

XOMA CORP

FORM 8-K (Current report filing)

Filed 03/16/17 for the Period Ending 03/16/17

Address	2910 SEVENTH ST BERKELEY, CA 94710
Telephone	5106441170
CIK	0000791908
Symbol	XOMA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): March 16, 2017

XOMA CORPORATION

(Exact name of registrant as specified in its charter)

**Delaware
(State of
incorporation)**

**000-14710
(Commission
File No.)**

**52-2154066
(IRS Employer
Identification No.)**

**XOMA Corporation
2910 Seventh Street
Berkeley, CA 94710
(Address of principal executive offices and zip code)**

Registrant's telephone number, including area code: (510) 204-7200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-

Item 2.02 Results of Operations and Financial Condition

On March 16, 2017, XOMA Corporation issued a press release announcing its financial results for the quarter and the year ended December 31, 2016. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Number</u>	<u>Description of Document</u>
99.1	Press release entitled “XOMA Reports Fourth Quarter and Full Year 2016 Financial Results” dated March 16, 2017

SIGNATURES

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.

Date: March 16, 2017

XOMA Corporation

By: /s/ Denis J. Quinlan

Denis J. Quinlan

Sr. Corporate Counsel and Corporate Secretary

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
99.1	Press release entitled “XOMA Reports Fourth Quarter and Full Year 2016 Financial Results” dated March 16, 2017

XOMA Reports Fourth Quarter and Full Year 2016 Financial Results

Actions taken in 2016 set the stage for reduced operating costs and capital requirements

In early 2017, Company established new strategic direction and value drivers

Berkeley, Calif., March 16, 2017 – XOMA Corporation (Nasdaq:XOMA), a pioneer in the discovery and development of therapeutic antibodies, today announced its fourth quarter and full year 2016 financial results, clinical development and operational highlights.

“Our key accomplishments in 2016 included monetizing certain license assets, reducing our operating costs, reducing our debt and appointing new leadership to reflect our changed strategy,” stated Jim Neal, recently appointed Chief Executive Officer of XOMA. “In early 2017, we established proof-of-concept for X358 in congenital hyperinsulinism (CHI) and hypoglycemia post-bariatric surgery (PBS). In addition, with the investment of \$25 million from BVF Partners, we launched a new strategy that leverages our extensive portfolio of partnered programs and licensed technologies that has the potential to generate substantial future milestone and royalty proceeds for the Company. Our objective is to drive shareholder value by combining the revenue from this portfolio of collaborator-funded programs with a lean cost structure. The positive momentum that began late in 2016 is growing in 2017, and we are excited about the future of the Company.”

Clinical Development Highlights – Assets Available for Out-licensing

In 2016, XOMA focused its clinical development efforts on advancing X358, a novel first-in-class fully human antibody that is a negative allosteric modulator of the insulin receptor. X358 is being investigated as a novel treatment for hyperinsulinemic hypoglycemia (low blood glucose caused by excessive insulin production). XOMA is conducting Phase 2 development activities for X358 in patients with CHI and in PBS patients. A therapy that safely and effectively mitigates insulin-induced hypoglycemia has the potential to address a significant unmet therapeutic need for these rare medical conditions associated with hyperinsulinism. The Company achieved the following milestones in the program during 2016 and in early 2017:

- Established proof-of-concept for X358 in 14 patients with CHI and 13 patients with PBS.
- Met with the UK’s Medicines and Healthcare Regulatory Authority (MHRA) and secured agreement to initiate a multi-dose Phase 2 clinical study of X358 in children older than age two diagnosed with hypoglycemia due to CHI.
- Received Orphan Drug Designation in the European Union for X358 for treatment of CHI.

As an extension of the X358 program, XOMA has developed X129, a fragment of the X358 antibody. This antibody has potential to treat severe acute hypoglycemia. At ENDO 2016, the Company presented results from preclinical studies demonstrating X129 decreases the activity of insulin on mammalian cells in a dose-dependent manner and confirming X129 binds to the INSR and acts as a negative allosteric modulator.

XOMA’s proprietary antibody phage display libraries continue to generate antibodies and highlight the Company’s expertise in identifying novel oncology and oncology-related candidates with the potential to positively affect outcomes in cancer patients. These programs are available for partnering. Most recently, the Company:

- Unveiled XOMA’s interleukin-2 (IL-2) monoclonal antibody program, a series of novel agents, that when combined with checkpoint inhibitors offer the potential to improve patient outcomes in certain cancers.
- Advanced XOMA’s parathyroid hormone receptor 1 (PTH1R) antibody antagonist program. In vivo studies show these antibodies could potentially address high unmet medical needs, including primary hyperparathyroidism (PHPT) and humoral hypercalcemia of malignancy (HHM).

The Company initiated a proof-of-mechanism study for X213 in lactation cessation. Similar to its other clinical and pre-clinical assets, XOMA intends to license this antibody for further development.

Operational Highlights

XOMA implemented multiple actions to improve the Company's financial health.

- Completed \$25 million Registered Offering of Common Stock and Convertible Stock to BVF Partners, L.P. (BVF) in February 2017. Associated with this investment, the Company appointed Matthew Perry, President of BVF Partners, L.P., a highly accomplished investor and industry professional, to XOMA's Board of Directors.
- Generated \$18 million through a sale of XOMA's rights under two license agreements to its patented bacterial cell expression technology to Healthcare Royalty Partners (HCRP). The Company may receive up to \$4 million in additional sales milestones if certain net sales targets are reached by Pfizer in 2017, 2018 and 2019.
- Reduced the debt balance on XOMA's loan from Hercules Technology Growth Capital, Inc., by \$10 million.
- Negotiated with Servier to delay a loan repayment by XOMA of €5 million until July 15, 2017.
- Initiated a significant corporate cost reduction plan; reduced headcount from approximately 80 to less than 20 and monthly operating costs by over 50 percent.
- Effected a reverse stock split to maintain compliance with Nasdaq's listing requirement.

Financial Results

XOMA recorded total revenues of \$0.5 million for the fourth quarter of 2016, compared to \$48.2 million for the fourth quarter of 2015. For the full year of 2016, XOMA recorded revenues of \$5.6 million, compared to \$55.4 million for the full year of 2015. The decrease in revenues for the fourth quarter and full year 2016 was due primarily to lower upfront and milestone payments relating to various out-licensing arrangements. Revenue related to the \$18 million received from HCRP will be recognized using the units-of-revenue method beginning in the first quarter of 2017.

Research and development (R&D) expenses were \$8.2 million for the fourth quarter of 2016, compared to \$13.6 million for the fourth quarter of 2015. R&D expenses for the full year of 2016 were \$44.2 million, compared to \$70.9 million for the same period in 2015. The decrease in 2016 was due primarily to a \$13.7 million reduction in salaries and related expenses, a \$6.8 million reduction in clinical trial costs and a \$2.2 million decrease in consulting services due to the Company's decision to cease further investments in the development of gevokizumab.

Selling, general and administrative (SG&A) expenses were \$5.2 million for the fourth quarter of 2016, compared to \$4.7 million for the fourth quarter of 2015. SG&A expenses were \$18.3 million for the full year of 2016, compared to \$20.6 million for the full year of 2015. The decrease in the full year 2016 SG&A expenses was due primarily to a reduction in salaries and related personnel costs due to the Company's restructuring activities in 2015.

Restructuring charges for the full year of 2016 were \$4.6 million, compared to \$3.7 million for the full year of 2015. These charges related primarily to severance, other termination benefits and outplacement services associated with the Company's restructuring activities in 2016.

Net loss for the fourth quarter of 2016 was \$17.5 million, compared to net income of \$25.4 million for the fourth quarter of 2015. Fourth quarter 2015 results reflected the favorable impact of upfront and milestone payments relating to various out-licensing arrangements recognized in the fourth quarter of 2015. Net loss for the full year of 2016 was \$53.5 million, compared to \$20.6 million for the full year of 2015. Net loss for the full year of 2016 and 2015 included gains of \$10.5 million and \$17.8 million, respectively, related to the revaluation of contingent warrant liabilities, which resulted primarily from fluctuations in XOMA's stock price. Excluding the gain from those revaluations, net loss for 2016 was \$64.0 million and net loss for 2015 was \$38.4 million.

On December 31, 2016, XOMA had cash and cash equivalents of \$25.7 million. The Company ended December 31, 2015, with cash and cash equivalents of \$65.8 million. In February 2017, the Company received \$25 million through a registered direct offering with BVF.

Conference Call Details

The Company will host a conference call at 9:00 a.m. ET today, to review its business highlights and describe XOMA's new strategic direction and initiatives. The webcast can be accessed via the Investors and Media section of XOMA's website at <http://investors.xoma.com/events.cfm> and will be available for replay. An accompanying slide presentation also can be accessed via the XOMA website. Telephone numbers for the live conference call are 1-877-369-6589 (U.S./Canada) and 1-408-337-0122 (international) with the passcode 82058103.

About Congenital Hyperinsulinism ^{i,ii,iii}

Congenital Hyperinsulinism (CHI) is a genetic disorder in which the insulin-secreting 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-Bariatric Surgery ^{iv}

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-bariatric surgery 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 possible 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 attempted reversal of the gastric bypass.

About XOMA Corporation

XOMA has an extensive portfolio of products, programs, and technologies that are the subject of licenses the Company has in place with other biotech and pharmaceutical companies. Many of these licenses are the result of the Company's pioneering efforts in the discovery and development of antibody therapeutics. There are more than 20 such programs that are fully funded by partners and could produce milestone payments and royalty payments in the future. In order to maximize its value in a licensing transaction, XOMA continues to invest in X358, an allosteric monoclonal antibody that reduces insulin receptor activity, as the antibody could have a major impact on the treatment of hyperinsulinism. For more information, visit www.xoma.com.

Forward-Looking Statements

Certain statements contained in this press release 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, including statements regarding: the potential of XOMA's portfolio of partnered programs and licensed technologies generating substantial milestone and royalty proceeds over time; positive momentum in 2017; the significant unmet therapeutic need for certain rare medical conditions associated with hyperinsulinism; the continued generation of antibodies by XOMA's proprietary phage display libraries; the potential of IL-2 to provide opportunities to improve patient outcomes; the potential for PTH1R to address high unmet medical needs; XOMA's intent to license X213 and X358; the possibility of the receipt of up to \$4 million in additional sales milestones under our agreements with HCRP; and statements that otherwise relate to future periods. 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.

- i Congenital hyperinsulinism. National Institutes of Health website. ghr.nlm.nih.gov/condition/congenital-hyperinsulinism. January 24, 2017. Accessed January 31, 2017.
- ii Congenital Hyperinsulinism. Children's Hospital of Philadelphia website. www.chop.edu/conditions-diseases/congenital-hyperinsulinism/about#.VXncFU3bKHt. Accessed January 31, 2017.
- iii Arnoux et al.: Congenital hyperinsulinism: current trends in diagnosis and therapy. *Orphanet Journal of Rare Diseases* 2011. 6:63.
- iv Singh et al.: Hypoglycemia After Gastric Bypass Surgery. *Diabetes Spectrum* 2012 Nov; 25(4): 217-221.

Investor contact:

Luke Heagle
 Pure Communications
 +1 910-726-1372
 lheagle@purecommunications.com

Media contact:

Colin Sanford
 Pure Communications
 +1 415-946-1094
 csanford@purecommunications.com

XOMA CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 (in thousands, except per share amounts)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenues:				
License and collaborative fees	\$ 100	\$ 47,212	\$ 3,296	\$ 49,064
Contract and other	424	971	2,268	6,383
Total revenues	<u>524</u>	<u>48,183</u>	<u>5,564</u>	<u>55,447</u>
Operating expenses:				
Research and development	8,248	13,598	44,234	70,852
Selling, general and administrative	5,184	4,707	18,322	20,620
Restructuring	4,551	1,138	4,566	3,699
Total operating expenses	<u>17,983</u>	<u>19,443</u>	<u>67,122</u>	<u>95,171</u>
Income (loss) from operations	(17,459)	28,740	(61,558)	(39,724)
Other income (expense):				
Interest expense	(955)	(1,041)	(3,946)	(4,194)
Other income, net	925	4,046	1,510	5,500
Revaluation of contingent warrant liabilities	9	(6,394)	10,464	17,812
Net (loss) income	<u>\$ (17,480)</u>	<u>\$ 25,351</u>	<u>\$ (53,530)</u>	<u>\$ (20,606)</u>
Basic net income (loss) per share of common stock	\$ (2.89)	\$ 4.27	\$ (8.89)	\$ (3.50)
Diluted net income (loss) per share of common stock	<u>\$ (2.89)</u>	<u>\$ 4.24</u>	<u>\$ (8.89)</u>	<u>\$ (3.50)</u>
Shares used in computing basic net income (loss) per share of common stock	<u>6,107</u>	<u>5,943</u>	<u>6,021</u>	<u>5,890</u>
Shares used in computing diluted net income (loss) per share of common stock	<u>6,107</u>	<u>5,973</u>	<u>6,021</u>	<u>5,890</u>
Other comprehensive loss:				
Net (loss) income	\$ (17,480)	\$ 25,351	\$ (53,530)	\$ (20,606)
Net unrealized gain on available-for-sale securities	—	—	—	—
Comprehensive income (loss)	<u>\$ (17,480)</u>	<u>\$ 25,351</u>	<u>\$ (53,530)</u>	<u>\$ (20,606)</u>

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

	December 31,	
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 25,742	\$ 65,767
Marketable securities	—	496
Trade and other receivables, net	566	4,069
Prepaid expenses and other current assets	852	1,887
Total current assets	<u>27,160</u>	<u>72,219</u>
Property and equipment, net	1,036	1,997
Other assets	481	664
Total assets	<u>\$ 28,677</u>	<u>\$ 74,880</u>
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 5,689	\$ 6,831
Accrued and other liabilities	4,215	6,566
Accrued restructuring costs	3,594	459
Deferred revenue	899	3,198
Interest bearing obligations – current	17,855	5,910
Accrued interest on interest bearing obligations – current	254	331
Total current liabilities	<u>32,506</u>	<u>23,295</u>
Deferred revenue – non-current	18,000	—
Interest bearing obligations – non-current	25,312	42,757
Contingent warrant liabilities	—	10,464
Other liabilities – non-current	69	673
Total liabilities	<u>75,887</u>	<u>77,189</u>
Stockholders' (deficit):		
Preferred stock, \$0.05 par value, 1,000,000 shares authorized, 0 issued and outstanding at December 31, 2016 and 2015	—	—
Common stock, \$0.0075 par value, 277,333,332 shares authorized, 6,114,145 and 5,952,278 shares issued and outstanding at December 31, 2016 and 2015, respectively	46	45
Additional paid-in capital	1,146,357	1,137,729
Accumulated deficit	<u>(1,193,613)</u>	<u>(1,140,083)</u>
Total stockholders' (deficit)	<u>(47,210)</u>	<u>(2,309)</u>
Total liabilities and stockholders' (deficit)	<u>\$ 28,677</u>	<u>\$ 74,880</u>