

# XOMA Reports 2009 Second Quarter Financial Results

BERKELEY, Calif., Aug. 6, 2009 (GLOBE NEWSWIRE) -- XOMA Ltd. (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced its financial results for the second quarter of 2009 and six months ended June 30, 2009.

"In the second quarter, XOMA achieved a key goal by completing the second and third parts of the XOMA 052 U.S. Phase 1 trial in patients with Type 2 diabetes. We reported encouraging results demonstrating a favorable safety profile and clinically meaningful improvements in diabetic and inflammatory measures. These results were observed after just three doses out to the last day of the study. In addition, the first evidence of improved peripheral insulin sensitivity was observed," said Steven Engle, Chairman and Chief Executive Officer of XOMA. "Although studies of larger size and longer duration will be required to determine XOMA 052's full potential, these positive biological activity results exceeded the usual expectations that are typical for a Phase 1 study. We believe these results position the company well to begin evaluating XOMA 052 in Phase 2 studies.

"We continued to educate physicians and scientists about XOMA 052 at the American Diabetes Association 69th Scientific Sessions in New Orleans in June and found interest in this novel anti-inflammatory approach to diabetes and cardiovascular disease was well-received," Mr. Engle said. "We significantly reduced operating expenses in the 2009 second quarter as compared to the 2008 second quarter, through the successful implementation of multiple cost reduction initiatives."

For the second quarter of 2009, XOMA recorded revenues of \$9.7 million, compared with \$11.1 million for the same period of 2008. The decrease was primarily due to a decrease in royalty revenue from RAPTIVA(r) sales, which was partially offset by higher contract revenue and royalty revenue from LUCENTIS(r) sales.

The company had a net loss of \$10.2 million, or \$0.07 per share in the 2009 second quarter, compared with a net loss of \$20.7 million, or \$0.16 per share, for the second quarter of 2008, a reduction of approximately 50%. The improvement was primarily due to a decrease in operating expenses.

Total operating expenses were \$19.5 million in the 2009 second quarter, compared with \$29.9 million for the second quarter of 2008. The decrease in expenses was primarily due to reduced expenses arising from the January 2009 restructuring which focused on manufacturing and related areas and associated general and administrative support, multiple cost control initiatives and a decrease in preclinical and clinical expenditures in order to focus on the clinical development of XOMA 052 in Type 2 diabetes and cardiovascular

#### disease.

At June 30, 2009, XOMA had unrestricted cash, cash equivalents and short-term investments of \$27.6 million, compared with \$10.8 million at December 31, 2008. In May and June 2009, XOMA completed two registered direct offerings that provided approximately \$20.4 million in net proceeds to the company. Additional financial information is provided below and in the accompanying tables.

#### Recent Highlights

\* Positive top line results from U.S. Phase 1 trial of XOMA 052 shown in patients with Type 2 diabetes: XOMA completed parts two and three of its U.S. Phase 1 trial which involved 26 of the 81 patients treated to date with XOMA 052; overall, 98 patients were enrolled, including 17 patients randomized to placebo. These parts were designed to evaluate subcutaneous administration of multiple doses or a single dose of XOMA 052. The results demonstrate that XOMA 052 is well tolerated with a pharmacokinetic profile that supports monthly or less frequent dosing and drug bioavailability of 62-70%. Patients receiving multiple XOMA 052 doses had a more consistent response compared to patients who received a single dose or placebo. The improvements were seen through the end of the 84 day study and 56 days after the last dose was administered.

For the first time, evidence of improved insulin sensitivity, one of two major problems in diabetic patients, was shown. Insulin sensitivity indicates the ability of fat, muscle and liver cells to respond to insulin and a lack thereof results in an increased risk of heart attack, stroke, blindness and other problems. As previously announced, the results from the first part of the Phase 1 study showed that patients treated with XOMA 052 had improved insulin production, the other major problem in diabetic patients.

Patients treated with XOMA 052 on the low 0.03 mg/kg multiple dose regimen showed, at day 56, a clinically meaningful median 0.6% reduction in glycosylated hemoglobin (HbAlc), the primary endpoint for approval of diabetes drugs. These patients also had a rapid, sustained and clinically meaningful median reduction in fasting blood glucose of 27mg/dL at day 56 and 29 mg/dL at day 84 as compared to baseline. Fasting blood glucose measures blood glucose levels at a single point in time whereas HbAlc represents past behavior and is an average of blood glucose levels over the previous 60 to 90 days.

The 0.6% reduction in HbAlc at day 56 is in the range that most of the new Type 2 diabetes medications achieve after six months of drug exposure and which was the primary basis for their initial approval. This finding, coupled with the sustained reduction in fasting blood glucose after only three 0.03 mg/kg doses of XOMA 052, suggests that further improvements in HbAlc may be expected. XOMA plans to further explore the effect of XOMA 052 on glycemic control in Type 2 diabetes patients in the upcoming Phase 2 program.

The Phase 1 study included the evaluation of two markers of systemic inflammation: high-sensitivity C-reactive protein (hs-CRP), a biomarker associated with increased cardiovascular

risk, and erythrocyte sedimentation rate (ESR), a standard measure of systemic inflammation. A clinically relevant reduction in median hsCRP levels was observed in all dose groups, and all patients treated with multiple doses showed improvement in hsCRP from day 14 to the last visit at day 84. ESR levels were also reduced in both multi-dose groups.

- \* Positive new XOMA 052 clinical results reported at American Diabetes Association (ADA) 69th Scientific Sessions: In June 2009, new results were presented from the U.S. and Swiss Phase 1 trials which evaluated intravenous administration of a single dose of XOMA 052. The biological activity results presented at the ADA meeting included data from 39 Type 2 diabetes patients for which combined data were available. Thirty patients were randomized to receive XOMA 052, and nine patients received placebo. The results demonstrated that XOMA 052 was well tolerated, with a pharmacokinetic profile consistent with subcutaneous administration and monthly or less frequent dosing. Consistent reductions in HbAlc and hsCRP were observed out to the end of the 91 day study period. In the Swiss patient cohort, observations of enhanced insulin production and secretion to day 91, indicated improved beta cell health. Poor beta cell health and beta cell death are major causes of diabetes.
- \* New animal model results with XOMA 052 demonstrate improvement in diabetes and inflammatory measures: Also at the ADA meeting in June, XOMA presented new preclinical results with XOMA 052 in the diet-induced obesity mouse model, a validated tool for evaluating the role of IL-1 in Type 2 diabetes that mimics the development of the disease in humans. The study compared mice that received either a normal or high fat and high sucrose diet and either XOMA 052 or control. At the end of the study period, mice on the high-fat and high sucrose diet receiving XOMA 052 showed, statistically significant improvements in multiple measures of glycemic control, insulin secretion and beta cell function and proliferation, and dyslipidemia compared to the control mice.
- \* First U.S. patent issued that protects intellectual property position surrounding XOMA 052: On May 12, 2009, the U.S. Patent and Trademark Office issued U.S. Patent No. 7,531,166, covering XOMA 052 and other antibodies and antibody fragments with similar binding properties for human interleukin-1 beta (IL-1 beta). The patent provides coverage into the year 2027 and is the first patent to issue from a series of patent applications expected to cover XOMA's unique intellectual property position. It also highlights XOMA's pioneering role in the IL-1 beta antibody field.
- \* Antibody technologies and expertise recognized through new award for new federal government biodefense program: XOMA was awarded a \$1.7 million subcontract by SRI International to produce novel antibody drugs against the virus that causes severe acute respiratory syndrome (SARS), a highly contagious infectious disease that often progresses to pneumonia and may be fatal. The project is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. XOMA's responsibilities will include the evaluation of several antibodies for growth, productivity, manufacturability and performance in bioreactors.

- \* In the third quarter, initiate XOMA 052 Phase 2 clinical development program in Type 2 diabetes and cardiovascular disease
- $^{\star}$  Establish a corporate partnership for the worldwide development and commercialization of XOMA 052
- \* Present XOMA 052 results at international medical conferences including the European Association for the Study of Diabetes and the International Diabetes Federation meetings
- \* Pursue additional revenue-generating licenses and alliances that utilize XOMA's broad antibody technologies and expertise

#### Additional Financial Results

XOMA's total revenues in the second quarter of 2009 included \$7.6 million in contract and other revenue, \$2.0 million in royalties, and \$155,000 in license and collaborative fees. In the 2008 second quarter, contract and other revenue was \$5.6 million, royalties were \$5.3 million and license and collaborative fees were \$155,000. The decrease in royalty revenue was due to lower worldwide sales of RAPTIVA(r) and an adjustment to reflect the lower than previously estimated RAPTIVA(r) royalty receipts for the first quarter of 2009. In April 2009, Genentech, Inc., a wholly owned member of the Roche Group, announced the voluntary withdrawal of RAPTIVA(r) from the U.S. market. In the first quarter of 2009, RAPTIVA(r) was recommended for withdrawal from ex-U.S. markets. XOMA anticipates nominal, if any, future revenues related to RAPTIVA(r) royalties.

XOMA receives royalties based on worldwide sales of LUCENTIS(r) and on U.S. and Swiss sales of CIMZIA(r). According to Genentech, and Novartis AG, who are responsible for U.S. and international sales of LUCENTIS(r), respectively, worldwide sales in the second quarter of 2009 were an estimated \$553 million compared with an estimated \$458 million in the 2008 second quarter, a 21% increase.

CIMZIA(r) is marketed in the U.S. and Switzerland by UCB SA for the treatment of moderate to severe Crohn's disease in adult patients who have not responded to conventional therapy. In May 2009, UCB announced FDA approval of CIMZIA(r) for the treatment of moderate to severe rheumatoid arthritis in adults, an estimated \$10 billion overall market. Royalties on sales of CIMZIA(r) in the second quarter of 2009 were not material, but are expected to increase as UCB continues the CIMZIA(r) launch in the U.S. rheumatoid arthritis market.

XOMA's research and development expense for the second quarter of 2009 was \$13.5 million, compared with \$23.5 million in the same period of 2008. The decrease in expenses in the 2009 period compared to the 2008 period was due to decreased personnel costs as a result of the January 2009 workforce reduction, reduced spending due to multiple additional cost control initiatives, and reduced preclinical and clinical expenditures. Selling, general and administrative expense for the second quarter of 2009 was \$5.7 million compared with \$6.4 million for the same period last year.

Interest expense for the second quarter of 2009 was \$1.7 million compared with \$2.2 million for the same period of 2008. This decrease is primarily due to a decrease in amortization of debt issuance costs in 2009 related to the restructuring of the Goldman Sachs term loan in May 2008, at which point the debt issuance costs related to the original term loan facility were fully amortized. Additionally, interest expense related to the Novartis note decreased in 2009 due to a decrease in the outstanding principal balance of this note.

Other income was \$1.1 million for the second quarter of 2009 compared to \$42,000 for the same period in 2008. In the second quarter of 2009, warrants were issued in connection with the two registered direct equity sales and were recorded as a liability at fair value at their issuance dates. The subsequent decrease in the fair value of the warrant liability of \$1 million at June 30, 2009 was recorded in other income. The warrant liability will be revalued each quarter for the term of the warrants.

#### **Debt Obligations**

At June 30, 2009, XOMA had an outstanding principal balance of \$42.0 million on a 5-year term loan from Goldman Sachs Specialty Lending Holdings, Inc. (Goldman Sachs) from a refinancing completed in May 2008. The company has a restricted cash account dedicated to the payment of principal and interest on this loan which had a balance of \$6.1 million at June 30, 2009. XOMA also has \$13.1 million of long-term debt due to Novartis.

As previously disclosed, XOMA is in discussions with its lenders to restructure the terms of its loan from Goldman Sachs, which is secured by the company's royalty revenue from sales of LUCENTIS(r), RAPTIVA(r), and CIMZIA(r). As a result of the market withdrawal of RAPTIVA(r), XOMA is no longer in compliance with certain requirements of the loan facility, and as a consequence the lender has the ability to accelerate payment of the loan. Accordingly, the outstanding principal balance under this loan is classified as a current obligation at June 30, 2009.

The long-term debt to Novartis represents XOMA's borrowings under a loan facility established to facilitate XOMA's participation in its collaboration with Novartis. The Novartis loan is secured by XOMA's interest in the collaboration and is due in 2015.

#### Liquidity and Capital Resources

Cash, cash equivalents and short-term investments at June 30, 2009 was \$27.6 million compared with \$10.8 million at December 31, 2008. In May and June 2009, XOMA completed two registered direct offerings that provided approximately \$20.4 million in net proceeds to the company. In addition, restricted cash as of June 30, 2009 and December 31, 2008 was \$6.1 million and \$9.5 million, respectively, and consisted primarily of funds reserved for repayment of the Goldman Sachs loan. Cash provided by operating activities during the first half of 2009 was \$1.4 million compared with cash used in operating activities of \$26.4 million during the first half of 2008.

A more detailed tabulation of XOMA's financial results appears below, and a fuller discussion is included in the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.

#### Guidance

The company will not be providing guidance on revenues or cash receipts for 2009 so as to best manage its ongoing negotiations for XOMA 052 and technology licensing and in light of general economic and market conditions.

The company expects that cash used in operating activities may range from \$15 million to cash neutral or positive. This guidance is unchanged and does not include cash from royalty

payments, which are reserved for the repayment of the Goldman Sachs loan.

#### Investor Conference Call

XOMA will host a conference call and webcast to discuss its first quarter 2009 financial results today, August 6, 2009, at 4:30 p.m. EDT. The webcast can be accessed via the Investors section of XOMA's website at <a href="http://investors.xoma.com/events.cfm">http://investors.xoma.com/events.cfm</a> and will be available for replay until close of business on November 6, 2009. Telephone numbers for the live audiocast are 877-681-3371(U.S./Canada) and 719-325-4941 (international). A telephonic replay will be available beginning approximately two hours after the conclusion of the call until close of business on August 13, 2009. Telephone numbers for the replay are 888-203-1112 (U.S./Canada) and 719-457-0820 (international), passcode 6785094.

#### About XOMA

XOMA discovers, develops and manufactures therapeutic antibody and other agents designed to treat inflammatory, autoimmune, infectious and cancerous diseases. The company's proprietary product pipeline includes XOMA 052, an anti-IL-1 beta antibody, and XOMA 3AB, a biodefense anti-botulism antibody candidate.

XOMA's proprietary development pipeline is primarily funded by multiple revenue streams resulting from the licensing of its antibody technologies, product royalties, development collaborations and biodefense contracts. XOMA's technologies and experienced team have contributed to the success of marketed antibody products, including LUCENTIS(r) (ranibizumab injection) for wet age-related macular degeneration and CIMZIA(r) (certolizumab pegol) for Crohn's disease and rheumatoid arthritis.

The company has a premier antibody discovery and development platform that incorporates leading antibody phage display libraries and XOMA's proprietary Human Engineering(tm) and Bacterial Cell Expression and manufacturing technologies. Bacterial Cell Expression is a key breakthrough biotechnology for the discovery and manufacturing of antibodies and other proteins. As a result, more than 50 pharmaceutical and biotechnology companies have signed BCE licenses.

In addition to developing its own products, XOMA develops products with premier pharmaceutical companies including Novartis AG, Schering-Plough Research Institute and Takeda Pharmaceutical Company Limited. XOMA has a fully integrated product development infrastructure, extending from pre-clinical science to approval, and a team of about 190 employees at its Berkeley location. For more information, please visit <a href="http://www.xoma.com">http://www.xoma.com</a>.

The XOMA Ltd. logo is available at <a href="https://www.globenewswire.com/newsroom/prs/?">https://www.globenewswire.com/newsroom/prs/?</a>
<a href="pkgid=5960">pkgid=5960</a>

#### Forward-Looking Statements

Certain statements contained herein concerning the anticipated levels of cash inflows, cash utilization, cash expenditures and reductions in cash expenditures; sales of approved products; timing of initiation, completion or availability of results of clinical trials, effects of or possible dosing of XOMA 052, 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.

Among other things, the anticipated levels of cash inflows, cash utilization, cash expenditures and reductions in cash expenditures may be other than as expected due to unanticipated changes in XOMA's research and development programs, unavailability of additional arrangements or higher than anticipated transaction costs; sales of approved products may be lower than anticipated as a result of actions or inaction by the third parties responsible for selling such products; the timing of initiation, completion or availability of results of clinical trials may be delayed or may never occur as a result of unavailability of resources, actions or inaction by our present or future collaboration partners, insufficient enrollment in such trials or unanticipated safety issues. The effects of XOMA 052 may differ in later preclinical or clinical data and dosing of XOMA 052 may be affected by later testing results.

These and other risks, including those related to XOMA's ability to remain in compliance with or renegotiate the requirements of its loan agreements; the declining and generally unstable nature of current economic conditions; the results of discovery and pre-clinical testing; the timing or results of pending and future clinical trials (including the design and progress of clinical trials; safety and efficacy of the 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; XOMA's ability to meet the demands of the United States government agency with which it has entered into its government contracts; competition; market demands for products; scale-up and marketing capabilities; availability of additional licensing or collaboration opportunities; international operations; share price volatility; XOMA's financing needs and opportunities; uncertainties regarding the status of biotechnology patents; uncertainties as to the costs 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 filing on Form 10-K and in other SEC filings. Consider such risks carefully when considering XOMA's prospects.

XOMA Ltd.							
CONDENSED	CONSOLIDATED	STATEMENTS	OF	OPERATIONS			
(unaudited)							
(in the	ousands, exce	pt per shar	e ar	mounts)			

	Three months ended June 30,			Six months ended June 30,			
	2	2009 2008		008	2009	2008	
Revenues: License and collaborative fees	\$	155	\$	155	\$ 27,855	\$	180
Contract and other			·		, , ,		

revenue Royalties	7,576 5,638 1,975 5,323		14,974 6,581	10011
ROYALCIES	1,975			10,244
Total revenues	9,706 11,116		49,410	23,173
Operating expenses: Research and development Selling, general and	13,507		30,028	42,730
administrative Restructuring	5,655 312	6,388 	11,775 3,601	12 <b>,</b> 260
Total operating expenses	19,474	29 <b>,</b> 907	45,404	54,990
<pre>Income (loss) from    operations Other income (expense):    Investment and interest</pre>			4,006	(31,817)
income	8	223	38	615
Interest expense	(1,671)	(2,164)	(3,439)	(3,614)
Other income (expense)	1,134		1,137	(49)
Net income (loss) before taxes Provision for income tax	(10,297)	(20,690)	1,742	(34,865)
(benefit) expense	(87)		5,713	
Net loss	\$(10,210) ======		\$ (3,971) ======	
Basic and diluted net loss per common share	\$ (0.07)	\$ (0.16)	\$ (0.03)	\$ (0.26)
Shares used in computing basic and diluted net loss per common share				
	======	======	======	======

## XOMA Ltd. CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)

June 30, December 31,

	2009		2008			
ASSETS		naudited)				
Current assets: Cash and cash equivalents Short-term investments Restricted cash Trade and other receivables, net Prepaid expenses and other current as Debt issuance costs	\$ ssets	27,616  6,061 6,283 1,658 1,173		9,513 1,299 9,545 16,686 1,296 365		
Total current assets Property and equipment, net Debt issuance costs - long-term Other assets		42,791 23,592  402		38,704 26,843 1,224 402		
Total assets	\$	66,785	\$	67,173		

### LIABILITIES AND SHAREHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)

Current liabilities:				
Accounts payable	\$	4,596	\$	9 <b>,</b> 977
Accrued liabilities		7,487		4,438
Accrued interest		1,217		1,588
Deferred revenue		4,573		9,105
Warrant liability		5 <b>,</b> 550		, 
Interest bearing obligations - current		41,993		
Other current liabilities		606		1,884
Total current liabilities		66,022		26 <b>,</b> 992
Deferred revenue - long-term		5,372		8,108
<pre>Interest bearing obligations - long-term</pre>		13,129		63,274
Other long-term liabilities		581		200
Total liabilities		85 <b>,</b> 104		98 <b>,</b> 574
Shareholders' equity (net capital deficiency)		(10 310)		(31,401)
deficiency		(10,319)		(31,401)
Total liabilities and shareholders'				
equity (net capital deficiency)	\$	66 <b>,</b> 785	\$	67 <b>,</b> 173
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