

August 3, 2016



# **XOMA Reports Second Quarter 2016 Achievements and Financial Results**

BERKELEY, Calif., Aug. 03, 2016 (GLOBE NEWSWIRE) -- XOMA Corporation (Nasdaq:XOMA), a leader in the discovery and development of therapeutic antibodies, today announced recent achievements and financial results for the second quarter ended June 30, 2016.

“The second quarter of 2016 marked our full transition to a solely endocrine-focused business as we have concluded all biodefense and Servier activities. During the quarter, we strategically focused on two antibody programs that are addressing areas of significant unmet medical need in endocrinology and that could create significant value for XOMA,” said John Varian, Chief Executive Officer of XOMA. “First, we continued to advance our Phase 2 proof-of-concept study of XOMA 358 in the United States and EU in patients with hypoglycemia due to congenital hyperinsulinism. We also initiated a Phase 2 proof-of-concept study of XOMA 358 in patients who experience severe hypoglycemia following gastric bypass surgery. We remain on track to provide an update on our clinical experience with this first-in-class compound later this summer.”

“Additionally, we advanced our second endocrine-focused asset into mid-stage clinical development with the initiation of a Phase 2 proof-of-concept study of XOMA 213 to confirm its ability to curtail prolactin signaling. This monoclonal antibody could be an important therapeutic option for people with prolactinomas, benign tumors of the pituitary gland, who do not respond to or are intolerant to current standard of care medications.”

## **Recent Achievements**

- Received Orphan Drug Designation in the European Union for XOMA 358 for the treatment of congenital hyperinsulinism, a rare genetic disorder in which the insulin cells of the pancreas (beta cells) secrete inappropriate and excessive insulin
- Initiated XOMA 358 proof-of-concept study in patients with hypoglycemia post gastric bypass surgery, representing the second rare hypoglycemic indication in which this first-in-class insulin receptor antibody is being studied
- Initiated an open-label, mechanism of action, single-dose, multi-center Phase 2 proof-of-concept study of XOMA 213

## **Second Quarter 2016 Financial Results**

XOMA recorded total revenues of \$0.4 million for the three months ended June 30, 2016, compared with \$2.5 million during the corresponding period of 2015. The decrease in second quarter 2016 revenues was due primarily to decreased revenues from the National Institute of Allergy and Infectious Diseases (NIAID) and Servier due to the Company’s decision to eliminate its non-endocrine assets. Going forward, revenues are expected to result from potential new transactions or payments under existing contracts.

Research and development (R&D) expenses for the second quarter of 2016 were \$13.7 million, compared with \$19.7 million in the corresponding 2015 period. The decrease was due primarily to a \$3.9 million reduction in salaries and related expenses, a \$1.2 million reduction in clinical trial costs, and a \$0.9 million reduction in outside consulting fees due to the termination of the Servier Phase 3 program, partially offset by an increase of over \$2.0 million in manufacturing costs related to the production of XOMA 358 material for the use in future clinical trials.

Selling, general and administrative expenses (SG&A) were \$4.8 million for the three months ended June 30, 2016, compared with \$5.1 million incurred during the same period in 2015, reflecting reduced salary and related personnel costs following the Company's restructuring activities that were initiated in the third quarter of 2015.

For the second quarter ended June 30, 2016, XOMA had a net loss of \$15.2 million, compared with a net loss of \$23.8 million in the quarter ended June 30, 2015. The net losses in the three months ended June 30, 2016 and 2015, included a \$3.3 million gain and \$0.2 million loss, respectively, in non-cash revaluations of contingent warrant liabilities, resulting primarily from fluctuations in XOMA's stock price. Excluding those revaluations, the net loss for the three months ended June 30, 2016, was \$18.5 million, compared with a net loss of \$23.6 million for the same reporting period in 2015.

On June 30, 2016, XOMA had cash and cash equivalents of \$33.9 million compared with \$65.8 million at December 31, 2015.

The Company expects its available capital will be sufficient to fund operations through at least the first quarter of 2017.

### **About XOMA 358**

Insulin is the major physiologic hormone for controlling blood glucose levels. Abnormal increases in insulin secretion can lead to profound hypoglycemia (low blood sugar), a state that can result in significant morbidities, including brain damage, seizures and epilepsy. XOMA, leveraging its scientific expertise in allosteric monoclonal antibodies, developed the XMet platform, consisting of separate classes of selective insulin receptor modulators (SIRMs) that could have a major effect on treating patients with abnormal metabolic states. XOMA 358 binds selectively to insulin receptors and attenuates insulin action.

XOMA 358 is being investigated as a novel treatment for non-drug-induced, endogenous hyperinsulinemic hypoglycemia, as well as hypoglycemia after bariatric surgery and other related disorders. XOMA recently initiated Phase 2 development activities for XOMA 358. One Phase 2 study is being conducted in patients with congenital hyperinsulinism at The Children's Hospital in Philadelphia (CHOP) and the Great Ormond Street Hospital (GOSH) in London. A second multi-center Phase 2 study is being conducted in patients who experience hypoglycemia post gastric bypass surgery. A therapy that safely and effectively mitigates insulin-induced hypoglycemia has the potential to address a significant unmet therapeutic need for certain rare medical conditions associated with hyperinsulinism. More information on the XOMA 358 clinical trial may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu).

### **About Congenital Hyperinsulinism<sup>i, ii, iii, iv</sup>**

Congenital Hyperinsulinism (CHI) is a genetic disorder in which the insulin cells of the

pancreas (beta cells) secrete inappropriate and excessive insulin. Ordinarily, beta cells secrete just enough insulin to keep blood sugar in the normal range. In people with CHI, the secretion of insulin is not properly regulated, causing excess insulin secretion and frequent episodes of low blood sugar (hypoglycemia). In infants and young children, these episodes are characterized by a lack of energy (lethargy), irritability or difficulty feeding. Repeated episodes of low blood sugar increase the risk for serious complications, such as breathing difficulties, seizures, intellectual disability, vision loss, brain damage, coma, and possibly death. About 60 percent of infants with CHI experience a hypoglycemic episode within the first month of life. Other affected children develop hypoglycemia by early childhood. Current treatments for CHI are limited to medical therapy and surgical removal of part or all of the pancreas (pancreatectomy).

### **About Hypoglycemia Post Gastric Bypass Surgery**

As the number of gastric bypass surgeries to treat severe obesity has increased, so too has the awareness that this population may experience postprandial hypoglycemia (low blood glucose following a meal) with symptoms developing months or years following the gastric bypass surgery. Postprandial hypoglycemia occurs with a range of severity in post-gastric bypass patients. The mild end of the spectrum may be managed largely through diet modification. The most severe forms are more prevalent in patients who underwent a Roux-en-Y procedure, and result in severe refractory postprandial hyperinsulinemic hypoglycemia with neuroglycopenic symptoms (altered mental status, loss of consciousness, seizures) that cannot be managed through diet modification. If currently available pharmacologic agents do not resolve the condition, these patients are treated with either a partial pancreatectomy or reversal of the gastric bypass.

### **About XOMA 213**

XOMA 213 (formerly LFA 102) is a monoclonal antibody that neutralizes prolactin-induced signaling. Prolactin is a protein that in normal post-partum females enables the production of milk. XOMA 213 is being developed for diseases of hyperprolactinemia -- specifically, prolactinomas, benign tumors of the pituitary gland that have serious medical consequences, particularly sexual dysfunction, infertility and osteoporosis. Prolactinomas also can lead to anti-psychotic-induced hyperprolactinemia, a side effect seen in patients treated with commonly used antipsychotics, antidepressants, and pain medications. Ten to twenty percent of patients do not respond to or are intolerant of current standard of care medications.

### **About XOMA Corporation**

XOMA Corporation is a leader in the discovery and development of therapeutic antibodies. The Company's innovative product candidates result from its expertise in developing groundbreaking monoclonal antibodies, including allosteric antibodies, which have created new opportunities to potentially treat a wide range of human diseases. XOMA's scientific research has produced a portfolio of five endocrine assets, each of which has the opportunity to address multiple indications. The Company's lead product candidate, XOMA 358, is an allosteric monoclonal antibody that reduces insulin receptor activity, which could have a major impact on the treatment of hyperinsulinism. The Company recently initiated Phase 2 development activities for XOMA 358 in patients with congenital hyperinsulinism, and in patients with hypoglycemia after bariatric surgery. For more information, visit [www.xoma.com](http://www.xoma.com).

## Forward-Looking Statements

Certain statements contained in this press release including, but not limited to, statements characterizing statements related to anticipated timing of clinical trials, anticipated timing of the release of clinical data, regulatory approval of unapproved product candidates, the anticipated process of clinical data analysis, the anticipated success of any clinical trial, cash usage, 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.

<sup>i</sup> [ghr.nlm.nih.gov/condition/congenital-hyperinsulinism](http://ghr.nlm.nih.gov/condition/congenital-hyperinsulinism). Accessed June 11, 2015.

<sup>i</sup> <sup>i</sup> [www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXncFU3bKHt](http://www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXncFU3bKHt). Accessed June 11, 2015.

<sup>i</sup> <sup>i</sup> <sup>i</sup> [www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXneYE3bKHu](http://www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXneYE3bKHu). Accessed June 11, 2015.

<sup>iv</sup> [www.ojrd.com/content/pdf/1750-1172-6-63.pdf](http://www.ojrd.com/content/pdf/1750-1172-6-63.pdf). Accessed June 11, 2015.

**XOMA CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(unaudited)  
(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues:				
License and collaborative fees	\$ 275	\$ 945	\$ 2,766	\$ 1,207
Contract and other	168	1,594	1,639	3,983
Total revenues	<u>443</u>	<u>2,539</u>	<u>4,405</u>	<u>5,190</u>
Operating expenses:				
Research and development	13,703	19,692	27,313	39,696
Selling, general and administrative	4,779	5,060	9,084	10,280
Restructuring	(21 )	-	15	-
Total operating expenses	<u>18,461</u>	<u>24,752</u>	<u>36,412</u>	<u>49,976</u>
Loss from operations	(18,018 )	(22,213 )	(32,007 )	(44,786 )
Other income (expense)				
Interest expense	(1,007 )	(1,007 )	(2,009 )	(2,123 )
Other income (expense), net	602	(363 )	296	1,648
Revaluation of contingent warrant liabilities	3,263	(176 )	10,195	(216 )
Net loss	<u>\$ (15,160 )</u>	<u>\$ (23,759 )</u>	<u>\$ (23,525 )</u>	<u>\$ (45,477 )</u>
Basic and diluted net loss per share of common stock	<u>\$ (0.13 )</u>	<u>\$ (0.20 )</u>	<u>\$ (0.20 )</u>	<u>\$ (0.39 )</u>
Shares used in computing basic and diluted net loss per share of common stock	<u>120,448</u>	<u>117,540</u>	<u>120,008</u>	<u>116,870</u>
Other comprehensive loss:				
Net loss	\$ (15,160 )	\$ (23,759 )	\$ (23,525 )	\$ (45,477 )
Net unrealized loss on marketable securities	(12 )	-	(54 )	-
Comprehensive loss	<u>\$ (15,172 )</u>	<u>\$ (23,759 )</u>	<u>\$ (23,579 )</u>	<u>\$ (45,477 )</u>

**XOMA CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share and per share amounts)

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
	(unaudited)	(audited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 33,854	\$ 65,767
Marketable securities	442	496
Trade and other receivables, net	959	4,069
Prepaid expenses and other current assets	1,070	1,887
Total current assets	36,325	72,219
Property and equipment, net	1,577	1,997
Other assets	664	664
Total assets	\$ 38,566	\$ 74,880
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 5,046	\$ 6,831
Accrued and other liabilities	5,737	7,025
Deferred revenue	1,024	3,198
Interest bearing obligations – current	12,138	5,910
Accrued interest on interest bearing obligations – current	288	331
Total current liabilities	24,233	23,295
Interest bearing obligations – non-current	34,386	42,757
Contingent warrant liabilities	269	10,464
Other liabilities – non-current	123	673
Total liabilities	59,011	77,189
Stockholders' deficit:		
Preferred stock, \$0.05 par value, 1,000,000 shares authorized, 0 issued and outstanding	-	-
Common stock, \$0.0075 par value, 277,333,332 shares authorized, 120,583,797 and 119,045,592 shares issued and outstanding at June 30, 2016, and December 31, 2015, respectively	904	893
Additional paid-in capital	1,142,313	1,136,881
Accumulated comprehensive loss	(54 )	-
Accumulated deficit	(1,163,608 )	(1,140,083 )
Total stockholders' deficit	(20,455 )	(2,309 )
Total liabilities and stockholders' deficit	\$ 38,566	\$ 74,880

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