

# XOMA Reports 2013 Operational Highlights and Fourth Quarter and Full-Year 2013 Financial Results

BERKELEY, Calif., March 4, 2014 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced 2013 operational highlights and financial results for the fourth quarter and year ended December 31, 2013.

# **2013 Operational Highlights**

- Announced the selection of pyoderma gangrenosum (PG) as its next Phase 3 indication for gevokizumab based upon the compelling results generated from 6 patients enrolled in the Company's PG clinical pilot program. In March 2014, the results will be shared with the FDA to determine the Phase 3 clinical protocol at an End of Phase 2 meeting. PG is one of a cluster of diseases under the umbrella of neutrophilic dermatosis.
- Reported Phase 2 data from the Company's gevokizumab study in patients with moderate to severe inflammatory acne and completed a thorough analysis of the acne market. Rather than pursuing the broader acne indication, the Company will consider focusing on less prevalent but more severe acne indications that also are considered indications under the neutrophilic dermatosis umbrella.
- Reported promising results in October 2013, from the Day 84 pain and function endpoint in the Company's gevokizumab Phase 2 study in patients with erosive osteoarthritis of the hand (EOA) and elevated C-reactive protein (CRP). Completed enrollment in a supplemental study in patients with EOA and non-elevated CRP. On March 4, 2014, XOMA reported that despite early positive results, the top-line data at Day 168 in the initial study, as well as at Day 84 in the supplemental study, were not positive and led to the Company's decision not to pursue the broad EOA indication for Phase 3 testing. The Company will continue to review the data to determine if there is a specific segment of the EOA population that could benefit from gevokizumab therapy.
- Increased the pace of enrollment at 70 U.S. study sites participating in the gevokizumab EYEGUARD™-A and EYEGUARD-C studies.
- XOMA's partner, SERVIER, continued to enroll patients in EYEGUARD-B, which is studying gevokizumab in patients who have non-infectious uveitis with underlying Behçet's disease, a rare indication.
- As of yearend, SERVIER had obtained approvals in 15 countries to conduct the EYEGUARD-A and -C clinical trials. These countries represent 53 clinical study centers.

- SERVIER initiated enrollment in three of its independent gevokizumab POC studies: polymyositis/dermatomyositis, Schnitzler's syndrome, and giant cell arteritis.
- Strengthened the Company's financial position by raising \$83.0 million in two public equity offerings, after deducting offering fees and out of pocket expenses.
- Received \$8.6 million in milestone payments from 2 collaborators and licensees.
- Was awarded a patent for XOMA's flexible manufacturing system.

"In 2013, our Proof-of-Concept program has provided us the evidence to support what we have known for some time, that gevokizumab has strong biological activity. In every patient population we have studied, we see a biological response to our compound, even if the results are not strong enough to pursue Phase 3 development in large patient populations. We were extremely excited by the dramatic results we achieved in the first six patients with pyoderma gangrenosum and have chosen this indication for pivotal development. We are looking forward to receiving the FDA's feedback on the data and its requirements for a Phase 3 clinical program in this underserved patient population," stated John Varian, Chief Executive Officer of XOMA. "We have identified other indications under the neutrophilic dermatoses classification that we hope to study in similar pilot studies with the goal of identifying others that are of value to pursue in Phase 3 development.

"The Proof-of-Concept program was designed to allow gevokizumab to point us to the right indications to pursue for pivotal development, while at the same time identifying the indications that we should not. The program has done that by pointing us to pyoderma gangrenosum and steering us away from EOA. The decisions we have made and continue to make are bringing us closer to realizing our vision of becoming a commercial company, selling XOMA's products to the U.S. specialist prescriber."

#### **Financial Results**

XOMA recorded total revenues of \$35.5 million for the twelve months ended December 31, 2013, compared with \$33.8 million during the same period of 2012. For the three months ended December 31, 2013, XOMA recorded revenues of \$12.5 million compared to \$7.4 million during the corresponding period of 2012. The increase in the fourth quarter and full-year 2013 revenues was due primarily to the receipt of license and collaboration fees, which were offset by reductions in contract revenue and related expenses from NIAID government contracts and from reimbursements by Servier for gevokizumab-related activities.

For the year ended December 31, 2013, XOMA had a net loss of \$124.1 million, or \$1.43 per share, compared with a net loss of \$71.1 million, or \$1.10 per share, in the year ended December 31, 2012. The full-year net losses in 2013 and 2012 included \$61.0 million and \$9.2 million, respectively, in non-cash revaluation of contingent warrant liabilities, which resulted primarily from the appreciation of XOMA's stock price. Excluding those revaluations, the net loss for 2013 was \$63.0 million, or \$0.72 per share, and the net loss for 2012 was \$61.9 million, or \$0.96 per share. For the three months ended December 31, 2013, XOMA reported a net loss of \$52.3 million, or \$0.55 per share, of which \$35.3 million, or \$0.37 per share, was related directly to the revaluation of contingent warrant liabilities. For the three months ended December 31, 2012, XOMA had a net income of \$2.4 million, or \$0.03 per share, due primarily to a \$16.6 million revaluation of contingent warrant liabilities. Excluding the non-cash revaluation of contingent warrant liabilities, the net loss for the three months ended December 31, 2013, was \$17.0 million, or \$0.18 per share.

Annual research and development (R&D) expenses for 2013 were \$74.9 million compared to \$68.5 million in 2012. For the three-month periods ended December 31, 2013 and 2012, R&D expenses were \$22.9 million and \$15.8 million, respectively. The increases in both of the 2013 periods reflect the increased external clinical trial costs associated with XOMA's gevokizumab clinical development programs. Selling, general and administrative expenses (SG&A) were \$18.5 million for the full year of 2013 compared to \$16.9 million incurred during 2012, primarily reflecting consulting expenses during 2013. For the three-month periods ended December 31, 2013 and 2012, SG&A expenses were \$5.0 million and \$3.9 million, respectively.

On December 31, 2013, XOMA had cash, cash equivalents, and short-term investments of \$121.6 million, compared with \$85.3 million at December 31, 2012. On December 18, 2013, the Company announced the closing of the offering of 10,925,000 shares of its common stock, including 1,425,000 shares of common stock that were issued upon the exercise in full of the underwriters' option to purchase additional shares, at a price to the public of \$5.25 per share. XOMA received \$53.6 million in net proceeds from the offering after deducting the underwriting discount and offering expenses.

#### 2014 Guidance

XOMA announced its anticipated cash used in ongoing operating activities during 2014 will be approximately \$55.0 million to \$60.0 million, primarily reflecting the costs associated with conducting the gevokizumab three Phase 3 clinical trials in the EYEGUARD program and the costs associated with conducting a Phase 3 clinical trial in patients with pyoderma gangrenosum.

#### **Investor Conference Call and Webcast**

XOMA will host a conference call and webcast today, March 4, 2014, at 6:00 p.m. ET / 3:00 PT. The webcast can be accessed via the Investors and Media 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 May 4, 2014.

Telephone numbers for the live audiocast are 877-369-6589 (U.S./Canada) and 408-337-0122 (international).

#### **About Gevokizumab**

Gevokizumab is a potent monoclonal antibody with unique allosteric modulating properties and the potential to treat patients with a wide variety of inflammatory and other diseases. Gevokizumab binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine, and modulates the cellular signaling events that produce inflammation. IL-1 beta has been shown to be involved in diverse array of disease states, including non-infectious uveitis (including Behçet's uveitis), cardiovascular disease, and other auto-inflammatory diseases.

Gevokizumab currently is being studied in a global Phase 3 clinical program, termed EYEGUARD™, which is being conducted by SERVIER and XOMA. This program is designed to determine gevokizumab's ability to treat acute non-infectious uveitis (NIU) in EYEGUARD-A, to prevent disease flares in patients with Behçet's uveitis in EYEGUARD-B, and to prevent disease flares in NIU patients who are controlled with steroids and

immunosuppressants in EYEGUARD-C.

XOMA has a Proof-of-Concept (POC) program underway in which the Company is exploring or has explored the efficacy and safety of gevokizumab in multiple indications: pyoderma gangrenosum, pustular psoriasis, moderate to severe inflammatory acne, erosive osteoarthritis of the hand, active non-infectious scleritis, autoimmune inner ear disease. Separately, SERVIER initiated a Phase 2 study to determine gevokizumab's ability to reduce arterial wall inflammation in patients with marked atherosclerotic plaque inflammation and who have experienced an acute coronary syndrome in the previous twelve months, as well as POC studies in polymyositis/dermatomyositis, Schnitzler syndrome, and giant cell arteritis. Information about gevokizumab clinical studies can be found at <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a> and <a href="https://www.clinicaltrialsregister.eu">www.clinicaltrials.gov</a> and <a href="https://www.clinicaltrialsregister.eu">www.clinicaltrialsregister.eu</a>

#### **About XOMA**

XOMA has built a portfolio of innovative therapeutic antibodies, both in late-stage clinical development and in preclinical research. XOMA focuses its antibody research and development on allosteric modulation, which offers opportunities for new classes of therapeutic antibodies to treat a wide range of human diseases. XOMA's lead product candidate, gevokizumab (IL-1 beta modulating antibody), is in a global Phase 3 program in non-infectious uveitis with its partner SERVIER and multiple proof-of-concept studies in other IL-1-mediated diseases. XOMA's scientific research also produced the XMet program, which consists of three classes of preclinical antibodies, including Selective Insulin Receptor Modulators (SIRMs) that could have a significant effect on the treatment of diabetes.

More detailed information can be found at www.xoma.com

#### **About Servier**

"Since the company's creation, all of our profits are ploughed back into research," Jacques Servier, Founding President of the Group.

Founded in 1954, Servier is an independent French pharmaceutical research company. Its development is based on the continuous pursuit of innovation in the therapeutic areas of cardiovascular, metabolic, neurologic, psychiatric, bone and joint diseases, as well as cancer. With a strong international presence in 140 countries, Servier employs more than 22,000 people worldwide. In 2012, the company recorded revenue of 3.9 billion euros, and 92% of Servier drugs are consumed internationally. The Servier Group contributed 57% to the 2012 French trade surplus in the pharmaceuticals sector. The Company reinvested 25% of its revenues into R&D in 2012.

More information is available at: www.servier.com

## **Forward-Looking Statements**

Certain statements contained in this press release including, but not limited to, statements related to anticipated timing of initiation and completion of clinical trials, Proof-of-Concept trials, anticipated size of clinical trials, regulatory approval of unapproved product candidates, sufficiency of our cash resources and anticipated levels of cash utilization, or statements 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, and 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. Potential risks to XOMA meeting these expectations 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. Any forward-looking statement in this press release represents XOMA's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. XOMA disclaims any obligation to update any forward-looking statement, except as required by applicable law.

## **XOMA Corporation**

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2013	2012	2013	2012
Revenues:				
License and collaborative fees	\$ 8,450	\$ 1,062	\$ 11,028	\$ 5,727
Contract and other	4,084	6,330	24,423	28,055
Total revenues	12,534	7,392	35,451	33,782
Operating expenses:				
Research and development	22,946	15,765	74,851	68,467
Selling, general and administrative	5,049	3,947	18,477	16,865
Restructuring	119	299	328	5,074
Total operating expenses	28,114	20,011	93,656	90,406
Loss from operations	(15,580)	(12,619)	(58,205)	(56,624)
Other (expense) income:				
Interest expense	(1,137)	(1,176)	(4,631)	(4,387)
Other expense	(287)	(414)	(197)	(956)
Revaluation of contingent warrant liabilities	(35,294)	16,574	(61,039)	(9,172)
Net (loss) income before taxes	(52,298)	2,365	(124,072)	(71,139)
Provision for income tax (expense) benefit	(1)		14	74
Net (loss) income	\$ (52,299)	\$ 2,365	\$ (124,058)	\$ (71,065)
Basic and diluted net (loss) income per share of common stock	\$ (0.55)	\$ 0.03	\$ (1.43)	\$ (1.10)
Shares used in computing basic net (loss) income per share of common stock	95,048	77,703	86,938	64,629
Shares used in computing diluted net (loss) income per share of common stock	95,048	93,862	86,938	64,629
Other comprehensive (loss) income:				
Net (loss) income	(52,299)	2,365	(124,058)	\$ (71,065)
Net unrealized (loss) gain on available-for-sale securities	(1)	1	(9)	8
Comprehensive (loss) income	\$ (52,300)	\$ 2,366	\$ (124,067)	\$ (71,057)

#### **XOMA Corporation**

## CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31,			
	2013	2012		
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 101,659	\$ 45,345		
Short-term investments	19,990	39,987		
Trade and other receivables, net	3,781	8,249		
Prepaid expenses and other current assets	1,630	2,256		
Total current assets	127,060	95,837		
Property and equipment, net	6,456	8,143		
Other assets	1,266	1,696		
Total assets	\$ 134,782	\$ 105,676		
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
Current liabilities:				
Accounts payable	\$ 9,616	\$ 3,867		
Accrued and other liabilities	9,934	13,045		
Deferred revenue	2,218	3,409		
Interest bearing obligation – current	5,835	3,391		
Accrued interest on interest bearing obligation – current	2,042	121		
Total current liabilities	29,645	23,833		
Deferred revenue – long-term	4,105	6,315		
Interest bearing obligations – long-term	35,150	37,653		
Contingent warrant liabilities	69,869	15,001		
Other liabilities - long-term		1,407		
Total liabilities	138,769	84,209		
Stockholders' (deficit) equity:				
Common stock, \$0.0075 par value, 138,666,666 shares authorized, 105,386,216 and 82,447,274 shares outstanding at December 31, 2013 and 2012, respectively	787	615		
Additional paid-in capital	1,076,403	977,962		
Accumulated comprehensive (loss) income	(1)	8		
Accumulated deficit	(1,081,176)	(957,118)		
Total stockholders' (deficit) equity	(3,987)	21,467		
Total liabilities and stockholders' (deficit) equity	\$ 134,782	\$ 105,676		

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