

XOMA LTD /DE/  
Form 10-Q  
November 10, 2008  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2008

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-14710

**XOMA Ltd.**

(Exact name of registrant as specified in its charter)

**Bermuda**  
(State or other jurisdiction)

of incorporation or organization)

**2910 Seventh Street, Berkeley,**

**California 94710**  
(Address of principal executive offices,

including zip code)

**52-2154066**  
(I.R.S. Employer  
Identification No.)

**(510) 204-7200**  
(Telephone Number)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act). (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act of 1934). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at November 6, 2008
Common shares US\$.0005 par value	132,433,080

**Table of Contents**

**XOMA Ltd.**

**FORM 10-Q**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I FINANCIAL INFORMATION</b>	
Item 1. Condensed Consolidated Financial Statements (unaudited)	
<u>Condensed Consolidated Balance Sheets as of September 30, 2008 and December 31, 2007</u>	1
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2008 and 2007</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2008 and 2007</u>	3
<u>Notes to Condensed Consolidated Financial Statements</u>	4
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	23
<b>PART II OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	23
Item 1a. <u>Risk Factors</u>	24
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	39
Item 3. <u>Defaults Upon Senior Securities</u>	39
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	39
Item 5. <u>Other Information</u>	39
Item 6. <u>Exhibits</u>	40
<u>Signatures</u>	41

**Table of Contents****PART I - FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)  
XOMA Ltd.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share amounts)

	September 30, 2008 (unaudited)	December 31, 2007 (Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,186	\$ 22,500
Short-term investments	4,381	16,067
Restricted cash	13,878	6,019
Receivables	7,962	12,135
Prepaid expenses and other current assets	1,858	1,113
Debt issuance costs	398	254
<b>Total current assets</b>	<b>34,663</b>	<b>58,088</b>
Property and equipment, net	27,970	25,603
Debt issuance costs long-term	1,436	722
Other assets	402	402
<b>Total assets</b>	<b>\$ 64,471</b>	<b>\$ 84,815</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY (NET CAPITAL DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$ 9,270	\$ 6,995
Accrued liabilities	8,095	7,710
Accrued interest	2,845	878
Deferred revenue	6,487	8,017
Other current liabilities	1,599	
<b>Total current liabilities</b>	<b>28,296</b>	<b>23,600</b>
Deferred revenue long-term	9,251	10,047
Interest bearing obligation long-term	76,262	50,850
Other long-term liabilities	353	
<b>Total liabilities</b>	<b>114,162</b>	<b>84,497</b>
Commitments and contingencies		
Shareholders equity (net capital deficiency):		
Preference shares, \$.05 par value, 1,000,000 shares authorized		
Series A, 210,000 designated, no shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively		
Series B, 8,000 designated, 2,959 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively; aggregate liquidation preference of \$29.6 million		
	1	1

Edgar Filing: XOMA LTD /DE/ - Form 10-Q

Common shares, \$.0005 par value, 210,000,000 shares authorized, 132,429,517 and 131,957,774 shares outstanding at September 30, 2008 and December 31, 2007, respectively	66	66
Additional paid-in capital	745,410	740,119
Accumulated comprehensive loss	(82)	(9)
Accumulated deficit	(795,086)	(739,859)
Total shareholders' equity (net capital deficiency)	(49,691)	318
Total liabilities and shareholders' equity (net capital deficiency)	\$ 64,471	\$ 84,815

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****XOMA Ltd.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited, in thousands, except per share amounts)**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>				
License and collaborative fees	\$ 1,286	\$ 31,311	\$ 1,466	\$ 35,859
Contract and other revenue	1,979	7,424	14,728	21,530
Royalties	4,629	4,405	14,873	12,139
<b>Total revenues</b>	<b>7,894</b>	<b>43,140</b>	<b>31,067</b>	<b>69,528</b>
<b>Operating costs and expenses:</b>				
Research and development (including contract related of \$3,294 and \$1,637 for the three months ended September 30, 2008 and 2007, respectively, and \$13,121 and \$10,861 for the nine months ended September 30, 2008 and 2007, respectively)	19,714	14,620	62,444	47,864
General and administrative	6,724	5,803	18,984	15,064
<b>Total operating costs and expenses</b>	<b>26,438</b>	<b>20,423</b>	<b>81,428</b>	<b>62,928</b>
Income (loss) from operations	(18,544)	22,717	(50,361)	6,600
Investment and interest income	182	337	797	1,316
Interest expense	(1,998)	(1,240)	(5,612)	(10,358)
Other income (expense)	(2)	3	(51)	(7)
Net income (loss)	\$ (20,362)	\$ 21,817	\$ (55,227)	\$ (2,449)
Basic net income (loss) per common share	\$ (0.15)	\$ 0.17	\$ (0.42)	\$ (0.02)
Diluted net income (loss) per common share	\$ (0.15)	\$ 0.16	\$ (0.42)	\$ (0.02)
Shares used in computing basic net income (loss) per common share	132,364	131,766	132,270	126,609
Shares used in computing diluted net income (loss) per common share	132,364	136,219	132,270	126,609

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****XOMA Ltd.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited, in thousands)**

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (55,227)	\$ (2,449)
<b>Adjustments to reconcile net loss to net cash (used in) provided by operating activities:</b>		
Depreciation and amortization	4,925	4,581
Common shares contribution to 401(k) and management incentive plans	1,008	1,321
Share-based compensation expense	3,968	2,135
Accrued interest on convertible notes and other interest bearing obligations	2,672	(754)
Revaluation of embedded derivative		6,101
Interest paid on conversion of convertible debt		(5,172)
Amortization of discount, premium and debt issuance costs of convertible debt and interest bearing obligations	1,133	443
Amortization of premiums on short-term investments	10	
Loss on disposal/retirement of property and equipment	50	14
Other non-cash adjustments	(17)	70
<b>Changes in assets and liabilities:</b>		
Receivables	4,173	(1,372)
Prepaid expenses and other current assets	(745)	(779)
Accounts payable	2,275	1,823
Accrued liabilities	385	(370)
Deferred revenue	(2,326)	1,796
Other liabilities	1,952	
<b>Net cash (used in) provided by operating activities</b>	<b>(35,764)</b>	<b>7,388</b>
<b>Cash flows from investing activities:</b>		
Proceeds from sales of investments	9,875	26,605
Proceeds from maturities of investments	5,469	3,840
Transfer of maturities to short-term investments	(526)	
Purchase of investments	(3,199)	(17,925)
Transfer of restricted cash	(7,859)	2,690
Purchase of property and equipment	(7,342)	(6,505)
<b>Net cash (used in) provided by investing activities</b>	<b>(3,582)</b>	<b>8,705</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of long-term debt	55,000	1,952
Principal payments of long-term debt	(32,284)	(4,708)
Proceeds from issuance of common shares	316	431
<b>Net cash provided by (used in) financing activities</b>	<b>23,032</b>	<b>(2,325)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(16,314)</b>	<b>13,768</b>
Cash and cash equivalents at the beginning of the period	22,500	28,002
<b>Cash and cash equivalents at the end of the period</b>	<b>\$ 6,186</b>	<b>\$ 41,770</b>

Edgar Filing: XOMA LTD /DE/ - Form 10-Q

*The accompanying notes are an integral part of these consolidated financial statements.*



---

**Table of Contents**

**XOMA Ltd.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**1. BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Business**

XOMA Ltd. ( XOMA or the Company ), a Bermuda company, is a biopharmaceutical company that discovers and develops for commercialization therapeutic antibodies and other genetically-engineered protein products for the treatment of immunological and inflammatory disorders, cancer and infectious diseases. The Company's products are presently in various stages of development and most are subject to regulatory approval before they can be commercially launched. The Company receives royalties from Genentech, Inc. ( Genentech ) on two approved products, RAPTIVA<sup>®</sup>, for the treatment of moderate-to-severe plaque psoriasis, and LUCENTIS<sup>®</sup>, for the treatment of neovascular (wet) age-related macular degeneration. XOMA also receives royalties from UCB Celltech ( UCB ) on sales of CIMZIA<sup>®</sup> in the U.S. and Switzerland for the treatment of Crohn's disease. XOMA's pipeline includes both proprietary products and collaborative programs at various stages of preclinical and clinical development.

The Company may be required to raise additional funds through public or private financings, strategic relationships, or other arrangements. The Company cannot assure that the funding, if needed, will be available on terms acceptable to it, or at all. Furthermore, any additional equity financings may be dilutive to shareholders and debt financing, if available, may involve restrictive covenants. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue business strategies. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its development programs. The Company's expense structure includes discretionary expenditures that are within the Company's control.

**Basis of Presentation**

The condensed consolidated financial statements include the accounts of XOMA and its subsidiaries. All intercompany accounts and transactions were eliminated during consolidation. The unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q. These financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these statements should be read in conjunction with the audited Consolidated Financial Statements and related Notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2007, as amended, filed with the SEC on March 11, 2008 and March 14, 2008 ( 2007 Form 10-K ).

In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which are necessary to present fairly the Company's consolidated financial position as of September 30, 2008, the consolidated results of the Company's operations for the three and nine months ended September 30, 2008 and 2007, and the Company's cash flows for the nine months ended September 30, 2008 and 2007. The condensed consolidated balance sheet amounts at December 31, 2007 have been derived from audited consolidated financial statements. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year or future periods.

On October 21, 2008, subsequent to the balance sheet date, the Company entered into a common share purchase agreement with Azimuth Opportunity, Ltd. ( Azimuth ), pursuant to which the Company obtained a committed equity line of credit facility under which the Company may sell up to \$60 million of the Company's registered common shares to Azimuth. See Subsequent Events for a further discussion.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, if any, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates.

In the third quarter of 2008, the National Institutes of Health ( NIH ) completed an audit of the Company's billing rates related to the research and development contract with the National Institute of Allergy and Infectious Diseases ( NIAID ), a part of the NIH, which is being funded with federal funds under Contract No. HHSN26620060008C/N01-A1-600081 ( NIAID 2 ). Prior to the NIH's audit, XOMA's billings were based on

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

provisional fringe, overhead and general and administrative rates supported by XOMA's 2005 actual data; these provisional rates are subject to NIH audits annually at the discretion of NIAID's contracting office. In September of 2008, the NIH completed an audit of XOMA's 2007 actual data and developed billing rates for the period from January of 2007 to

## **Table of Contents**

June of 2009 to be used for all of the Company's government contracts. While the NIH rates are considered final for 2007 billings, these NIH rates are considered provisional for the period from January of 2008 to June of 2009 and thus are subject to future audits at the discretion of NIAID's contracting office. In September of 2008, XOMA retroactively applied these NIH rates to the invoices from 2007 through the third quarter of 2008 resulting in an adjustment to decrease revenue by \$2.7 million. The adjustment increased the Company's loss from operations and net loss for the three and nine months ended September 30, 2008 by \$2.7 million. The adjustment also increased basic and diluted net loss per common share by \$0.02 for the three and nine months ended September 30, 2008. As the NIH audit only covered 2007 actual data, which differs significantly from 2006 actual data primarily due to a 22% increase in headcount from 2006 to 2007, management has determined that the original provisional rates are more reflective of 2006 actual data than the (audited) 2007 actual data. Based on this understanding, the parties agreed to not adjust the 2006 billings with the provision that those billings are subject to future NIH audit at the discretion of the NIAID contracting office.

### **Significant Accounting Policies**

There have been no notable changes in significant accounting policies during the nine months ended September 30, 2008, except as noted below, as compared with those previously disclosed in the 2007 Form 10-K.

#### ***Fair Value Measurements***

In September of 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standard ( SFAS ) No. 157 Fair Value Measurements ( SFAS 157 ). SFAS 157 establishes a common definition for fair value, creates a framework for measuring fair value, and expands disclosure requirements about such fair value measurements. Effective January 1, 2008, XOMA adopted SFAS 157 for financial assets and liabilities recognized at fair value on a recurring basis. The adoption of SFAS 157 for financial assets and liabilities did not have a material impact on the Company's consolidated financial position, results of operations or cash flows. See Footnote 2 Fair Value for information and related disclosures regarding our fair value measurements.

#### ***Fair Value Option for Financial Assets and Financial Liabilities***

In February of 2007, the FASB issued SFAS No. 159 The Fair Value Option for Financial Assets and Financial Liabilities ( SFAS 159 ). Under SFAS 159, a company may choose, at specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. SFAS 159 became effective beginning with the Company's first quarter of 2008. At this time, XOMA currently does not have any instruments eligible for election of the fair value option and as such has chosen not to adopt the fair value option of SFAS 159 at this time.

#### ***Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development***

In June of 2007, the Emerging Issues Task Force issued EITF Issue 07-03, Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development ( EITF 07-03 ). EITF 07-03 addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 was effective for fiscal years beginning after December 15, 2007 and interim periods within those years. The adoption of EITF 07-03 did not have a material impact on the Company's statements of financial position, results of operations or cash flows.

### **Concentration of Risk**

Cash equivalents, short-term investments, restricted cash and receivables are financial instruments, which potentially subject the Company to concentrations of credit risk. The Company maintains money market funds and short-term investments that were previously thought to bear a minimal risk. Recent volatility in the financial markets has created liquidity problems in these types of investments, and money market fund investors have recently been unable to retrieve the full amount of funds, even in highly-rated liquid money market accounts, upon maturity. In the third quarter of 2008, the Company had \$0.8 million invested in a money market fund, for which it has only been allowed access to \$0.3 million in cash. The Company was informed that the remaining \$0.5 million will be accessible in cash on or around December 17, 2008; however, due to the uncertainty of the financial markets, this balance has been included in short-term investments at September 30, 2008.

The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the nine months ended September 30, 2008, three customers represented 48%, 34% and 11% of total revenues and two of these customers and two additional

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

customers represented 57%, 13%, 12% and 11% of the \$7.8 million trade receivables outstanding at September 30, 2008. For the nine months ended September 30, 2007 four customers represented 43%, 17%, 13%, and 10% of total revenues.

## Table of Contents

### Royalty Revenue

Royalty revenue and royalty receivables are generally recorded in the period royalties are earned, in advance of collection. The royalty revenue and receivables in these instances are based on communication with collaborative partners, historical information and forecasted sales trends. Under some of XOMA's agreements with licensees that include receipt of royalty revenue, the Company does not have sufficient historical information to estimate royalty revenues or receivables in the period that these royalties are earned. For these contracts, the Company records royalty revenue upon receipt of a royalty statement or cash. Royalties from the sales of CIMZIA<sup>®</sup> are recorded upon receipt of a royalty statement until a sufficient historical base can be established. CIMZIA<sup>®</sup> royalties recorded for the three and nine months ended September 30, 2008 were not material.

### Share-Based Compensation

The Company grants qualified and non-qualified share options, shares and other share related awards under various plans to directors, officers, employees and other individuals. To date, share-based compensation issued under these plans consists of qualified and non-qualified incentive share options and shares. Share options are granted at exercise prices of not less than the fair market value of the Company's common shares on the date of grant. Generally, share options granted to employees fully vest four years from the grant date and expire ten years from the date of the grant or three months from the date of termination of employment (longer in case of death or certain retirements). Certain options granted to directors fully vest on the date of grant and certain options may fully vest upon a change of control of the Company. Additionally, the Company has an Employee Share Purchase Plan ( ESPP ) that allows employees to purchase Company shares at a purchase price equal to 95% of the closing price on the exercise date.

In February of 2008, the Board of Directors of the Company (the Board ) approved a company-wide grant of an aggregate of 3,521,300 share options as part of its annual incentive compensation package. The distribution of the 3,521,300 options was subject to shareholder approval of an increase in the number of shares available for the grant of options under the Company's existing share option plans. Combined with the company-wide grant made in October of 2007 as discussed in the 2007 Form 10-K, a total of 8,706,300 were not deemed granted for accounting purposes until shareholder approval was obtained.

In May of 2008, XOMA's shareholders approved the increase to the number of shares available for issuance under the existing share option plans; therefore all options described above were included in the options outstanding disclosures, options granted disclosures and share-based compensation expense beginning in the second quarter of 2008. These shares vest according to the Company's standard four year vesting schedule which provides for 25% cliff vesting on the first year anniversary of the legal date of grant and monthly vesting of the remaining 75% of shares over the following three years. For accounting purposes the expense related to the cliff vesting feature will be recognized from May of 2008 through the first corresponding anniversary of the legal grant date.

As of September 30, 2008, the Company had approximately 6.0 million common shares reserved for future grant under its share option plans and ESPP.

The following table shows total share-based compensation expense included in the condensed consolidated statements of operations for the three and nine months ended September 30, 2008 and 2007 (in thousands).

	Three Months Ended September 30, 2008		Nine Months Ended September 30, 2008	
	2007	2008	2007	2008
Research and development	\$ 547	\$ 178	\$ 1,806	\$ 625
General and administrative	540	824	2,162	1,510
<b>Total share-based compensation expense</b>	<b>\$ 1,087</b>	<b>\$ 1,002</b>	<b>\$ 3,968</b>	<b>\$ 2,135</b>

There was no capitalized share-based compensation cost as of September 30, 2008 and there were no recognized tax benefits during the three and nine months ended September 30, 2008 and 2007.

To estimate the value of an award, the Company uses the Black-Scholes option pricing model. This model requires inputs such as expected life, expected volatility and risk-free interest rate. The forfeiture rate also impacts the amount of aggregate compensation. These inputs are subjective and generally require significant analysis and judgment to develop. While estimates of expected life, volatility and forfeiture rate are derived

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

primarily from the Company's historical data, the risk-free rate is based on the yield available on U.S. Treasury zero-coupon issues.

**Table of Contents**

The fair value of share-based awards was estimated using the Black-Scholes model with the following weighted-average assumptions for the three and nine months ended September 30, 2008 and 2007:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Dividend yield	0%	0%	0%	0%
Expected volatility	64.3%	65.3%	63.9%	67.7%
Risk-free interest rate	3.020%	4.260%	3.017%	4.423%
Expected life	5.3 years	5.3 years	5.3 years	5.3 years

Share option activity for the nine months ended September 30, 2008 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2007	11,108,120	\$ 3.66		
Granted	9,874,250	3.17		
Exercised	(82,177)	1.54		
Forfeited, expired or canceled	(2,257,807)	3.59		
Options outstanding at September 30, 2008	18,642,386	\$ 3.42	7.96	\$ 960
Options exercisable at September 30, 2008	6,817,198	\$ 4.06	6.07	\$ 764

Total intrinsic value of the options exercised for the nine months ended September 30, 2008 was \$49,625.

At September 30, 2008, there was \$10.9 million of unrecognized share-based compensation expense related to unvested share options with a weighted average remaining recognition period of 2.9 years.

**Comprehensive Income (Loss)**

Unrealized gain (loss) on the Company's available-for-sale securities is included in accumulated comprehensive income (loss). Comprehensive income (loss) and its components for the three and nine months ended September 30, 2008 and 2007 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Net income (loss)	\$ (20,362)	\$ 21,817	\$ (55,227)	\$ (2,449)
Unrealized gain (loss) on securities available-for-sale	(93)	(8)	(73)	1
Comprehensive income (loss)	\$ (20,455)	\$ 21,809	\$ (55,300)	\$ (2,448)

**Net Income (Loss) Per Common Share**

Basic net income (loss) per common share is based on the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is based on the weighted average number of common shares and other dilutive securities outstanding during the period, provided that including these dilutive securities does not increase the net income (loss) per share.





**Table of Contents**

Potentially dilutive securities are excluded from the calculation of earnings per share if their inclusion is antidilutive. The following table shows the total outstanding securities considered antidilutive and therefore excluded from the computation of diluted net income (loss) per share (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2008	2007	September 30, 2008	2007
Options for common shares	18,642	6,361	18,642	9,671
Convertible preference shares	3,818		3,818	3,818
Warrants for common shares <sup>(1)</sup>		125		125

<sup>(1)</sup> Expired in July of 2008

For the three and nine months ended September 30, 2008 and the nine months ended September 30, 2007, all outstanding securities were considered antidilutive, and therefore the calculations of basic and diluted net loss per share are the same. For the three months ended September 30, 2007, the following is a reconciliation of the numerators and denominators of the basic and diluted net income per share (in thousands):

	Three Months Ended September 30, 2007
<b>Numerator</b>	
Net income used for diluted net income per share	\$ 21,817
<b>Denominator</b>	
Weighted average shares outstanding used for basic net income per share	131,766
Effect of dilutive share options	635
Effect of convertible preference shares	3,818
Weighted average shares outstanding and dilutive securities used for diluted net income per share	136,219

**Table of Contents****Cash and Cash Equivalents**

The Company considers all highly liquid debt instruments with maturities of three months or less at the time the Company acquires them to be cash equivalents. At September 30, 2008 and December 31, 2007, cash and cash equivalents consisted of overnight deposits, money market funds, commercial paper, repurchase agreements and debt securities with maturities of less than 90 days and are reported at fair value. Cash and cash equivalent balances were as follows as of September 30, 2008 and December 31, 2007 (in thousands):

	September 30, 2008			Estimated Fair Value
	Cost Basis	Unrealized Gains	Unrealized Losses	
Cash	\$ 955	\$	\$	\$ 955
Cash equivalents	5,232		(1)	5,231
<b>Total cash and cash equivalents</b>	<b>\$ 6,187</b>	<b>\$</b>	<b>\$ (1)</b>	<b>\$ 6,186</b>

	December 31, 2007			Estimated Fair Value
	Cost Basis	Unrealized Gains	Unrealized Losses	
Cash	\$ 5,011	\$	\$	\$ 5,011
Cash equivalents	17,493	1	(5)	17,489
<b>Total cash and cash equivalents</b>	<b>\$ 22,504</b>	<b>\$ 1</b>	<b>\$ (5)</b>	<b>\$ 22,500</b>

**Short-term Investments**

Short-term investments include debt securities classified as available-for-sale. Available-for-sale securities are stated at fair value, with unrealized gains and losses, net of tax, if any, reported in other comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are also included in investment and other income. The cost of investments sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are also included in investment and other income.

In the third quarter of 2008, the Company had \$0.8 million invested in a money market fund, for which it has only been allowed access to \$0.3 million in cash. The Company was informed that the remaining \$0.5 million will be accessible in cash on or around December 17, 2008; however, due to the uncertainty of the financial markets, this balance has been included in short-term investments at September 30, 2008.

Due to the recent adverse developments in the credit markets, XOMA may experience reduced liquidity with respect to some of its investments. These investments are generally held to maturity, which is typically less than one year. However, if the need arose to liquidate such securities before maturity, the Company may experience losses on liquidation.

In August of 2008, the Company sold its remaining state and municipal debt securities with an auction reset feature ( auction rate securities or ARS ). All sales were at par value, which was equal to recorded fair value, and no loss was incurred by the Company.

**Table of Contents**

Short-term investments by security type at September 30, 2008 and December 31, 2007 were as follows (in thousands):

	September 30, 2008			Estimated Fair Value
	Cost Basis	Unrealized Gains	Unrealized Losses	
Corporate notes and bonds	\$ 3,936	\$	\$ (81)	\$ 3,855
Money market funds	526			526
<b>Total Investments</b>	<b>\$ 4,462</b>	<b>\$</b>	<b>\$ (81)</b>	<b>\$ 4,381</b>

	December 31, 2007			Estimated Fair Value
	Cost Basis	Unrealized Gains	Unrealized Losses	
Corporate notes and bonds	\$ 7,447	\$	\$ (5)	\$ 7,442
State and municipal debt securities	8,625			8,625
<b>Total Investments</b>	<b>\$ 16,072</b>	<b>\$</b>	<b>\$ (5)</b>	<b>\$ 16,067</b>

**Receivables**

Receivables consist of the following (in thousands):

	September 30, 2008	December 31, 2007
Trade receivables	\$ 7,847	\$ 11,655
Other receivables	115	480
<b>Total</b>	<b>\$ 7,962</b>	<b>\$ 12,135</b>

Other receivables include related party transactions consisting of a relocation loan to one employee. The initial loan of \$150,000 was granted in 2004 and is being forgiven, along with related interest, over four years, contingent on the employee's continued employment with the Company. The forgiveness will be complete in November of 2008. The total related party balance was \$38,000 as of September 30, 2008 and December 31, 2007.

**Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	September 30, 2008	December 31, 2007
Accrued management incentive compensation	\$ 2,953	\$ 4,135
Accrued payroll costs	2,838	2,635
Accrued professional fees	1,135	617
Other	1,169	323
<b>Total</b>	<b>\$ 8,095</b>	<b>\$ 7,710</b>



**Table of Contents****2. FAIR VALUE**

In accordance with SFAS 157, the following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and investments) measured at fair value on a recurring basis as of September 30, 2008 (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Repurchase agreements	\$ 4,108	\$ 4,108	\$	\$
Money market funds	526	526		
Commercial paper	1,123		1,123	
Corporate notes and bonds	3,855		3,855	
<b>Total</b>	<b>\$ 9,612</b>	<b>\$ 4,634</b>	<b>\$ 4,978</b>	<b>\$</b>

Level 3 assets held during 2008 consisted of auction rate securities. During the first nine months of 2008, the Company sold all of its ARS investments at par value, which equaled the recorded fair value, and has recognized no loss on the sale of such investments. The following table provides a summary of changes in fair value of the Company's Level 3 financial assets as of September 30, 2008 (in thousands):

	Auction Rate Securities
Balance at December 31, 2007	\$ 8,625
Unrealized gains/losses included in other comprehensive income	
Sales	(8,625)
Balance at September 30, 2008	\$

**3. COLLABORATIVE AND OTHER ARRANGEMENTS****NIAID 3**

In September of 2008, the Company announced that it had been awarded a \$65 million multiple year contract funded with Federal funds from NIAID, a part of the NIH (Contract No. HHSN272200800028C) (NIAID 3), to support XOMA's ongoing development of drug candidates towards clinical trials in the treatment of botulism poisoning, a potentially deadly muscle paralyzing disease. The Company will recognize revenue under the arrangement as the related research and development costs are incurred. Revenue recognized in the third quarter of 2008 relating to this contract was insignificant.

**4. LONG-TERM DEBT**

As of September 30, 2008, the Company had long-term debt of \$76.3 million, including \$55.0 million outstanding under the term loan from Goldman Sachs Specialty Lending Holdings, Inc. (Goldman Sachs) and \$21.3 million outstanding under the Company's note with Novartis AG (Novartis). For the three and nine months ended September 30, 2008, XOMA incurred interest expense and amortization of debt issuance costs of \$2.0 million and \$5.6 million, respectively.

**Goldman Sachs Term Loan**

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

In November of 2006, the Company entered into a five-year, \$35.0 million term loan facility (the original facility ) with Goldman Sachs and borrowed the full amount thereunder. Indebtedness under the original facility incurred interest at an annual rate equal to six-month LIBOR plus 5.25%, and was secured by all rights to receive payments due the Company relating to RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup>.

**Table of Contents**

In May of 2008, the Company entered into a five-year, \$55.0 million amended and restated term loan facility with Goldman Sachs (the new facility) refinancing the original facility. Indebtedness under the new facility bears interest at an annual rate equal to the greater of (x) six-month LIBOR or (y) 3.0%, plus 8.5% and is subject to reset on April 1 and October 1 of each year. The debt is secured by all rights to receive payments due to the Company relating to RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup>, and CIMZIA<sup>®</sup> and payments received by the Company in respect of these payment rights, in addition to a standing reserve equal to the next semi-annual interest payment, are held in a custodial account which is classified as restricted cash. This cash account and the interest earned thereon can be used solely for the payment of the semi-annual interest amounts due on April 1 and October 1 of each year and, at that time, amounts in excess of the interest reserve requirement may be used to pay down principal or be distributed back to the Company, at the discretion of Goldman Sachs. The Company may prepay indebtedness under the facility at any time, subject to certain prepayment premiums if prepaid during the first four years. The Company is required to comply with a financial covenant determined by the ratio of royalties collected to interest payable and the Company was in compliance with this covenant as of September 30, 2008. Proceeds from the new facility were used to pay the outstanding principal and accrued interest under the original facility, certain fees and expenses in connection with the new facility and for general corporate purposes. As of September 30, 2008, the outstanding principal balance was \$55.0 million and the interest rate was 11.5%.

Debt issuance costs under the new facility of \$2.0 million are being amortized on a straight-line basis over the five year life of the new loan and are disclosed as current and long-term debt issuance costs on the Company's balance sheet.

**Novartis Note**

In May of 2005, the Company executed a secured note agreement with Chiron Corporation (now Novartis). Under the note agreement, Novartis agreed to make semi-annual loans to the Company to fund up to 75% of the Company's research and development and commercialization costs under the Company's collaboration arrangement with Novartis, not to exceed \$50.0 million in aggregate principal amount. Any unpaid principal amount together with accrued and unpaid interest shall be due and payable in full on June 21, 2015, the tenth anniversary date of the advance date on which the first loan was made. Interest on the unpaid balance of the principal amount of each loan accrues at a rate equal to the six-month LIBOR plus 2%, which was equal to 5.18% at September 30, 2008, and is payable semi-annually in June and December of each year. Additionally, the interest rate resets in June and December of each year. At the Company's election, the semi-annual interest payments can be added to the outstanding principal amount, in lieu of a cash payment, as long as the aggregate principal amount does not exceed \$50.0 million and the Company has made this election for each payment. Loans under the note agreement are secured by the Company's interest in its collaboration with Novartis, including its share of any profits arising therefrom. At September 30, 2008, the outstanding principal balance under this note agreement totaled \$21.3 million.

Interest expense and amortization of debt issuance costs for the Goldman Sachs term loan and Novartis note are shown below (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
<b>Interest Expense</b>				
Goldman Sachs - Original facility	\$	\$ 818	\$ 976	\$ 2,556
Goldman Sachs - New facility	1,616		2,530	
Novartis	281	358	974	972
Expenses related to convertible debt				6,450
Total Interest Expense	1,897	1,176	4,480	9,978
<b>Amortization of Debt Issuance Costs</b>				
Goldman Sachs - Original facility		64	975	380
Goldman Sachs - New facility	101		157	
Total Amortization of Debt Issuance Costs	101	64	1,132	380
<b>Total Interest Expense and Amortization of Debt Issuance Costs</b>	<b>\$ 1,998</b>	<b>\$ 1,240</b>	<b>\$ 5,612</b>	<b>\$ 10,358</b>

**Letter of Credit**

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

In April of 2008, XOMA entered into an irrevocable letter of credit ( LOC ) arrangement in favor of an insurance company agent that is certified to draw funds on the LOC not to exceed \$942,000. The LOC is intended to cover any potential liability, loss, or costs incurred by the agent under any bonds or undertakings for the purpose of clearing manufacturing materials through U.S. Customs and Border Protection. The LOC will expire, if not renewed, in one year, and requires XOMA to record the LOC balance as restricted short-term cash on the consolidated balance sheet. The balance is included in restricted cash on XOMA s balance sheet as of September 30, 2008.



---

**Table of Contents**

***Convertible Debt***

During the first quarter of 2007, the Company eliminated the remaining balance of its convertible debt issued in February of 2006. For the nine months ended September 30, 2007, the Company incurred \$0.2 million in interest expense related to its convertible debt, amortized a net of \$0.1 million in debt issuance costs, premium and discount, and recognized \$6.1 million in interest expense related to the revaluation of the embedded derivative.

**5. LEGAL PROCEEDINGS, COMMITMENTS AND CONTINGENCIES**

There were no developments material to XOMA in the United States Bankruptcy Court proceedings involving Aphton Corporation (described in XOMA's Annual Report on Form 10-K for the fiscal year ended December 31, 2007) during the nine months ended September 30, 2008.

**6. SUBSEQUENT EVENTS**

***Equity Line of Credit***

On October 21, 2008, XOMA entered into a common share purchase agreement (the "Purchase Agreement") with Azimuth, pursuant to which XOMA obtained a committed equity line of credit facility (the "Facility") under which it may sell up to \$60 million of its registered common shares to Azimuth over a 24-month period, subject to certain conditions and limitations. XOMA is not obligated to utilize any of the \$60 million facility and remains free to enter other financing transactions. Pursuant to the terms of the Purchase Agreement, XOMA determines, in its sole discretion, the timing, dollar amount and floor price per share of each draw down under the Facility, subject to certain conditions and limitations. The number and price of shares sold in each draw down are determined by a contractual formula designed to approximate fair market value, less a discount. The Purchase Agreement also provides that from time to time and in XOMA's sole discretion, XOMA may grant Azimuth the right to exercise one or more options to purchase additional common shares during each draw down pricing period for the amount of shares based upon the maximum option dollar amount and the option threshold price specified by XOMA. Shares under the Facility are sold pursuant to a prospectus which forms a part of a registration statement declared effective by the Securities and Exchange Commission on May 29, 2008. From the inception of the Facility through November 10, 2008, XOMA has sold 3,909,906 common shares under the Facility for aggregate gross proceeds of \$4,500,000.

***Novartis***

On November 10, 2008, XOMA announced the restructuring of its product development collaboration with Novartis, which involves six development programs including the ongoing HCD 122 program. Under the restructured agreement, Novartis will pay XOMA \$6.2 million, fully fund all future R&D expenses, reduce existing debt by \$7.5 million, pay potential milestones of up to \$14 million and double-digit royalties for two ongoing product programs (including HCD 122) and provide XOMA with options to develop or receive royalties on four additional programs currently pending selection. In exchange, Novartis will have control over the HCD 122 program and the additional ongoing program, as well as the right to expand the development of these programs into additional indications outside of oncology. As part of the agreement, Novartis will pay XOMA for all project costs incurred after July 1, 2008.

---

## **Table of Contents**

### **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The accompanying discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our consolidated financial statements and accompanying notes. On an on-going basis, we evaluate our estimates, including those related to terms of research collaborations, investments, share compensation, impairment issues and the estimated useful life of assets and contingencies. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

#### **Overview**

We are a leader in the discovery, development and manufacture of therapeutic antibodies. Our proprietary development pipeline includes XOMA 052, an anti-IL-1 beta antibody, and XOMA 629, a synthetic peptide compound derived from bactericidal/permeability-increasing protein.

Our proprietary development pipeline is primarily funded by multiple revenue streams resulting from the licensing of our antibody technologies, product royalties, development collaborations and biodefense contracts. Our technologies and experienced team have contributed to the success of marketed antibody products, including RAPTIVA® (efalizumab) for chronic moderate-to-severe plaque psoriasis, LUCENTIS® (ranibizumab injection) for wet age-related macular degeneration and CIMZIA® (certolizumab pegol, CDP870) for Crohn's disease.

We have a premier antibody discovery and development platform that includes six antibody phage display libraries and our proprietary Human Engineering and bacterial cell expression (BCE) technologies. For example, our BCE technology is a key 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 with us.

In addition to developing our own potential products, we develop products for premier pharmaceutical companies including Schering-Plough Research Institute (SPRI) and Takeda Pharmaceutical Company Limited (Takeda). We have a fully integrated product development infrastructure, extending from preclinical science to manufacturing and, as of September 30, 2008, a team of 336 employees at our Berkeley, California location.

#### **Recent Developments**

##### ***Review of Research and Development Priorities***

In response to current economic conditions, we have reviewed our research and development (R&D) priorities in light of the interim data on XOMA 052 discussed below and the need to establish a sustainable level of R&D investment.

Our collaboration business costs are fully funded by contract revenues from collaborators, including Takeda and SPRI. Our biodefense business costs, including funding for XOMA 3AB, XOMA's biodefense anti-botulism product candidate, are fully funded by the U.S. Government through contracts such as the \$65 million multiple year contract awarded in September of 2008 (Contract No. HHSN272200800028C) funded with Federal funds from the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH).

Most of the increase in R&D spending and cash expenditures in the first three quarters of 2008 was related to spending on our proprietary projects such as XOMA 052 and to a lesser extent, XOMA 629. We have reviewed our portfolio to establish priorities intended to build potential value and devote additional resources to our lead clinical program, XOMA 052. Accordingly, we are narrowing the focus of our R&D efforts to XOMA 052 and away from our other programs. Specifically, we plan to complete Phase 1 clinical testing of XOMA 052 in Type 2 diabetes, which includes four studies. We also plan to initiate a major Phase 2 diabetes study in 2009 and a pharmacokinetic study in rheumatoid arthritis in the fourth quarter of 2008, and conduct small XOMA 052 proof-of-concept trials in other indications which may include systemic juvenile idiopathic arthritis and other diseases. We will curtail all spending on XOMA 629 including the ongoing Phase 2 study. We also intend to continue funding our antibody technologies, such as our custom human antibody library business, internally or with partners.

Significant cash expenditures were also made in the first three quarters of 2008 to improve our manufacturing plant. We have completed the production requirements for key proprietary programs and have the capability and capacity in place to meet the anticipated production needs for biodefense and other key projects. We have a relatively high degree of control over the timing of new capital expenditures and as a result, we expect capital costs in 2009 to decrease as compared to 2008. We have also taken steps to reduce and control other operating costs and

accordingly expect to decrease general and administrative expenses in 2009.

**Table of Contents****XOMA 052**

On September 8, 2008, we announced interim data from two Phase I clinical studies of XOMA 052, an antibody drug candidate with an ultra high binding affinity of 300 femtomolar, which indicate support for a novel anti-inflammatory approach to Type 2 diabetes treatment that may preserve insulin-producing cells. XOMA 052 potentially addresses inflammation as an underlying cause of diabetes by targeting Interleukin-1 beta (IL-1 beta), a master signaling protein which triggers inflammatory pathways in the body. Although these Phase 1 studies were designed to test drug safety and pharmacokinetics, rather than efficacy, we believe these studies are important additions to the other medical research indicating that decreasing inflammation may reduce disease progression in diabetes.

Interim results from these two Phase 1 studies suggest that XOMA 052 may demonstrate biological activity in patients with Type 2 diabetes as measured by select diabetes and inflammatory markers. The interim analysis of two single-dose, dose-escalation, Phase 1 studies included 48 patients with Type 2 diabetes from five dose groups in a U.S. study and three dose groups in a European study. Forty patients received XOMA 052 and eight received placebo. Patients were followed for two to three months.

**Other Developments**

On September 9, 2008, we announced that we were awarded a \$65 million multiple year contract, funded with Federal funds from NIAID, a component of the NIH, to support XOMA's ongoing development of drug candidates towards clinical trials in the treatment of botulism poisoning, a potentially deadly muscle paralyzing disease. The contract is the third that NIAID has awarded us for the development of botulinum antitoxins and brings the program's total to nearly \$100 million.

On September 10, 2008, we announced that XOMA and the Texas A&M University System have entered into an agreement to explore options for the development and manufacture of antibodies and protein-based therapeutics for human and veterinary applications. We and the Texas A&M University System will discuss working together to develop next-generation systems and processes to improve and accelerate protein and antibody manufacturing.

On September 15, 2008, we announced that we had initiated new therapeutic antibody programs under an existing antibody discovery and development collaboration between us and Takeda. The new programs add to the multiple discovery and development programs already being advanced through the collaboration.

**Results of Operations****Revenues**

Total revenues for the three and nine months ended September 30, 2008, and 2007, were as follows (in thousands):

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
License and collaborative fees	\$ 1,286	\$ 31,311	\$ 1,466	\$ 35,859
Contract and other revenue	1,979	7,424	14,728	21,530
Royalties	4,629	4,405	14,873	12,139
Total revenues	\$ 7,894	\$ 43,140	\$ 31,067	\$ 69,528

License and collaborative fees include up-front payments related to the outlicensing of our products and technologies and other collaborative arrangements. The \$30.0 million decrease for the three months ended September 30, 2008 compared with the corresponding period of 2007 is due to a \$30.0 million non-recurring license fee received from Pfizer Inc. (Pfizer) in the third quarter of 2007. The \$34.4 million decrease for the nine months ended September 30, 2008 compared to the same period of 2007 is

**Table of Contents**

also primarily due to the \$30.0 million license fee received from Pfizer in 2007. In addition, \$4.3 million in revenue was recognized during the first quarter of 2007 representing the unamortized revenue from the \$10.0 million up-front collaboration fee received in connection with our collaboration with Novartis AG ( Novartis ) in February of 2004. This revenue was recognized upon the termination of our mutual exclusivity clause as discussed in our 2007 Form 10-K.

Contract revenues decreased by \$5.4 million and \$6.8 million for the three and nine months ended September 30, 2008 compared to the corresponding periods of 2007. The decreases are primarily due to the Company nearing the end of contracted service arrangements with AVEO Pharmaceuticals, Inc. (now with SPRI and referred to herein together as SPRI/AVEO ) and NIAID, a part of the NIH, Department of Health and Human Services which is being funded with federal funds under Contract No. HHSN26620060008C/N01-A1-600081 ( NIAID 2 ). The decreases are partially offset by increased activity related to our contracts with SPRI and Takeda and may be further offset by new collaboration agreements and/or the expansion of existing agreements.

Contract revenue for the three and nine months ended September 30, 2008 includes an adjustment for NIAID 2. In the third quarter of 2008, the NIH completed an audit of our billing rates related to the NIAID 2 research and development contract. Prior to the NIH's audit, we billed based on upon provisional fringe, overhead and general and administrative rates generated from our 2005 actual data; these provisional rates are subject to NIH audits annually at the discretion of NIAID's contracting office. In September of 2008, the NIH completed an audit of our 2007 actual data and developed billing rates for the period from January of 2007 to June of 2009 to be used for all of the Company's government contracts. While the NIH rates are considered final for 2007 billings, these NIH rates are considered provisional for the period from January of 2008 to June of 2009 and thus are subject to future audits at the discretion of NIAID's contracting office. In September of 2008, we retroactively applied these NIH rates to the invoices from 2007 through the third quarter of 2008 resulting in an adjustment to decrease revenue by \$2.7 million. The adjustment increased our loss from operations and net loss for the three and nine months ended September 30, 2008 by \$2.7 million. As the NIH audit only covered 2007 actual data, which differs significantly from 2006 actual data primarily due to a 22% increase in headcount from 2006 to 2007, management has determined that the original provisional rates are more reflective of 2006 actual data than the (audited) 2007 actual data. Based on this understanding, the parties agreed to not adjust the 2006 billings with the provision that those billings are subject to future NIH audit at the discretion of the NIAID contracting office.

Royalty revenue increased in the first three quarters of 2008 as a result of higher sales of LUCENTIS® and RAPTIVA® outside the U.S. Revenues from royalties are expected to decrease in the fourth quarter of 2008 compared with 2007 due to the expiration in July of 2008 of most of the more important European patents in our BCE patent portfolio, which currently cover LUCENTIS®. Decreases in royalty revenues may adversely impact our ability to remain in compliance with the covenants contained in our loan agreement with Goldman Sachs, in particular the financial covenant that requires us to maintain a specified ratio of royalties collected to interest payable. However, UCB Celltech ( UCB ) announced in April of 2008 that CIMZIA® received marketing approval from the U.S. Food and Drug Administration for the treatment of Crohn's disease and, consequently, we expect decreases in royalties from sales of LUCENTIS® outside the U.S. to be offset in part by royalties from sales of CIMZIA® in the U.S. and continued sales of LUCENTIS® in the U.S. UCB provides CIMZIA® related sales and royalty statements to us within 60 days of the end of each quarter. Due to the lack of sufficient historical information, royalties received on sales of CIMZIA® are recorded upon receipt of the royalty statement until we establish sufficient historical information on which to estimate related royalty revenues. During the first nine months of 2008, royalties received for the sale of CIMZIA® were not material.

**Research and Development Expenses**

Biopharmaceutical development includes a series of steps, including *in vitro* and *in vivo* preclinical testing, and Phase 1, 2 and 3 clinical studies in humans. Each of these steps is typically more expensive than the previous step, but actual timing and the cost to us depends on the product being tested, the nature of the potential disease indication and the terms of any collaborative arrangements with other companies. After successful conclusion of all of these steps, regulatory filings for approval to market the products must be completed, including approval of manufacturing processes and facilities for the product. Our research and development expenses currently include costs of personnel, supplies, facilities and equipment, consultants, patent expenses and third party costs related to preclinical and clinical testing.

Research and development expenses were \$19.7 million and \$62.4 million for the three and nine months ended September 30, 2008, respectively, compared with \$14.6 million and \$47.9 million for the corresponding periods in 2007. The increase of \$5.1 million for the third quarter of 2008 compared with the third quarter of 2007 and \$14.5 million year to date over the same period in the prior year primarily reflects increased spending on development of XOMA 052 (including Phase 1 clinical trials), XOMA 629, and our contracts with SPRI and Takeda. These increases are partially offset by a decrease in spending on NIAID 2, Taligen Therapeutics, Inc. ( Taligen ) and SPRI/AVEO-related contract activities. Of the \$5.1 million increase in research and development expenses in the third quarter of 2008 compared with the same period of 2007, \$0.8 million related to an increase in salaries and related expenses including a \$0.4 million increase in share-based compensation expense. Of the \$14.5 million increase for the nine months ended September 30, 2008 compared with the nine months ended September 30, 2007, \$4.2 million related to an increase in salaries and related expenses including a \$1.2 million increase in share-based compensation expense. See Accounting for Share-Based Compensation for further discussion related to our share-based compensation expense for 2008.



**Table of Contents**

Our research and development activities can be divided into earlier stage programs, which include molecular biologics, process development, pilot-scale production and preclinical testing, and later stage programs, which include clinical testing, regulatory affairs and manufacturing clinical supplies. The costs associated with these programs approximate the following (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Earlier stage programs	\$ 11,921	\$ 10,490	\$ 36,932	\$ 39,408
Later stage programs	7,793	4,130	25,512	8,456
<b>Total</b>	<b>\$ 19,714</b>	<b>\$ 14,620</b>	<b>\$ 62,444</b>	<b>\$ 47,864</b>

Our research and development activities can also be divided into those related to our internal projects and those projects related to collaborative and contract arrangements. The costs related to internal projects versus collaborative and contract arrangements approximate the following (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007
Internal projects	\$ 14,623	\$ 12,090	\$ 44,398	\$ 33,867
Collaborative and contract arrangements	5,091	2,530	18,046	13,997
<b>Total</b>	<b>\$ 19,714</b>	<b>\$ 14,620</b>	<b>\$ 62,444</b>	<b>\$ 47,864</b>

For the three and nine months ended September 30, 2008, one development program (XOMA 052) accounted for more than 20% but less than 30%, and no development program accounted for more than 30% of our total research and development expenses. For the three months ended September 30, 2007, two development programs (SPRI/AVEO and XOMA 052) accounted for more than 10% but less than 20% and no development program accounted for more than 20% of our total research and development expenses. For the nine months ended September 30, 2007, two development programs (NIAID and XOMA 052) accounted for more than 10% but less than 20% and no development program accounted for more than 20% of our total research and development expenses.

We currently anticipate that R&D expenses will be higher for 2008 as compared with 2007; however we expect to decrease our R&D spending in the fourth quarter of 2008. Most of the increase in R&D spending in 2008 was on our proprietary projects such as XOMA 052 and to a lesser extent, XOMA 629. Going forward, we plan to narrow the focus of our research and development efforts to XOMA 052, and away from our other programs. Specifically, we plan to complete Phase 1 clinical testing of XOMA 052 in Type 2 diabetes, which includes four studies. We also plan to initiate a major Phase 2 diabetes study in 2009 and a pharmacokinetic study in rheumatoid arthritis in the fourth quarter of 2008, and conduct small XOMA 052 proof-of-concept trials in other indications. We will curtail all spending on XOMA 629 including the ongoing Phase 2 study. We also expect to continue our spending on our collaborations with SPRI and Takeda and our research and development agreements with NIAID. In addition, we have been approached by several companies offering to collaborate on our testing and development of XOMA 052 and will seek to enter into such a collaboration in the second half of 2009.

Future research and development spending may also be impacted by potential new licensing or collaboration arrangements, as well as the termination of existing agreements. Beyond this, the scope and magnitude of future research and development expenses are difficult to predict at this time.

**General and Administrative Expenses**

General and administrative ( G&A ) expenses include salaries and related personnel costs, facilities costs and professional fees. G&A expenses were \$6.7 million and \$19.0 million for the three and nine months ended September 30, 2008, respectively, compared with \$5.8 million and \$15.1 million for the corresponding periods of 2007. The \$0.9 million increase for the third quarter of 2008 compared with the third quarter of

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

2007 included an increase in salaries of \$0.3 million, travel and related expenses of \$0.2 million, consulting fees of \$0.4 million related to employee training, legal fees supporting internal projects of \$0.3 million and marketing and communications costs of \$0.4 million. These increases were offset by a decrease in bonus expense of \$0.4 million and share-based compensation expense of \$0.3 million.



---

## **Table of Contents**

The increase of \$3.9 million for the nine months ended September 30, 2008 compared with September 30, 2007 was primarily due to an increase of \$1.2 million in salaries and related expenses, a \$1.5 million increase in legal fees supporting internal projects, a \$0.9 million increase in marketing and communications and a \$0.8 million increase in consulting fees primarily related to employee training. These increases were offset by a decrease in bonus expense of \$0.2 million.

See *Accounting for Share-Based Compensation* for further discussion related to our share-based compensation expense for 2008.

### ***Other Income (Expense)***

Investment and interest income was \$0.2 million and \$0.8 million for the three and nine months ended September 30, 2008, respectively, compared with \$0.3 million and \$1.3 million for the corresponding periods of 2007. Investment and interest income consists primarily of interest earned on our cash and investment balances.

Interest expense was \$2.0 million and \$5.6 million for the three and nine months ended September 30, 2008, respectively, compared with \$1.2 million and \$10.4 million for the corresponding periods of 2007. The increase for the third quarter of 2008 compared with the same period of 2007 is due to the higher principal balance and interest rate associated with our new term loan facility with Goldman Sachs Specialty Lending Holdings, Inc. ( *Goldman Sachs* ). The decrease in interest expense for the nine months ended September 30, 2008 compared to the same period of 2007 is due to the elimination of our convertible debt in 2007, which represented \$6.5 million of the total interest expense reported in the first nine months of 2007, partially offset by an increase in interest expense related to the higher principal balance and interest rate associated with our new term loan facility with Goldman Sachs.

### **Accounting for Share-Based Compensation**

In February of 2008, our Board of Directors (the *Board* ) approved a company-wide grant of 3,521,300 share options as part of our annual incentive compensation package. The distribution of the 3,521,300 options was subject to shareholder approval of an increase in the number of shares available for the grant of options under the Company's existing share option plans. Combined with the company-wide grant in October of 2007 as discussed in our 2007 Form 10-K, a total of 8,706,300 were not deemed granted for accounting purposes until shareholder approval was obtained.

In May of 2008, our shareholders approved the increase in the number of shares available for issuance under our existing share option plans; therefore all options described above were included in the options outstanding disclosures, options granted disclosures and share-based compensation expense beginning in the second quarter of 2008. These shares vest according to our standard four year vesting schedule which provides for 25% cliff vesting on the first year anniversary of the legal date of grant and monthly vesting of the remaining 75% of shares over the next three years. For accounting purposes, the expense related to the cliff vesting feature will be recognized from May of 2008 through the first corresponding anniversary of the legal grant date. We expect our share-based compensation expense to continue to be higher than prior periods over the four year vesting period related to these options.

During the three and nine months ended September 30, 2008 we recognized \$1.1 million and \$4.0 million, respectively, in share-based compensation expense, compared to \$1.0 million and \$2.1 million for the same periods of 2007, respectively. The slight increase in share-based compensation expense for the third quarter of 2008 compared with the third quarter of 2007 is in line with a higher number of options granted. The increase in share-based compensation expense for the nine months ended September 30, 2008 compared with the nine months ended September 30, 2007 is due to the options discussed above granted in October of 2007 and February of 2008. As of September 30, 2008, there was \$10.9 million of unrecognized share-based compensation expense related to unvested shares with a weighted average remaining recognition period of 2.9 years.

### **Liquidity and Capital Resources**

Cash, cash equivalents and short-term investments at September 30, 2008 was \$10.6 million compared with \$38.6 million at December 31, 2007. Net cash used in operating activities was \$35.8 million for the nine months ended September 30, 2008, compared with cash provided of \$7.4 million for the same period in 2007. The \$43.2 million increase in cash used for operations during the nine months ended September 30, 2008, compared with the corresponding period of 2007, consisted of a net loss of \$55.2 million with non-cash add-backs for depreciation and amortization of \$4.9 million, equity related compensation of \$5.0 million, accrued interest of \$2.7 million and amortization of debt issuance costs of \$1.1 million. During the nine month period, we collected \$36.7 million in outstanding accounts receivable related to our revenue streams and made payments of \$26.2 million relating to payroll, \$4.0 million for the annual bonus paid in the first quarter, \$48.8 million relating to payment of vendors and \$34.0 million for loan-related payments including principal payments, interest payments and payment of debt issuance costs. During the nine months ended September 30, 2008, as compared to the same period in 2007, we substantially increased our

spending on XOMA 052.

**Table of Contents**

Net cash provided by operations for the nine months ended September 30, 2007 consisted of a net loss of \$2.4 million with non-cash add-backs for the revaluation of our embedded derivative of \$6.1 million, depreciation and amortization of \$4.6 million, equity related compensation of \$3.5 million and an increase in the amortization of debt issuance costs and the premium or discount on convertible notes of \$0.5 million, as well as a net increase in liabilities of \$3.2 million and a net decrease in assets of \$2.2 million. This was partially offset by cash payments for the additional interest feature of our convertible debt of \$5.2 million and \$0.8 million of accrued interest on convertible debt and other interest bearing obligations. During the same period, payments of \$6.6 million for interest were made on convertible debt, \$2.9 million for interest on our Goldman Sachs term loan and \$1.0 million for the annual bonus which was paid in the first quarter.

Net cash used for investing activities for the nine months ended September 30, 2008 was \$3.6 million compared with net cash provided by investing activities of \$8.7 million for the same period of 2007. The decrease in this balance as compared to 2007 is due to the transfer to restricted cash of \$7.9 million relating to our new facility with Goldman Sachs and purchases of fixed assets of \$7.3 million primarily relating to lab and production equipment, partially offset by net sales and maturities of investments of \$11.6 million. In the third quarter of 2008, the Company had \$0.8 million invested in a money market fund, for which it has only been allowed access to \$0.3 million in cash. The Company was informed that the remaining \$0.5 million will be accessible in cash on or around December 17, 2008; however, due to the uncertainty of the financial markets, this balance has been included in short-term investments at September 30, 2008.

Net cash provided by investing activities for the nine months ended September 30, 2007 of \$8.7 million included net sales and maturities of investments of \$12.5 million and transfer from restricted cash of \$2.7 million, partially offset by purchases of fixed assets of \$6.5 million primarily relating to lab and production equipment and leasehold improvements.

Net cash provided by financing activities for the nine months ended September 30, 2008, was \$23.0 million compared with cash used of \$2.3 million for the same period of 2007. The \$23.0 million provided in 2008 was a result of the refinancing of our original facility with Goldman Sachs in May of 2008, which netted proceeds of approximately \$30.9 million, partially offset by a principal payment of \$8.2 million paid against the outstanding balance of the original facility with Goldman Sachs in the first quarter. In comparison, during the nine months ending September 30, 2007, we paid \$4.7 million toward the principal balance of the original facility with Goldman Sachs and received proceeds of \$2.0 million from our note with Novartis in the second quarter.

***Goldman Sachs Term Loan***

In November of 2006, we entered into a five-year, \$35.0 million term loan facility (the original facility) with Goldman Sachs and borrowed the full amount thereunder. Indebtedness under the original facility incurred interest at an annual rate equal to six-month LIBOR plus 5.25% and was secured by all rights to receive payments due us relating to RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup>.

In May of 2008, we entered into a five-year, \$55.0 million amended and restated term loan facility with Goldman Sachs (the new facility) refinancing the original facility. Indebtedness under the new facility bears interest at an annual rate equal to the greater of (x) six-month LIBOR or (y) 3.0%, plus 8.5% and is subject to reset on April 1 and October 1 of each year. The debt is secured by all rights to receive payments due to the Company relating to RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup>, and CIMZIA<sup>®</sup>. As of September 30, 2008, the interest rate was 11.5%. Payments received by XOMA in respect of these payment rights, in addition to a standing reserve equal to the next semi-annual interest payment, are held in a custodial account which is classified as restricted cash. This cash account and the interest earned thereon can be used solely for the payment of the semi-annual interest amounts due on April 1 and October 1 of each year and, at that time, amounts in excess of the interest reserve requirement may be used to pay down principal or be distributed back to us, at the discretion of Goldman Sachs. We may prepay indebtedness under the facility at any time, subject to certain prepayment premiums if prepaid during the first four years. We are required to comply with a financial covenant determined by the ratio of royalties collected to interest payable and we were in compliance with this covenant as of September 30, 2008. Proceeds from the new facility were used to pay the outstanding principal and accrued interest under the original facility, certain fees and expenses in connection with the new facility and for general corporate purposes.

At September 30, 2008, the outstanding principal amount under the new facility totaled \$55.0 million and the balance in restricted cash was \$12.9 million. On October 1, 2008, our restricted cash was used to pay \$2.5 million in interest on the new facility with Goldman Sachs, \$2.6 million was released to us and \$4.6 million was applied to principal, reducing the outstanding loan balance to \$50.4 million as of that date. Our remaining restricted cash balance held by Goldman Sachs was \$3.2 million and will be used to pay our interest payment due in April of 2009. In addition, the interest rate on our new facility with Goldman Sachs has increased to 12.3% due to an increase in the six-month LIBOR rate.

---

## **Table of Contents**

Debt issuance costs under the new facility of \$2.0 million are being amortized on a straight-line basis over the five year life of the loan and are disclosed as current and long-term debt issuance costs on the balance sheet.

### ***Novartis Note***

In May of 2005, we executed a secured note agreement with Chiron Corporation (now Novartis). Under the note agreement, Novartis agreed to make semi-annual loans to us to fund up to 75% of our research and development and commercialization costs under the collaboration arrangement, not to exceed \$50.0 million in aggregate principal amount. Any unpaid principal amount together with accrued and unpaid interest shall be due and payable in full on June 21, 2015, the tenth anniversary date of the advance date on which the first loan was made. Interest on the unpaid balance of the principal amount of each loan shall accrue at a floating rate per annum which was equal to 5.18% at September 30 2008, and is payable semi-annually in June and December of each year. Additionally, the interest rate resets in June and December of each year. At our election, the semi-annual interest payments can be added to the outstanding principal amount, in lieu of a cash payment, as long as the aggregate principal amount does not exceed \$50.0 million and we have made this election for each interest payment. Loans under the note agreement are secured by our interest in the collaboration with Novartis, including any payments owed to us thereunder. At September 30, 2008, the outstanding principal balance under this note agreement totaled \$21.3 million. Pursuant to a restructured collaboration agreement with Novartis, the outstanding principal balance under this note agreement has been reduced and no additional draw downs may be made by XOMA. See Subsequent Events Novartis for a description of the restructured agreement.

### ***Equity Line of Credit***

On October 21, 2008, we entered into a common share purchase agreement (the Purchase Agreement) with Azimuth Opportunity, Ltd. (Azimuth), pursuant to which we obtained a committed equity line of credit facility (the Facility) under which we may sell up to \$60 million of our registered common shares to Azimuth over a 24-month period, subject to certain conditions and limitations. We are not obligated to utilize any of the \$60 million facility and remain free to enter other financing transactions. Pursuant to the terms of the Purchase Agreement, we determine, in our sole discretion, the timing, dollar amount and floor price per share of each draw down under the Facility, subject to certain conditions and limitations. The number and price of shares sold in each draw down are determined by a contractual formula designed to approximate fair market value, less a discount. The Purchase Agreement also provides that from time to time and in our sole discretion, we may grant Azimuth the right to exercise one or more options to purchase additional common shares during each draw down pricing period for the amount of shares based upon the maximum option dollar amount and the option threshold price specified by us. Shares under the Facility are sold pursuant to a prospectus which forms a part of a registration statement declared effective by the Securities and Exchange Commission on May 29, 2008. From the inception of the Facility through November 7, 2008, we have sold 3,909,906 common shares under the Facility for aggregate gross proceeds of \$4,500,000.

During the fourth quarter of 2008, we expect to continue using our cash, cash equivalents and short-term investments to fund ongoing operations and capital investments. Additional licensing, antibody discovery collaboration agreements and financing arrangements may positively impact our cash balances. Based on anticipated spending levels, revenues, collaborator funding, our equity line of credit with Azimuth and other sources of funding we believe to be available, we estimate that we have sufficient cash resources to meet our anticipated net cash needs through at least the next twelve months. Any significant revenue shortfalls, increases in planned spending on development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. Progress or setbacks by potentially competing products may also affect our ability to raise new funding on acceptable terms. For a further discussion of the risks related to our business and their effects on our cash flow and ability to raise new funding on acceptable terms, see Risk Factors included in Item 1A.

### **Critical Accounting Policies**

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition and recognition of research and development expenses to be critical policies. There have been no significant changes in our critical accounting policies during the nine months ended September 30, 2008, except as noted below, as compared with those previously disclosed in our 2007 Form 10-K.

In September of 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standard (SFAS) 157 Fair Value Measurements (SFAS 157). SFAS 157 establishes a common definition for fair value, creates a framework for measuring fair value, and expands disclosure requirements about such fair value measurements. Effective January 1, 2008, we adopted SFAS 157 for financial assets and liabilities recognized at fair value on a recurring basis. The adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our consolidated financial position, results of operations or cash flows. See Footnote 2 to the Consolidated Financial Statements, Fair Value for information and related disclosures regarding our fair value measurements.



---

**Table of Contents**

In February 2007, the FASB issued SFAS No. 159 The Fair Value Option for Financial Assets and Financial Liabilities ( SFAS 159 ). Under SFAS 159, a company may choose, at specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. SFAS 159 became effective beginning with our first quarter of 2008. We currently do not have any instruments eligible for election of the fair value option and as such have not elected to adopt the fair value option of SFAS 159 at this time.

In June of 2007, the Emerging Issues Task Force issued EITF Issue 07-03, Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development ( EITF 07-03 ). EITF 07-03 addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 was effective for fiscal years beginning after December 15, 2007 and interim periods within those years. The adoption of EITF 07-03 did not have a material impact on our statements of financial position, results of operations or cash flows.

**Subsequent Events**

***SPRI/ AVEO***

In October of 2008, we entered into a letter agreement with SPRI related to the Process Development and Manufacturing Agreement effective September 27, 2006, originally entered into with AVEO Pharmaceuticals, Inc. and subsequently assigned to SPRI. Under the letter agreement, we will provide future process development and technology transfer materials and services for approximately \$3.4 million.

***RAPTIVA®***

On October 2, 2008, Genentech announced that it was sending a Dear Healthcare Provider letter to advise potential prescribers that RAPTIVA® may have had a contributory role in the development of progressive multifocal leukoencephalopathy ( PML ) in a 70-year old patient. On October 16, 2008, the FDA announced that it had approved labeling changes, including a so-called Boxed Warning, to highlight the risk of life-threatening infections, including PML, with the use of RAPTIVA®.

***NEUPREX®***

In October of 2009, the Board approved a resolution to cease all development of NEUPREX®, including any further investments or expenses in NEUPREX® and any efforts to find a research, development, commercial, marketing or other partner, buyer or licensee. We anticipate that the financial implications of this resolution will be immaterial.

***Lexicon***

Effective as of November 7, 2008, we terminated our Collaboration and License Agreement dated as of June 20, 2005 with Lexicon Pharmaceuticals, Inc. We anticipate that the financial implications of this termination will be immaterial.

***Novartis***

On November 10, 2008, we announced the restructuring of our product development collaboration with Novartis, which involves six development programs including the ongoing HCD 122 program. Under the restructured agreement, Novartis will pay XOMA \$6.2 million, fully fund all future R&D expenses, reduce existing debt by \$7.5 million, pay potential milestones of up to \$14 million and double-digit royalties for two ongoing product programs (including HCD 122) and provide XOMA with options to develop or receive royalties on four additional programs currently pending selection. In exchange, Novartis will have control over the HCD 122 program and the additional ongoing program, as well as the right to expand the development of these programs into additional indications outside of oncology. As part of the agreement, Novartis will pay XOMA for all project costs incurred after July 1, 2008.

**Table of Contents****Forward-Looking Information and Cautionary Factors That May Affect Future Results**

Certain statements contained herein related to the sufficiency of our cash resources, levels of future revenues, losses, expenses and cash, future sales of approved products, as well as other statements related to current plans for product development and existing and potential collaborative and licensing relationships, 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 period for which our cash resources are sufficient could be shortened if expenditures are made earlier or in larger amounts than anticipated or are unanticipated, if anticipated revenues or cost sharing arrangements do not materialize, if funds are not otherwise available on acceptable terms; revenue levels may be other than as expected if sales of approved products are lower than expected; losses may be other than as expected for any of the reasons affecting revenues and expenses; expense levels and cash utilization may be other than as expected due to unanticipated changes in our research and development programs; and the sales efforts for approved products may not be successful if the parties responsible for marketing and sales fail to meet their commercialization goals, due to the strength of the competition, if physicians do not adopt the product as treatment for their patients or if remaining regulatory approvals are not obtained. These and other risks, including those related to the results of pre-clinical studies; 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 United States Food and Drug Administration ( 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; our ability to meet the demand of the United States government agency with which we have entered our first government contract; competition; market demands for products; scale-up and marketing capabilities; availability of additional licensing or collaboration opportunities; international operations; share price volatility; our financing needs and opportunities; uncertainties regarding the status of biotechnology patents; uncertainties as to the costs of protecting intellectual property; and risks associated with our status as a Bermuda company, are described in more detail in Item 1A Risk Factors .

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*****Interest Rate Risk***

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio and our loan facilities. By policy, we make our investments in high quality debt securities, limit the amount of credit exposure to any one issuer and limit duration by restricting the term of the instrument. We generally hold investments to maturity, with a weighted average portfolio period of less than 12 months. We do not invest in derivative financial instruments.

In November of 2006, we entered into a five-year senior term loan facility in the aggregate amount of \$35.0 million with the principal due at maturity. In May of 2008, this facility was replaced with a new loan facility. As of September 30, 2008, \$55.0 million was outstanding under the new facility. Interest on the new facility will be at a rate of the greater of (x) USD six-month LIBOR or (y) 3.0%, plus 8.5%, which was 11.5% at September 30, 2008. The interest rate was reset to 12.3% on October 1, 2008.

As of September 30, 2008, we had drawn down \$21.3 million against the Novartis \$50.0 million loan facility that is due in 2015 at an interest rate of USD six month LIBOR plus 2%, which was 5.18% at September 30, 2008. No further draws are available under this facility.

The variable interest rates related to our long-term debt instruments are based on LIBOR. We estimate that a hypothetical 100 basis point change in interest rates could increase or decrease our interest expense by approximately \$773,000 on an annualized basis.

**Table of Contents**

We hold interest-bearing instruments that are classified as cash, cash equivalents, and short-term investments. Fluctuations in interest rates can affect the principal values and yields of fixed income investments. If interest rates in the general economy were to rise rapidly in a short period of time, our fixed income investments could lose value. The following table presents the amounts and related weighted interest rates of our cash and investments at September 30, 2008 and December 31, 2007 (in thousands, except interest rate):

	<b>Maturity</b>	<b>Carrying Amount (in thousands)</b>	<b>Fair Value (in thousands)</b>	<b>Average Interest Rate</b>
<b>September 30, 2008</b>				
Cash and cash equivalents	Daily to 90 days	\$ 6,187	\$ 6,186	3.02%
Short-term investments	Less than 12 months	4,462	4,381	4.69%
<b>December 31, 2007</b>				
Cash and cash equivalents	Daily to 90 days	\$ 22,504	\$ 22,500	5.01%
Short-term investments	91 days to less than 18 months	16,072	16,067	5.19%

Due to the adverse developments in the credit markets in 2008, we may experience reduced liquidity with respect to some of our investments. Our investments are generally held to maturity, with a weighted average portfolio period of less than 12 months. However, if the need arose to liquidate such securities before maturity, we may experience losses on liquidation.

We have the ability and intent to hold our debt securities to maturity when they will be redeemed at full par value. Accordingly, we consider any unrealized losses to be temporary and have not recorded an impairment charge during the nine months ended September 30, 2008.

**ITEM 4. CONTROLS AND PROCEDURES***Evaluation of Controls and Procedures*

Under the supervision and with the participation of our management, including our Chairman, Chief Executive Officer and President and our Chief Accounting Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based on this evaluation, our Chairman, Chief Executive Officer and President and our Chief Accounting Officer concluded that our disclosure controls and procedures are effective as of the end of the period covered by this report in timely alerting them to material information relating to us and our consolidated subsidiaries required to be included in our periodic SEC filings.

*Changes in Internal Control*

There have been no changes in our internal controls over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**PART II OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

There were no developments material to XOMA in the United States Bankruptcy Court proceedings involving Apton Corporation (described in XOMA's Annual Report on Form 10-K for the fiscal year ended December 31, 2007) during the nine months ended September 30, 2008.



---

**Table of Contents**

**ITEM 1a. RISK FACTORS**

The following risk factors and other information included in this quarterly report should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us also may impair our business operations. If any of the following risks occur, our business, financial condition, operating results and cash flows could be materially adversely affected.

**Because our product candidates are still being developed, we will require substantial funds to continue; we cannot be certain that funds will be available and, if they are not available, we may have to take actions that could adversely affect your investment and may not be able to continue as a going concern.**

If adequate funds are not available, we may have to raise additional funds in a manner that may dilute or otherwise adversely affect the rights of existing shareholders, curtail or cease operations, or file for bankruptcy protection in extreme circumstances. We have spent, and we expect to continue to spend, substantial funds in connection with:

research and development relating to our product candidates and production technologies,

expansion of our production capabilities,

various human clinical trials, and

protection of our intellectual property.

Based on current spending levels, anticipated revenues, collaborator funding, our equity line of credit with Azimuth Opportunity, Ltd. ( Azimuth ), signed October 21, 2008, and other sources of funding we believe to be available, we estimate that we have sufficient cash resources to meet our anticipated net cash needs through at least the next twelve months. Any significant revenue shortfalls, increases in planned spending on development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. In the event we are not able to maintain at least twelve months of cash resources, there may be substantial doubt as to our ability to continue as a going concern. Progress or setbacks by potentially competing products may also affect our ability to raise new funding on acceptable terms. As a result, we do not know when or whether:

operations will generate meaningful funds,

additional agreements for product development funding can be reached,

strategic alliances can be negotiated, or

adequate additional financing will be available for us to finance our own development on acceptable terms, or at all.

Cash balances and operating cash flow are influenced primarily by the timing and level of payments by our licensees and development partners, as well as by our operating costs.

**Capital market conditions may reduce our ability to access capital and cash.**

Traditionally, we have funded a large portion of our research and development expenditures through raising capital in the equity markets. Recent events, including failures and bankruptcies among large commercial and investment banks, have led to considerable declines and uncertainties in these and other capital markets and may lead to new regulatory and other restrictions that may broadly affect the nature of these markets. These

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

circumstances could severely restrict the raising of new capital by companies such as us in the future.

Recent volatility in the financial markets has also created liquidity problems in investments previously thought to bear a minimal risk. For example, money market fund investors, including us, have recently been unable to retrieve the full amount of funds, even in highly-rated liquid money market accounts, upon maturity. An inability to retrieve funds from money market and similar short-term investments as they mature could have a material and adverse impact on our business, results of operations and cash flows.

---

**Table of Contents**

**Our level of leverage and debt service obligations could adversely affect our financial condition.**

As of September 30, 2008, we had approximately \$76.3 million of indebtedness outstanding. We may not be able to generate cash sufficient to pay the principal of, interest on and other amounts due in respect of our indebtedness when due. We may also incur additional debt that may be secured. In connection with our collaboration with Novartis, Novartis extended a loan to us (through our U.S. subsidiary) to fund up to 75% of our expenses thereunder, of which \$21.3 million was outstanding as of September 30, 2008. This loan is secured by a pledge of our interest in the collaboration. In November of 2006, XOMA (US) LLC entered into a five-year, \$35.0 million term loan facility with Goldman Sachs and borrowed the full amount thereunder. In May 2008, this term loan facility was replaced with a new term loan facility. The outstanding balance of the new facility as of September 30, 2008 was \$55.0 million. The new loan is guaranteed by XOMA and secured by the payment rights relating to RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup>. So long as this loan is outstanding, these assets will not be available to XOMA or any other lender to secure future indebtedness.

Our level of debt and debt service obligations could have important effects on us and our investors. These effects may include:

making it more difficult for us to satisfy our obligations with respect to our obligations to other persons with respect to our other debt;

limiting our ability to obtain additional financing or renew existing financing at maturity on satisfactory terms to fund our working capital requirements, capital expenditures, acquisitions, investments, debt service requirements and other general corporate requirements;

increasing our vulnerability to general economic downturns, competition and industry conditions, which could place us at a competitive disadvantage compared with our competitors that are less leveraged;

increasing our exposure to rising interest rates to the extent any of our borrowings are at variable interest rates;

reducing the availability of our cash flow to fund our working capital requirements, capital expenditures, acquisitions, investments and other general corporate requirements because we will be required to use a substantial portion of our cash flow to service debt obligations; and

limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

Our ability to satisfy our debt obligations will depend upon our future operating performance and the availability of refinancing debt. If we are unable to service our debt and fund our business, we may be forced to reduce or delay capital expenditures, seek additional debt financing or equity capital, restructure or refinance our debt or sell assets. We cannot assure you that we would be able to obtain additional financing, refinance existing debt or sell assets on satisfactory terms or at all. In particular, although we may prepay our debt to Goldman Sachs at any time, in order to do so we would be required to pay certain specified prepayment premiums if prepaid within the first four years which we may not have sufficient funds to pay or which may be prohibitively high under the circumstances at the time we would otherwise choose to repay such debt.

**If the trading price of our common shares fails to comply with the continued listing requirements of The Nasdaq Global Market, we would face possible delisting, which would result in a limited public market for our common shares and make obtaining future debt or equity financing more difficult for us.**

If we do not continue to comply with the continued listing requirements for The Nasdaq Global Market, then Nasdaq may provide written notification regarding the delisting of our securities. At that time, we would have the right to request a hearing to appeal the Nasdaq determination and would also have the option to apply to transfer our securities to The Nasdaq Capital Market.

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

We cannot be sure that our price will comply with the requirements for continued listing of our common shares on The Nasdaq Global Market, or that any appeal of a decision to delist our common shares will be successful. If our common shares lose their status on The Nasdaq Global Market and we are not successful in obtaining a listing on The Nasdaq Capital Market, our common shares would likely trade in the over-the-counter market.

If our shares were to trade on the over-the-counter market, selling our common shares could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and security analysts' coverage of us may be reduced. In addition, in the event our common shares are delisted, broker-dealers have certain regulatory burdens imposed upon them, which may discourage broker-dealers from effecting transactions in our common shares, further limiting the liquidity thereof. These factors could result in lower prices and larger spreads in the bid and ask prices for common shares.

---

## **Table of Contents**

Such delisting from The Nasdaq Global Market or future declines in our share price could also greatly impair our ability to raise additional necessary capital through equity or debt financing, and could significantly increase the ownership dilution to shareholders caused by our issuing equity in financing or other transactions. Consent under the Exchange Control Act 1972 (and its related regulations) has been obtained from the Bermuda Monetary Authority for the issue and transfer of our shares, notes and other securities to and between non-residents of Bermuda for exchange control purposes, but this consent is conditional on our shares remaining listed on an appointed stock exchange. We cannot assure you that the Bermuda Monetary Authority will give the same or a similar consent in the event our common shares are no longer listed on The Nasdaq Global Market or another appointed stock exchange. In the absence of such a general consent, specific consents of the Bermuda Monetary Authority would be required for certain issues and transfers of our shares, notes and other securities.

### **Because all of our product candidates are still being developed, we have sustained losses in the past and we expect to sustain losses in the future.**

We have experienced significant losses and, as of September 30, 2008, we had an accumulated deficit of \$795.1 million.

For the three and nine months ended September 30, 2008, we had a net loss of approximately \$20.4 million and \$55.2 million, respectively, or \$0.15 and \$0.42 per common share (basic and diluted), respectively. For the year ended December 31, 2007, we had a net loss of approximately \$12.3 million or \$0.10 per common share (basic and diluted).

Our ability to achieve profitability is dependent in large part on the success of our development programs, obtaining regulatory approval for our product candidates and entering into new agreements for product development, manufacturing and commercialization, all of which are uncertain. Our ability to fund our ongoing operations is dependent on the foregoing factors and on our ability to secure additional funds. Because our product candidates are still being developed, we do not know whether we will ever achieve sustained profitability or whether cash flow from future operations will be sufficient to meet our needs.

### **We may issue additional equity securities and thereby materially and adversely affect the price of our common shares.**

We are authorized to issue, without shareholder approval, 1,000,000 preference shares, of which 2,959 were issued and outstanding as of September 30, 2008, which may give other shareholders dividend, conversion, voting, and liquidation rights, among other rights, which may be superior to the rights of holders of our common shares. In addition, we are authorized to issue, generally without shareholder approval, up to 210,000,000 common shares, of which 132,429,517 were issued and outstanding as of September 30, 2008. If we issue additional equity securities, the price of our common shares may be materially and adversely affected. On October 21, 2008, we entered into a common share purchase agreement with Azimuth Opportunity, Ltd. ( Azimuth ), pursuant to which we obtained a committed equity line of credit facility under which we may sell up to \$60 million of our registered common shares to Azimuth over a 24-month period, subject to certain conditions and limitations. To date, we have sold 3,909,906 common shares under this facility for aggregate gross proceeds of \$4,500,000.

### **The financial terms of future collaborative or licensing arrangements could result in dilution of our share value.**

Funding from collaboration partners and others has in the past and may in the future involve issuance by us of our shares. Because we do not currently have any such arrangements, we cannot be certain how the purchase price of such shares, the relevant market price or premium, if any, will be determined or when such determinations will be made. Any such issuance could result in dilution in the value of our issued and outstanding shares.

### **Our share price may be volatile and there may not be an active trading market for our common shares.**

There can be no assurance that the market price of our common shares will not decline below its present market price or that there will be an active trading market for our common shares. The market prices of biotechnology companies have been and are likely to continue to be highly volatile. Fluctuations in our operating results and general market conditions for biotechnology stocks could have a significant impact on the volatility of our common share price. We have experienced significant volatility in the price of our common shares. From January 1, 2008 through November 5, 2008, our share price has ranged from a high of \$3.43 to a low of \$0.96. On November 5, 2008, the closing price of the common shares as reported on the Nasdaq Global Market was \$1.12 per share. Factors contributing to such volatility include, but are not limited to:

sales and estimated or forecasted sales of products for which we receive royalties,



**Table of Contents**

results of preclinical studies and clinical trials,

information relating to the safety or efficacy of products or product candidates,

developments regarding regulatory filings,

announcements of new collaborations,

failure to enter into collaborations,

developments in existing collaborations,

our funding requirements and the terms of our financing arrangements,

technological innovations or new indications for our therapeutic products and product candidates,

introduction of new products or technologies by us or our competitors,

government regulations,

developments in patent or other proprietary rights,

the number of shares issued and outstanding,

the number of shares trading on an average trading day,

announcements regarding other participants in the biotechnology and pharmaceutical industries, and

market speculation regarding any of the foregoing.

**Our therapeutic product candidates have not received regulatory approval. If these product candidates do not receive regulatory approval, neither our third party collaborators nor we will be able to manufacture and market them.**

Our product candidates cannot be manufactured and marketed in the United States and other countries without required regulatory approvals. The United States government and governments of other countries extensively regulate many aspects of our product candidates, including:

testing,

manufacturing,

promotion and marketing, and

exporting.

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. At the present time, we believe that most of our product candidates will be regulated by the FDA as biologics. Initiation of clinical trials requires approval by health authorities. Clinical trials involve the administration of the investigational new drug to healthy volunteers or to patients under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with FDA and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ( ICH ) Good Clinical Practices and the European Clinical Trials Directive under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Other national, foreign and local regulations may also apply. The developer of the drug must provide information relating to the characterization and controls of the product before administration to the patients participating in the clinical trials. This requires developing approved assays of the product to test before administration to the patient and during the conduct of the trial. In addition, developers of pharmaceutical products must provide periodic data regarding clinical trials to the FDA and other health authorities, and these health authorities may issue a clinical hold upon a trial if they do not believe, or cannot confirm, that the trial can be conducted without unreasonable risk to the trial participants. We cannot assure you that U.S. and foreign health authorities will not issue a clinical hold with respect to any of our clinical trials in the future.



---

## **Table of Contents**

The results of the preclinical studies and clinical testing, together with chemistry, manufacturing and controls information, are submitted to the FDA and other health authorities in the form of a new drug application for a pharmaceutical product, and in the form of a biologics license application for a biological product, requesting approval to commence commercial sales. In responding to a new drug application or an antibody license application, the FDA or foreign health authorities may grant marketing approvals, request additional information or further research, or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Regulatory approval of a new drug application, biologics license application, or supplement is never guaranteed, and the approval process can take several years and is extremely expensive. The FDA and foreign health authorities have substantial discretion in the drug and biologics approval processes. Despite the time and expense incurred, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical, clinical or manufacturing-related studies.

Changes in the regulatory approval policy during the development period, changes in, or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. Even if the FDA or other regulatory agency approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product. Even for approved products such as RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup>, the FDA may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials, and may subsequently withdraw approval based on these additional trials. The FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. State regulations may also affect our proposed products. The FDA has substantial discretion in both the product approval process and manufacturing facility approval process and, as a result of this discretion and uncertainties about outcomes of testing, we cannot predict at what point, or whether, the FDA will be satisfied with our or our collaborators' submissions or whether the FDA will raise questions which may be material and delay or preclude product approval or manufacturing facility approval. As we accumulate additional clinical data, we will submit it to the FDA, which may have a material impact on the FDA product approval process.

### **We face uncertain results of clinical trials of our potential products.**

Our potential products, including XOMA 052 and XOMA 629, will require significant additional research and development, extensive preclinical studies and clinical trials and regulatory approval prior to any commercial sales. This process is lengthy and expensive, often taking a number of years. As clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly. As a result, it is uncertain whether:

our future filings will be delayed,

our preclinical and clinical studies will be successful,

we will be successful in generating viable product candidates to targets,

we will be able to provide necessary additional data,

results of future clinical trials will justify further development, or

we will ultimately achieve regulatory approval for any of these product candidates.

For example, in 2003, we completed two Phase 1 trials of XOMA 629, a BPI-derived topical peptide compound targeting acne, evaluating the safety, skin irritation and pharmacokinetics. In January of 2004, we announced the initiation of Phase 2 clinical testing in patients with mild-to-moderate acne. In August of 2004, we announced the results of a Phase 2 trial with XOMA 629 gel. The results were inconclusive in terms of clinical benefit of XOMA 629 compared with vehicle gel. In 2007, after completing an internal evaluation of this program, we chose to reformulate and focus development efforts on the use of this reformulated product candidate in superficial skin infections, including impetigo and the eradication of staphylococcus aureus, including MRSA.

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

The timing of the commencement, continuation and completion of clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the

---

## **Table of Contents**

existence of competing clinical trials and the availability of alternative or new treatments. In addition, we will conduct clinical trials in foreign countries in the future which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign clinical research organizations, as well as expose us to risks associated with foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in the foreign currency where the trial is being conducted.

All of our product candidates are prone to the risks of failure inherent in drug development. Preclinical studies may not yield results that would satisfactorily support the filing of an IND (or a foreign equivalent) with respect to our product candidates. Even if these applications would be or have been filed with respect to our product candidates, the results of preclinical studies do not necessarily predict the results of clinical trials. Similarly, early-stage clinical trials in healthy volunteers do not predict the results of later-stage clinical trials, including the safety and efficacy profiles of any particular product candidates. In addition, there can be no assurance that the design of our clinical trials is focused on appropriate indications, patient populations, dosing regimens or other variables which will result in obtaining the desired efficacy data to support regulatory approval to commercialize the drug. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, FDA officials or officials from foreign regulatory authorities could interpret the data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval.

Administering any of our products or potential products may produce undesirable side effects, also known as adverse effects. Toxicities and adverse effects that we have observed in pre-clinical studies for some compounds in a particular research and development program may occur in preclinical studies or clinical trials of other compounds from the same program. Such toxicities or adverse effects could delay or prevent the filing of an IND (or a foreign equivalent) with respect to such products or potential products or cause us to cease clinical trials with respect to any drug candidate. In clinical trials, administering any of our products or product candidates to humans may produce adverse effects. These adverse effects could interrupt, delay or halt clinical trials of our products and product candidates and could result in the FDA or other regulatory authorities denying approval of our products or product candidates for any or all targeted indications. The FDA, other regulatory authorities, our partners or we may suspend or terminate clinical trials at any time. Even if one or more of our product candidates were approved for sale, the occurrence of even a limited number of toxicities or adverse effects when used in large populations may cause the FDA to impose restrictions on, or stop, the further marketing of such drugs. Indications of potential adverse effects or toxicities which may occur in clinical trials and which we believe are not significant during the course of such clinical trials may later turn out to actually constitute serious adverse effects or toxicities when a drug has been used in large populations or for extended periods of time. Any failure or significant delay in completing preclinical studies or clinical trials for our product candidates, or in receiving and maintaining regulatory approval for the sale of any drugs resulting from our product candidates, may severely harm our reputation and business.

Given that regulatory review is an interactive and continuous process, we maintain a policy of limiting announcements and comments upon the specific details of regulatory review of our product candidates, subject to our obligations under the securities laws, until definitive action is taken.

### **Certain of our technologies are relatively new and are in-licensed from third parties, so our capabilities using them are unproven and subject to additional risks.**

We license technologies from third parties. These technologies include but are not limited to phage display technologies licensed to us in connection with our BCE technology licensing program. However, our experience with some of these technologies remains relatively limited and, to varying degrees, we are still dependent on the licensing parties for training and technical support for these technologies. In addition, our use of these technologies is limited by certain contractual provisions in the licenses relating to them and, although we have obtained numerous licenses, intellectual property rights in the area of phage display are particularly complex. If the owners of the patent rights underlying the technologies we license do not properly maintain or enforce those patents, our competitive position and business prospects could be harmed. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce our licensed intellectual property. Our licensors may not successfully prosecute the patent applications to which we have licenses, or our licensors may fail to maintain existing patents. They may determine not to pursue litigation against other companies that are infringing these patents, or they may pursue such litigation less aggressively than we would. Our licensors may also seek to terminate our license, which could cause us to lose the right to use the licensed intellectual property and adversely affect our ability to commercialize our technologies, products or services.

### **Manufacturing risks and inefficiencies may adversely affect our ability to manufacture products for ourselves or others.**

We are subject to manufacturing risks which may hinder our ability to provide manufacturing services for our own benefit or to third parties. Additionally, unanticipated fluctuations in customer requirements may lead to manufacturing inefficiencies. We must provide our manufacturing services in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining acceptable product quality and manufacturing costs. Additional resources and changes in our manufacturing processes may be required for each new product or customer or to meet increasing customer requirements once a contract has been initiated, and this work may not be successfully or efficiently completed.



---

## **Table of Contents**

In addition, the development work and products addressed in new contracts may not share production attributes with our existing projects to the extent we anticipate, and consequently these new contracts may require the development of new manufacturing technologies and expertise. If we are unable to develop manufacturing capabilities as needed, on acceptable terms, our ability to complete these contracts or enter into additional contracts may be adversely affected.

Manufacturing and quality problems may arise in the future as we continue to perform these services for our own benefit and under additional manufacturing contracts. Consequently, our internal development goals or milestones under our contracts may not be achieved in a timely manner or at a commercially reasonable cost, or at all. In addition, we continue to make investments to improve our manufacturing processes and to design, develop and purchase manufacturing equipment that may not yield the improvements that we expect. Inefficiencies or constraints related to our manufacturing may adversely affect our overall financial results. Such inefficiencies or constraints may also result in delays or loss of current or potential customers due to their dissatisfaction.

### **Our present and future revenues rely significantly on sales of products marketed and sold by others.**

Currently, our revenues rely significantly upon sales of RAPTIVA<sup>®</sup> and LUCENTIS<sup>®</sup>, in which we have only royalty interests. RAPTIVA<sup>®</sup> was approved by the FDA on October 27, 2003, for the treatment of chronic moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Genentech and Merck Serono, Genentech's international marketing partner for RAPTIVA<sup>®</sup>, are responsible for the marketing and sales effort in support of this product. In September of 2004, Merck Serono announced that RAPTIVA<sup>®</sup> had received approval for use in the European Union and the product was launched in several European Union countries in the fourth quarter of 2004. LUCENTIS<sup>®</sup> was approved by the FDA on June 30, 2006, for the treatment of age-related macular degeneration. Genentech and Novartis, Genentech's international marketing partner for LUCENTIS<sup>®</sup>, are responsible for the marketing and sales effort in support of this product. We also receive revenues from sales of CIMZIA, in which we only have a royalty interest, and royalties received therefrom through September 30, 2008 have been immaterial. CIMZIA<sup>®</sup> was approved by the FDA on April 22, 2008 for the treatment of moderate to severe Crohn's disease in adults who have not responded to conventional therapies. In March of 2008, UCB announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had rejected UCB's appeal following CHMP's previously-announced refusal of UCB's marketing authorization application for CIMZIA in the treatment of Crohn's disease. UCB is responsible for the marketing and sales effort in support of this product. We have no role in marketing and sales efforts, and Genentech, Merck Serono, Novartis and UCB do not have an express contractual obligation to us regarding the marketing or sales of RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> or CIMZIA<sup>®</sup>.

Under our current arrangements with Genentech, we are entitled to receive royalties on worldwide sales of RAPTIVA<sup>®</sup> and LUCENTIS<sup>®</sup>. Under our current arrangements with UCB, we are entitled to receive royalties on U.S. sales of CIMZIA<sup>®</sup>. Successful commercialization of these products is subject to a number of risks, including, but not limited to:

Genentech's, Merck Serono's, Novartis' and UCB's willingness and ability to implement their marketing and sales effort and achieve sales;

the strength of competition from other products being marketed or developed to treat psoriasis, age-related macular degeneration and Crohn's disease;

the occurrence of adverse events which may give rise to safety concerns;

physicians' and patients' acceptance of RAPTIVA<sup>®</sup> as a treatment for psoriasis, LUCENTIS<sup>®</sup> as a treatment for age-related macular degeneration and CIMZIA<sup>®</sup> as a treatment for Crohn's disease;

manufacturer's ability to provide manufacturing capacity to meet demand for the products; and

pricing and reimbursement issues.

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

For example, on October 2, 2008, Genentech announced that it was sending a Dear Healthcare Provider letter to advise potential prescribers that RAPTIVA® may have had a contributory role in the development of progressive multifocal leukoencephalopathy, or PML, in a 70-year old patient. On October 16, 2008, the FDA announced that it had approved labeling changes, including a so-called Boxed Warning, to highlight the risk of life-threatening infections, including PML, with the use of RAPTIVA®. We do not know what, if any, impact this will have on future royalties from sales of RAPTIVA®.

In addition, the terms of our debt with Goldman Sachs include a financial covenant that requires us to maintain a specified ratio of royalties collected to interest payable, which means our ability to comply with this covenant is dependent on the sales by Genentech, UCB and their partners for these products and may be adversely impacted by decreases in royalty revenues.

---

## **Table of Contents**

According to Genentech, United States sales of RAPTIVA® for the first nine months of 2008 were \$82 million, compared with \$80 million for the first nine months of 2007. According to Merck Serono, sales of RAPTIVA® outside of the U.S. for the first nine months of 2008 were \$101 million, compared with \$78 million for the first nine months of 2007. According to Genentech, U.S. sales of LUCENTIS® were \$639 million for the first nine months of 2008 compared with \$618 million for the first nine months of 2007. According to Novartis, sales of LUCENTIS® outside the United States for the first nine months of 2008 were \$658 million compared with \$223 million for the first nine months of 2007.

Given our current reliance on RAPTIVA® and LUCENTIS® as principal sources of revenues, any material adverse developments with respect to the commercialization of RAPTIVA® or LUCENTIS® may cause our revenues to decrease and may cause us to incur losses in the future.

**We do not know whether there will be, or will continue to be, a viable market for the products in which we have an ownership or royalty interest.**

Although RAPTIVA® was approved in the United States in October of 2003 and in the European Union in 2004 and LUCENTIS® was approved in June of 2006 and in the European Union in January of 2007, their acceptance in the marketplace may not continue. Although CIMZIA® was approved in the United States in April of 2008, it may not be accepted in the marketplace. Furthermore, even if other products in which we have an interest receive approval in the future, they may not be accepted in the marketplace. In addition, we or our collaborators or licensees may experience difficulties in launching new products, many of which are novel and based on technologies that are unfamiliar to the healthcare community. We have no assurance that healthcare providers and patients will accept such products, if developed. For example, physicians and/or patients may not accept a product for a particular indication because it has been biologically derived (and not discovered and developed by more traditional means) or if no biologically derived products are currently in widespread use in that indication. Similarly, physicians may not accept a product, such as RAPTIVA®, LUCENTIS®, or CIMZIA®, if they believe other products to be more effective or are more comfortable prescribing other products. Safety concerns may also arise in the course of on-going clinical trials or patient treatment as a result of adverse events or reactions. For example, on October 2, 2008, Genentech announced that it was sending a Dear Healthcare Provider letter to advise potential prescribers that RAPTIVA® may have had a contributory role in the development of progressive multifocal leukoencephalopathy, or PML, in a 70-year old patient, who had received RAPTIVA® for more than four years for treatment of chronic plaque psoriasis. On October 16, 2008, the FDA announced that it had approved labeling changes, including a so-called Boxed Warning, to highlight the risk of life-threatening infections, including PML, with the use of RAPTIVA®.

Furthermore, government agencies, as well as private organizations involved in healthcare, from time to time publish guidelines or recommendations to healthcare providers and patients. Such guidelines or recommendations can be very influential and may adversely affect the usage of any products we may develop directly (for example, by recommending a decreased dosage of a product in conjunction with a concomitant therapy or a government entity withdrawing its recommendation to screen blood donations for certain viruses) or indirectly (for example, by recommending a competitive product over our product). Consequently, we do not know if physicians or patients will adopt or use our products for their approved indications.

**We or our third party collaborators or licensees may not have adequate manufacturing capacity sufficient to meet market demand.**

Genentech is responsible for manufacturing or arranging for the manufacturing of commercial quantities of RAPTIVA® and LUCENTIS®. Should Genentech have difficulty in providing manufacturing capacity to produce these products in sufficient quantities, we do not know whether they will be able to meet market demand. If not, we will not realize revenues from the sales of these products. If any of our product candidates are approved, because we have never commercially introduced any pharmaceutical products, we do not know whether the capacity of our existing manufacturing facilities can be increased to produce sufficient quantities of our products to meet market demand. Also, if we or our third party collaborators or licensees need additional manufacturing facilities to meet market demand, we cannot predict that we will successfully obtain those facilities because we do not know whether they will be available on acceptable terms. In addition, any manufacturing facilities acquired or used to meet market demand must meet the FDA's quality assurance guidelines.

**Our agreements with third parties, many of which are significant to our business, expose us to numerous risks.**

Our financial resources and our marketing experience and expertise are limited. Consequently, our ability to successfully develop products depends, to a large extent, upon securing the financial resources and/or marketing capabilities of third parties.

In April of 1996, we entered into an agreement with Genentech whereby we agreed to co-develop Genentech's humanized monoclonal antibody product RAPTIVA®. In April of 1999, March of 2003, and January of 2005, the companies amended the agreement. In October of 2003, RAPTIVA® was approved by the FDA for the treatment of adults with chronic moderate-to-severe

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

plaque psoriasis who are candidates for systemic therapy or phototherapy and, in September of 2004, Merck Serono announced the product's approval in the European Union. In January of 2005, we entered into a restructuring of our collaboration agreement with Genentech which ended our existing cost and profit sharing arrangement related to RAPTIVA® in the United States and entitles us to a royalty interest on worldwide net sales.



---

**Table of Contents**

In March of 2004, we announced we had agreed to collaborate with Chiron Corporation (now Novartis) for the development and commercialization of antibody products for the treatment of cancer. In April of 2005, we announced the initiation of clinical testing of the first product candidate out of the collaboration, HCD122, an anti-CD40 antibody, in patients with advanced CLL. In October of 2005, we announced the initiation of the second clinical trial of HCD122 in patients with multiple myeloma. In November of 2008, we announced the restructuring of this product development collaboration, which involves six development programs including the ongoing HCD 122 program. In exchange for cash, contingent consideration and options for XOMA to develop or receive royalties on the four programs currently pending selection, Novartis will have control over the HCD 122 program and the additional ongoing program, as well as the right to expand the development of these programs into additional indications outside of oncology.

In March of 2005, we entered into a contract with NIAID to produce three monoclonal antibodies designed to protect United States citizens against the harmful effects of botulinum neurotoxin used in bioterrorism. In July of 2006, we entered into an additional contract with NIAID for the development of an appropriate formulation for human administration of these three antibodies in a single injection. In September of 2008, we announced that we were rewarded an additional contract with NIAID to support our on-going development of drug candidates toward clinical trials in the treatment of botulism poisoning.

We have licensed our BCE technology, an enabling technology used to discover and screen, as well as develop and manufacture, recombinant antibodies and other proteins for commercial purposes, to over 50 companies. As of September 30, 2008, we were aware of two antibody products manufactured using this technology that have received FDA approval, Genentech's LUCENTIS (ranibizumab injection) for treatment of neovascular (wet) age-related macular degeneration and UCB's CIMZIA (certolizumab pegol) for treatment of Crohn's disease.

Because our collaborators and licensees are independent third parties, they may be subject to different risks than we are and have significant discretion in determining the efforts and resources they will apply related to their agreements with us. If these collaborators and licensees do not successfully develop and market these products, we may not have the capabilities, resources or rights to do so on our own. We do not know whether our collaborators or licensees will successfully develop and market any of the products that are or may become the subject of one of our collaboration or licensing arrangements. In particular, each of these arrangements provides for either sharing of collaboration expenses, which means that not only we but our collaborators must have sufficient available funds for the collaborations to continue, or funding solely by our collaborators or licensees. Furthermore, our contracts with NIAID contain numerous standard terms and conditions provided for in the applicable federal acquisition regulations and customary in many government contracts. Uncertainty exists as to whether we will be able to comply with these terms and conditions in a timely manner, if at all. In addition, given our relative lack of experience in programs under contract with government agencies, we are uncertain as to the extent of NIAID's demands and the flexibility that will be granted to us in meeting those demands.

Even when we have a collaborative relationship, other circumstances may prevent it from resulting in successful development of marketable products.

In September of 2004, we entered into a collaboration with Apton for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In January of 2006, Apton announced that its common stock had been delisted from Nasdaq. In May of 2006, Apton filed for bankruptcy protection under Chapter 11, Title 11 of the United States Bankruptcy Code.

In September of 2005, we signed a letter agreement with Cubist to develop production processes and to manufacture a novel two-antibody biologic in quantities sufficient to conduct Phase 3 clinical trials. In July of 2006, Cubist announced that it had decided to cease investment in this product candidate because of stringent FDA requirements for regulatory approval, and as a result we have terminated our letter agreement with Cubist.

In September of 2006, we entered into an agreement with Taligen which formalized an earlier letter agreement, which was signed in May of 2006, for the development and Good Manufacturing Practices (cGMP) manufacture of a novel antibody fragment for the potential treatment of inflammatory diseases. In May of 2007, we and Taligen entered into a letter agreement (the letter agreement) which provides that we will not produce a cGMP batch at clinical scale pursuant to the terms of the agreement entered into in

September of 2006. In addition, the letter agreement provides

---

**Table of Contents**

that we will conduct and complete the technical transfer of the process to Avecia Biologics Limited or its designated affiliate ( Avecia ). The letter agreement also provides that, subject to payment by Taligen of approximately \$1.7 million, we will grant to Avecia a non-exclusive, worldwide, paid-up, non-transferable, non-sublicensable, perpetual license under our-owned project innovations. We have received \$0.6 million as the first installment under the payment terms of the letter agreement and are entitled to receive two additional payments totaling approximately \$1.1 million upon fulfillment of certain obligations. We have not received any further payments from Taligen and do not know whether we will receive the remaining \$1.1 million. This amount has not been recognized as revenue and is not included as an accounts receivable asset as of September 30, 2008.

Although we continue to evaluate additional strategic alliances and potential partnerships, we do not know whether or when any such alliances or partnerships will be entered into.

**Products and technologies of other companies may render some or all of our products and product candidates noncompetitive or obsolete.**

Developments by others may render our products, product candidates, or technologies obsolete or uncompetitive. Technologies developed and utilized by the biotechnology and pharmaceutical industries are continuously and substantially changing. Competition in the areas of genetically engineered DNA-based and antibody-based technologies is intense and expected to increase in the future as a number of established biotechnology firms and large chemical and pharmaceutical companies advance in these fields. Many of these competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

significantly greater financial resources,

larger research and development and marketing staffs,

larger production facilities,

entered into arrangements with, or acquired, biotechnology companies to enhance their capabilities, or

extensive experience in preclinical testing and human clinical trials.

These factors may enable others to develop products and processes competitive with or superior to our own or those of our collaborators. In addition, a significant amount of research in biotechnology is being carried out in universities and other non-profit research organizations. These entities are becoming increasingly interested in the commercial value of their work and may become more aggressive in seeking patent protection and licensing arrangements. Furthermore, many companies and universities tend not to announce or disclose important discoveries or development programs until their patent position is secure or, for other reasons, later; as a result, we may not be able to track development of competitive products, particularly at the early stages. Positive or negative developments in connection with a potentially competing product may have an adverse impact on our ability to raise additional funding on acceptable terms. For example, if another product is perceived to have a competitive advantage, or another product's failure is perceived to increase the likelihood that our product will fail, then investors may choose not to invest in us on terms we would accept or at all.

The examples below pertain to competitive events in the market which we review quarterly and are not intended to be representative of all existing competitive events. Without limiting the foregoing, we are aware that:

*XOMA 052*

XOMA has initiated clinical testing of XOMA 052, a potent anti-inflammatory monoclonal antibody targeting Interleukin 1-beta (IL-1beta), in Type 2 diabetes patients. It is possible that other companies may be developing other products based on the same therapeutic target as XOMA 052 and that these products may prove more effective than XOMA 052. We are aware that:

Amgen Inc.'s Kineret® (anakinra) is an interleukin-1 receptor antagonist (IL-1ra) currently marketed to treat rheumatoid arthritis ( RA ) and that has been evaluated over the years in multiple IL-1 mediated diseases, including Type 2 diabetes and other indications we are considering for XOMA 052.

Amgen has been developing AMG 108, a fully human monoclonal antibody that targets inhibition of the action of IL-1. On April 28, 2008, Amgen discussed results from its recently completed Phase 2 study in RA. AMG 108 showed statistically significant improvement in the signs and symptoms of RA and was well tolerated. Amgen announced it is focusing on other opportunities for the antibody.

**Table of Contents**

In February of 2008, Regeneron Pharmaceuticals, Inc. ( Regeneron ) announced it had received marketing approval from the FDA for ARCALYST™ (rilonacept) Injection for Subcutaneous Use, an interleukin-1 blocker or IL-1 Trap, for the treatment of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome in adults and children 12 and older. In September of 2007, Regeneron also announced that treatment with rilonacept demonstrated a statistically significant reduction in patient pain scores in a single-blind, placebo run-in-controlled study of 10 patients with chronic active gout. In November of 2007, Regeneron announced it had initiated a Phase 2 safety and efficacy trial of rilonacept in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease. In September of 2008, Regeneron announced that the recently completed Phase 2 study of rilonacept demonstrated a statistically significant reduction in gout flares versus the placebo.

Novartis has been developing ACZ885, a fully human anti-IL-1beta monoclonal antibody targeting interleukin-1 beta, and that they reported positive results in Phase 1 proof of concept clinical trials in rheumatoid arthritis and in Muckle-Wells Syndrome in June 2006. In July of 2007, they reported advancing ACZ885 into Phase 3 clinical trial for Muckle-Wells Syndrome and in December of 2007, they entered Phase 2 testing of ACZ885 in patients with Type 2 Diabetes Mellitus.

*XOMA 629*

There are several companies developing topical peptide treatments which may compete with XOMA 629. GlaxoSmithKline has two products approved for impetigo, mupirocin and retapamulin. Helix Biomedix, Inc. is developing several peptide compounds. In addition, mupirocin is approved for use in eradication of MRSA nasal colonization and for secondary traumatic skin lesions. Retapamulin is being investigated for eradication of *S. aureus* nasal colonization.

*RAPTIVA®*

In April of 2004, Amgen Inc. and its partner Wyeth Pharmaceuticals, a division of Wyeth, announced that their rheumatoid arthritis and psoriatic arthritis drug, Enbrel®, had been approved by the FDA for the same psoriasis indication as RAPTIVA® and, in September of 2004, they announced that the product received approval in the European Union in this same indication;

On January 18, 2008, Abbott Labs announced that the FDA had approved Humira® (adalimumab) as a treatment for adult patients with moderate to severe chronic plaque psoriasis. Abbott Labs had previously announced in December of 2007 that Humira® (adalimumab) had received marketing authorization from the European Commission for use as a treatment for moderate-to-severe plaque psoriasis;

In September of 2006, Centocor, Inc. ( Centocor ), a unit of Johnson & Johnson, announced that its rheumatoid arthritis and Crohn's disease drug, Remicade® (infliximab) had been approved by the FDA for the treatment of adult patients with chronic severe (i.e. extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. This drug had already been approved to treat plaque psoriasis in the European Union, psoriatic arthritis in the United States and, in combination with methotrexate, in the European Union;

Biogen Idec Inc. ( Biogen ) sold its worldwide rights to Amev® which has been approved in the United States and Canada to treat the same psoriasis indication as RAPTIVA®, to Astellas Pharma US, Inc., in March of 2006;

In June of 2008, Centocor announced that an advisory panel to the FDA has unanimously recommended approval of ustekinumab (CNTO 1275), a fully human monoclonal antibody that targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23) for the treatment of moderate-to-severe plaque psoriasis. The MAA regulatory submission for chronic moderate-to-severe plaque psoriasis was filed with the EMEA in the EU in December of 2007; and

Other companies are developing monoclonal antibody or other products for treatment of inflammatory skin disorders.

---

## **Table of Contents**

### *LUCENTIS®*

In addition to LUCENTIS®, there are two other FDA-approved therapies to treat macular degeneration: Pfizer, Inc.'s and OSI Pharmaceuticals, Inc.'s Macugen® and Novartis' and QLT Inc.'s Visudyne. LUCENTIS® also competes with Genentech's cancer drug Avastin®.

### *CIMZIA®*

In addition to CIMZIA®, there are two other FDA-approved anti-TNF therapies to treat moderate to severe active Crohn's disease in adults: Johnson & Johnson's Remicade® (infliximab) and Abbott Laboratories' HUMIRA® (adalimumab).

### *HCD122*

At the current time, there are several CD40-related programs under development, mostly focused on the development of CD40 ligand products. For example, SGN-40 is a humanized monoclonal antibody under development by Seattle Genetics, Inc. (Seattle Genetics) which is targeting CD40 antigen. Seattle Genetics is currently conducting a Phase 2 clinical trial for patients with diffuse large B-cell lymphoma, the most common type of aggressive non-Hodgkin's lymphoma, and Phase 1 trials for patients with multiple myeloma or chronic lymphocytic leukemia. In January of 2007, Seattle Genetics entered into an exclusive worldwide license agreement with Genentech to develop and commercialize SGN-40. Under the agreement, Genentech will fund future research, development, manufacturing and commercialization costs. In January of 2007, Kirin Brewery Company, Limited and Astellas Pharma Inc. announced that they have entered into a license and collaborative research and development agreement under which they will exclusively collaborate in developing and marketing a fully human anti-CD40 antagonistic monoclonal antibody worldwide with a first target indication of prophylaxis of organ rejection associated with organ transplantation.

### *Biodefense*

In May of 2006, the US Department of Health & Human Services (DHHS) awarded Cangene Corporation a five-year, \$362 million contract under Project Bioshield. The contract requires Cangene to manufacture and supply 200,000 doses of an equine heptavalent botulism anti-toxin to treat individuals who have been exposed to the toxins that cause botulism.

Emergent BioSolutions, Inc. is currently in development of a botulism immunoglobulin candidate that may compete with our anti-botulinum neurotoxin monoclonal antibodies

We are aware of additional companies that are pursuing biodefense-related antibody products. PharmAthene, Elusys Therapeutics, Inc. and Human Genome Sciences, Inc. are developing anti-anthrax antibodies. Cangene and Emergent BioSolutions, Inc. are developing anti-anthrax immune globulin products. These products may compete with our efforts in the areas of other monoclonal antibody-based biodefense products, and the manufacture of antibodies to supply strategic national stockpiles.

**Because many of the companies we do business with are also in the biotechnology sector, the volatility of that sector can affect us indirectly as well as directly.**

As a biotechnology company that collaborates with other biotech companies, the same factors that affect us directly can also adversely impact us indirectly by affecting the ability of our collaborators, partners and others we do business with to meet their obligations to us and reduce our ability to realize the value of the consideration provided to us by these other companies.

For example, in connection with our licensing transactions relating to our BCE technology, we have in the past and may in the future agree to accept equity securities of the licensee in payment of license fees. The future value of these or any other shares we receive is subject both to market risks affecting our ability to realize the value of these shares and more generally to the business and other risks to which the issuer of these shares may be subject.

**As we do more business internationally, we will be subject to additional political, economic and regulatory uncertainties.**

We may not be able to successfully operate in any foreign market. We believe that, because the pharmaceutical industry is global in nature, international activities will be a significant part of our future business activities and that, when and if we are able to generate income, a

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

substantial portion of that income will be derived from product sales and other activities outside the United States. Foreign regulatory agencies often establish standards different from those in the United States, and an inability to obtain foreign regulatory approvals on a timely basis could put us at a competitive disadvantage or make it uneconomical to proceed with a product or product candidate's development. International operations and sales may be limited or disrupted by:

imposition of government controls,



**Table of Contents**

export license requirements,

political or economic instability,

trade restrictions,

changes in tariffs,

restrictions on repatriating profits,

exchange rate fluctuations,

withholding and other taxation, and

difficulties in staffing and managing international operations.

**If we and our partners are unable to protect our intellectual property, in particular our patent protection for our principal products, product candidates and processes, and prevent its use by third parties, our ability to compete in the market will be harmed, and we may not realize our profit potential.**

We rely on patent protection, as well as a combination of copyright, trade secret, and trademark laws to protect our proprietary technology and prevent others from duplicating our products or product candidates. However, these means may afford only limited protection and may not:

prevent our competitors from duplicating our products;

prevent our competitors from gaining access to our proprietary information and technology, or

permit us to gain or maintain a competitive advantage.

Because of the length of time and the expense associated with bringing new products to the marketplace, we and our partners hold and are in the process of applying for a number of patents in the United States and abroad to protect our product candidates and important processes and also have obtained or have the right to obtain exclusive licenses to certain patents and applications filed by others. However, the mere issuance of a patent is not conclusive as to its validity or its enforceability. The United States Federal Courts or equivalent national courts or patent offices elsewhere may invalidate our patents or find them unenforceable. In addition, the laws of foreign countries may not protect our intellectual property rights effectively or to the same extent as the laws of the United States. If our intellectual property rights are not adequately protected, we may not be able to commercialize our technologies, products, or services, and our competitors could commercialize our technologies, which could result in a decrease in our sales and market share that would harm our business and operating results. Specifically, the patent position of biotechnology companies generally is highly uncertain and involves complex legal and factual questions. The legal standards governing the validity of biotechnology patents are in transition, and current defenses as to issued biotechnology patents may not be adequate in the future. Accordingly, there is uncertainty as to:

## Edgar Filing: XOMA LTD /DE/ - Form 10-Q

whether any pending or future patent applications held by us will result in an issued patent, or that if patents are issued to us, that such patents will provide meaningful protection against competitors or competitive technologies,

whether competitors will be able to design around our patents or develop and obtain patent protection for technologies, designs or methods that are more effective than those covered by our patents and patent applications, or

the extent to which our product candidates could infringe on the intellectual property rights of others, which may lead to costly litigation, result in the payment of substantial damages or royalties, and/or prevent us from using technology that is essential to our business.

---

## **Table of Contents**

We have established an extensive portfolio of patents and applications, both United States and foreign, related to our BPI-related product candidates, including novel compositions, their manufacture, formulation, assay and use. We have also established a portfolio of patents, both United States and foreign, related to our BCE technology, including claims to novel promoter sequences, secretion signal sequences, compositions and methods for expression and secretion of recombinant proteins from bacteria, including immunoglobulin gene products. Most of the more important European patents in our BCE patent portfolio expired in July of 2008.

If certain patents issued to others are upheld or if certain patent applications filed by others issue and are upheld, we may require licenses from others in order to develop and commercialize certain potential products incorporating our technology or we may become involved in litigation to determine the proprietary rights of others. These licenses, if required, may not be available on acceptable terms, and any such litigation may be costly and may have other adverse effects on our business, such as inhibiting our ability to compete in the marketplace and absorbing significant management time.

Due to the uncertainties regarding biotechnology patents, we also have relied and will continue to rely upon trade secrets, know-how and continuing technological advancement to develop and maintain our competitive position. All of our employees have signed confidentiality agreements under which they have agreed not to use or disclose any of our proprietary information. Research and development contracts and relationships between us and our scientific consultants and potential customers provide access to aspects of our know-how that are protected generally under confidentiality agreements. These confidentiality agreements may be breached or may not be enforced by a court. To the extent proprietary information is divulged to competitors or to the public generally, such disclosure may adversely affect our ability to develop or commercialize our products by giving others a competitive advantage or by undermining our patent position.

### **Litigation regarding intellectual property can be costly and expose us to risks of counterclaims against us.**

We may be required to engage in litigation or other proceedings to protect our intellectual property. The cost to us of this litigation, even if resolved in our favor, could be substantial. Such litigation could also divert management's attention and resources. In addition, if this litigation is resolved against us, our patents may be declared invalid, and we could be held liable for significant damages. In addition, we may be subject to a claim that we are infringing another party's patent. If such claim is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing products, processes or services unless we obtain a license from the other party. Such license may not be available on reasonable terms, thus preventing us from using these products, processes or services and adversely affecting our revenue.

### **Even if we or our third party collaborators or licensees bring products to market, we may be unable to effectively price our products or obtain adequate reimbursement for sales of our products, which would prevent our products from becoming profitable.**

If we or our third party collaborators or licensees succeed in bringing our product candidates to the market, they may not be considered cost-effective, and reimbursement to the patient may not be available or may not be sufficient to allow us to sell our products on a competitive basis. In both the United States and elsewhere, sales of medical products and treatments are dependent, in part, on the availability of reimbursement to the patient from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and services. Our business is affected by the efforts of government and third-party payors to contain or reduce the cost of healthcare through various means. In the United States, there have been and will continue to be a number of federal and state proposals to implement government controls on pricing. In addition, the emphasis on managed care in the United States has increased and will continue to increase the pressure on the pricing of pharmaceutical products. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

### **Healthcare reform measures and other statutory or regulatory changes could adversely affect our business.**

The pharmaceutical and biotechnology industries are subject to extensive regulation, and from time to time legislative bodies and governmental agencies consider changes to such regulations that could have significant impact on industry participants. For example, in light of certain highly-publicized safety issues regarding certain drugs that had received marketing approval, the U.S. Congress is considering various proposals regarding drug safety, including some which would require additional safety studies and monitoring and could make drug development more costly. We are unable to predict what additional legislation or regulation, if any, relating to safety or other aspects of drug development may be enacted in the future or what effect such legislation or regulation would have on our business.

The business and financial condition of pharmaceutical and biotechnology companies are also affected by the efforts of governments, third-party payors and others to contain or reduce the costs of healthcare to consumers. In the United States and various foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system, such as proposals relating to the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price) and government control of prescription drug pricing. The pendency or approval of such proposals could result in a decrease in our share price or

limit our ability to raise capital or to obtain strategic collaborations or licenses.

---

**Table of Contents**

**We are exposed to an increased risk of product liability claims.**

The testing, marketing and sales of medical products entails an inherent risk of allegations of product liability. In the event of one or more large, unforeseen awards of damages against us, our product liability insurance may not provide adequate coverage. A significant product liability claim for which we were not covered by insurance would have to be paid from cash or other assets. To the extent we have sufficient insurance coverage, such a claim would result in higher subsequent insurance rates. In addition, product liability claims can have various other ramifications including loss of future sales opportunities, increased costs associated with replacing products, and a negative impact on our goodwill and reputation, which could also adversely affect our business and operating results.

**The loss of key personnel, including our Chief Executive Officer, could delay or prevent achieving our objectives.**

Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, particularly our executive officers: Steven B. Engle, our Chairman, Chief Executive Officer and President; Patrick J. Scannon, M.D., Ph.D., our Executive Vice President and Chief Biotechnology Officer; and Christopher J. Margolin, our Vice President, General Counsel and Secretary. We currently have no key person insurance on any of our employees.

**Because we are a relatively small biopharmaceutical company with limited resources, we may not be able to attract and retain qualified personnel.**

Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific and management personnel, particularly in areas requiring specific technical, scientific or medical expertise. We had approximately 335 employees as of September 30, 2008, and we anticipate that we will require additional experienced executive, accounting, research and development, legal, administrative and other personnel in the future. There is intense competition for the services of these personnel, especially in California. Moreover, we expect that the high cost of living in the San Francisco Bay Area, where our headquarters and manufacturing facilities are located, may impair our ability to attract and retain employees in the future. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to implement our current initiatives or grow effectively.

**Calamities, power shortages or power interruptions at our Berkeley headquarters and manufacturing facility could disrupt our business and adversely affect our operations, and could disrupt the businesses of our customers.**

Our principal operations are located in Northern California, including our corporate headquarters and manufacturing facility in Berkeley, California. In addition, many of our collaborators and licensees are located in California. All of these locations are in areas of seismic activity near active earthquake faults. Any earthquake, terrorist attack, fire, power shortage or other calamity affecting our facilities or our customers facilities may disrupt our business and could have material adverse effect on our business and results of operations.

**We may be subject to increased risks because we are a Bermuda company.**

Alleged abuses by certain companies that have changed their legal domicile from jurisdictions within the United States to Bermuda have created an environment where, notwithstanding that we changed our legal domicile in a transaction that was approved by our shareholders and fully taxable to our company under United States law, we may be exposed to various prejudicial actions, including:

blacklisting of our common shares by certain pension funds,

legislation restricting certain types of transactions, and

punitive tax legislation.

We do not know whether any of these things will happen, but if implemented one or more of them may have an adverse impact on our future operations or our share price.



**Table of Contents**

**If you were to obtain a judgment against us, it may be difficult to enforce against us because we are a foreign entity.**

We are a Bermuda company. All or a substantial portion of our assets, including substantially all of our intellectual property, may be located outside the United States. As a result, it may be difficult for shareholders and others to enforce in United States courts judgments obtained against us. We have irrevocably agreed that we may be served with process with respect to actions based on offers and sales of securities made hereby in the United States by serving Christopher J. Margolin, c/o XOMA Ltd., 2910 Seventh Street, Berkeley, California 94710, our United States agent appointed for that purpose. Uncertainty exists as to whether Bermuda courts would enforce judgments of United States courts obtained in actions against us or our directors and officers that are predicated upon the civil liability provisions of the United States securities laws or entertain original actions brought in Bermuda against us or such persons predicated upon the United States securities laws. There is no treaty in effect between the United States and Bermuda providing for such enforcement, and there are grounds upon which Bermuda courts may not enforce judgments of United States courts. Certain remedies available under the United States federal securities laws may not be allowed in Bermuda courts as contrary to that nation's policy.

**Our shareholder rights agreement or by-laws may prevent transactions that could be beneficial to our shareholders and may insulate our management from removal.**

In February of 2003, we adopted a new shareholder rights agreement (to replace the shareholder rights agreement that had expired), which could make it considerably more difficult or costly for a person or group to acquire control of us in a transaction that our Board of Directors opposes.

Our by-laws:

require certain procedures to be followed and time periods to be met for any shareholder to propose matters to be considered at annual meetings of shareholders, including nominating directors for election at those meetings;

authorize our Board of Directors to issue up to 1,000,000 preference shares without shareholder approval and to set the rights, preferences and other designations, including voting rights, of those shares as the Board of Directors may determine; and

contain provisions, similar to those contained in the Delaware General Corporation Law that may make business combinations with interested shareholders more difficult.

These provisions of our shareholders rights agreement and our by-laws, alone or in combination with each other, may discourage transactions involving actual or potential changes of control, including transactions that otherwise could involve payment of a premium over prevailing market prices to holders of common shares, could limit the ability of shareholders to approve transactions that they may deem to be in their best interests, and could make it considerably more difficult for a potential acquirer to replace management.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**ITEM 5. OTHER INFORMATION**

None.



**Table of Contents**

**ITEM 6. EXHIBITS**

**Exhibit**

**Number**

10.39	Agreement dated September 15, 2008, between XOMA (US) LLC and the National Institute of Allergy and Infectious Diseases
31.1	Certification of Steven B. Engle, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Karen K. Thomas, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Steven B. Engle, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Karen K. Thomas, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1	Press Release dated November 10, 2008, furnished herewith

**Table of Contents**

**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, thereunto duly authorized.

XOMA Ltd.

Date: November 10, 2008

By: /s/ STEVEN B. ENGLE  
Steven B. Engle  
Chairman, Chief Executive Officer and President

Date: November 10, 2008

By: /s/ KAREN K. THOMAS  
Karen K. Thomas  
Chief Accounting Officer