their cell target, rather than blocking it, and were created using a rational design and selection process proprietary to AAT. The first rationally designed human antibody of this new class was designed to accelerate the return of blood platelet levels to normal following a toxic assault on the bone marrow, which commonly results in cancer patients undergoing chemotherapy. The TPO agonist antibody has been designed to bind to and stimulate the c-MPL receptor on the surface of platelet precursors and then to stimulate platelet-specific proliferation with a specificity and activity similar to the body's own natural platelet hormone, thrombopoietin. However, this antibody lacks any protein sequences related to native thrombopoietin, providing additional therapeutic benefit by potentially eliminating the harmful immune responses that have been associated with recombinant thrombopoietin. Alexion recently presented the status of its rationally designed human c-MPL agonist program at the American Society of Hematology Meeting held in December 2003 in San Diego. Administration of the antibody showed an increase in platelets to normal levels in an animal model following chemotherapy, without production of neutralizing antibodies against native thrombopoietin. An abstract of the presentation, made by Dr. Yi Wang, PhD., Senior Director of Preclinical sciences at Alexion, is available at the Society's website, www.hematology.org

About Chemotherapy-induced thrombocytopenia

Chemotherapy-induced thrombocytopenia is a disease state where a patient's clot forming platelets are depleted as a byproduct of treatment with chemotherapeutic agents. Certain drugs used as chemotherapeutic agents are known to eliminate cells that are a part of the pathway that leads to formation of platelets.

These cells, known as megakaryocytes, are found in the bone marrow and are the precursor cells to platelets. Platelets play a critical role in the formation of blood clots and act by sticking together at the site of a wound to help stop the blood flow out of the wound. The normal level of platelets usually is in excess of the level required to support normal clot formation. However, following chemotherapy, these levels can fall to a level that requires blood transfusions to protect the patient from excessive bleeding.

About XOMA

XOMA develops and manufactures antibody and other protein-based biopharmaceuticals for disease targets that include cancer, immunological and inflammatory disorders, and infectious diseases. XOMA's programs include collaborations with Genentech, Inc. on the RAPTIVA(TM) antibody for psoriasis (being marketed), psoriatic arthritis (Phase II) and other indications and with Millennium Pharmaceuticals, Inc. on a recombinant protein, MLN 2222 for reducing the incidence of post-operative events in coronary artery bypass graft surgery patients employing cardiopulmonary bypass (Phase I).

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Bactericidal/permeability-increasing protein (BPI)-derived programs include NEUPREX(R) in a Phase I/II study to limit complications following pediatric cardiopulmonary bypass surgery, and XMP.629, a topical formulation of a BPI-derived compound for acne (Phase I). Other development programs focus on antibodies and other compounds developed by XOMA for the treatment of cancer and retinopathies. For more information about XOMA's pipeline and activities, please visit XOMA's website at <http://www.xoma.com/>.

About Alexion

Alexion is engaged in the discovery and development of therapeutic products

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aimed at treating patients with a wide array of severe disease states, including cardiovascular and autoimmune disorders, inflammation and cancer. Alexion's two lead product candidates, pexelizumab and eculizumab, are currently undergoing evaluation in several clinical development programs. Alexion has completed a Phase III clinical study with pexelizumab in coronary artery bypass graft surgery patients undergoing cardiopulmonary bypass, and two large Phase II studies with pexelizumab in acute myocardial infarction patients. The Phase III trial and Phase II trials were conducted in collaboration with Procter & Gamble Pharmaceuticals. In addition, eculizumab is in Phase II clinical trials in rheumatoid arthritis and membranous nephritis, and has completed pilot programs for the treatment of paroxysmal nocturnal hemoglobinuria and dermatomyositis. Alexion is engaged in discovering and developing a pipeline of additional antibody therapeutics targeting severe unmet medical needs, through its wholly owned subsidiary, Alexion Antibody Technologies, Inc. This press release and further information about Alexion Pharmaceuticals, Inc. can be found on the World Wide Web at: www.alexionpharm.com.

Re: XOMA

Certain statements contained herein related to the development of the c-MPL antibody and XOMA's collaborative arrangement with Alexion, 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 and other risks, including those related to the results of pre-clinical testing, the timing or results of future clinical trials (including the design and progress of clinical trials; safety and efficacy of products being tested; action, inaction or delay by the FDA, European or other regulators or their advisory bodies; and analysis or interpretation by, or submission to, these entities or others of scientific data), changes in the status of existing collaborative relationships, the ability of collaborators and other partners to meet their obligations, market demand for products, scale-up and marketing capabilities, competition, XOMA's financing needs and opportunities, share price volatility, international operations, uncertainties regarding the status of biotechnology patents, uncertainties as to the cost of protecting intellectual property and risks associated with XOMA's status as a Bermuda company, are described in more detail in XOMA's most recent annual report on Form 10-K and in its other SEC filings.

Re: Alexion

This news release contains forward-looking statements. Such statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including the results of pre-clinical or clinical studies (including termination or delay in clinical programs), the need for additional research and testing, delays in arranging satisfactory manufacturing capability, inability to acquire funding on timely and satisfactory terms, de-

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lays in developing or adverse changes in commercial relationships, the possibility that results of earlier clinical trials are not predictive of safety and efficacy results in later clinical trials, dependence on Procter & Gamble Pharmaceuticals for development and commercialization of pexelizumab, the risk that third parties won't agree to license any necessary intellectual property to

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us on reasonable terms, and a variety of other risks set forth from time to time in Alexion's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Annual Report on Form 10-K for the year ended July 31, 2003 and in our other filings with the Securities and Exchange Commission. In particular, Alexion is not currently able to predict the determination of the United States Food and Drug Administration (FDA) and other regulatory agencies regarding the results of the PRIMO-CABG trial. Such determinations may include, but not be limited to, the view that the results may be sufficient for filing and approval of a Biologics License Application (BLA), supportive of the filing and approval of a BLA together with additional studies, or not supportive of the filing or approval of a BLA. Further, Alexion is not currently able to predict the reaction of P&GP to the results of the PRIMO-CABG trial, including how those results may affect P&GP's views of pexelizumab for CABG or other indications. P&GP retains the development rights and the termination rights discussed in Alexion's Form 10-K referred to above. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

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