

XOMA LTD /DE/  
Form 10-Q  
August 06, 2009  
Table of Contents

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

Washington, D.C. 20549

**FORM 10-Q**

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2009

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)

<p><b>Bermuda</b> (State or other jurisdiction of incorporation or organization)</p> <p><b>2910 Seventh Street, Berkeley,</b>  <b>California 94710</b> (Address of principal executive offices,  including zip code)</p>	<p><b>52-2154066</b> (I.R.S. Employer Identification No.)</p> <p><b>(510) 204-7200</b> (Telephone Number)</p>
--	---

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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 August 3, 2009
Common Shares, U.S. \$0.0005 par value	164,593,517

**Table of Contents**

**XOMA Ltd.**

**FORM 10-Q**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
Item 1. <u>Condensed Consolidated Financial Statements (unaudited)</u>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2009 and December 31, 2008</u>	1
<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2009 and 2008</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2009 and 2008</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>	18
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
Item 4. <u>Controls and Procedures</u>	29
<b><u>PART II OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	29
Item 1a. <u>Risk Factors</u>	30
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	47
Item 3. <u>Defaults Upon Senior Securities</u>	47
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	47
Item 5. <u>Other Information</u>	48
Item 6. <u>Exhibits</u>	49
<u>Signatures</u>	50

**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)**

	<b>June 30, 2009 (unaudited)</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 27,616	\$ 9,513
Short-term investments		1,299
Restricted cash	6,061	9,545
Trade and other receivables, net	6,283	16,686
Prepaid expenses and other current assets	1,658	1,296
Debt issuance costs	1,173	365
<b>Total current assets</b>	<b>42,791</b>	<b>38,704</b>
Property and equipment, net	23,592	26,843
Debt issuance costs long-term		1,224
Other assets	402	402
<b>Total assets</b>	<b>\$ 66,785</b>	<b>\$ 67,173</b>

**LIABILITIES AND SHAREHOLDERS EQUITY****(NET CAPITAL DEFICIENCY)**

Current liabilities:		
Accounts payable	\$ 4,596	\$ 9,977
Accrued liabilities	7,487	4,438
Accrued interest	1,217	1,588
Deferred revenue	4,573	9,105
Warrant liability	5,550	
Interest bearing obligations current	41,993	
Other current liabilities	606	1,884
<b>Total current liabilities</b>	<b>66,022</b>	<b>26,992</b>
Deferred revenue long-term	5,372	8,108
Interest bearing obligations long-term	13,129	63,274
Other long-term liabilities	581	200
<b>Total liabilities</b>	<b>85,104</b>	<b>98,574</b>

## Commitments and contingencies

## Shareholders' equity (net capital deficiency):

Preference shares, \$0.05 par value, 1,000,000 shares authorized

Series A, 210,000 designated, no shares issued and outstanding at June 30, 2009 and December 31, 2008

Series B, 8,000 designated, 2,959 shares issued and outstanding at June 30, 2009 and December 31, 2008

(aggregate liquidation preference of \$29.6 million)

1

1

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

Common shares, \$0.0005 par value, 210,000,000 shares authorized, 164,587,434 and 140,467,529 shares outstanding at June 30, 2009 and December 31, 2008, respectively	82	70
Additional paid-in capital	770,673	753,634
Accumulated comprehensive loss		(2)
Accumulated deficit	(789,075)	(785,104)
<b>Total shareholders' equity (net capital deficiency)</b>	<b>(18,319)</b>	<b>(31,401)</b>
Total liabilities and shareholders' equity (net capital deficiency)	\$ 66,785	\$ 67,173

*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 June 30,</b>		<b>Six months ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
<b>Revenues:</b>				
License and collaborative fees	\$ 155	\$ 155	\$ 27,855	\$ 180
Contract and other revenue	7,576	5,638	14,974	12,749
Royalties	1,975	5,323	6,581	10,244
<b>Total revenues</b>	<b>9,706</b>	<b>11,116</b>	<b>49,410</b>	<b>23,173</b>
<b>Operating expenses:</b>				
Research and development (including contract related of \$3,156, and \$4,439 for the three months ended June 30, 2009 and 2008, respectively, and \$10,094 and \$9,827 for the six months ended June 30, 2009 and 2008, respectively)	13,507	23,519	30,028	42,730
Selling, general and administrative	5,655	6,388	11,775	12,260
Restructuring	312		3,601	
<b>Total operating expenses</b>	<b>19,474</b>	<b>29,907</b>	<b>45,404</b>	<b>54,990</b>
<b>Income (loss) from operations</b>	<b>(9,768)</b>	<b>(18,791)</b>	<b>4,006</b>	<b>(31,817)</b>
<b>Other income (expense):</b>				
Investment and interest income	8	223	38	615
Interest expense	(1,671)	(2,164)	(3,439)	(3,614)
Other income (expense)	1,134	42	1,137	(49)
<b>Net income (loss) before taxes</b>	<b>(10,297)</b>	<b>(20,690)</b>	<b>1,742</b>	<b>(34,865)</b>
Provision for income tax (benefit) expense	(87)		5,713	
<b>Net loss</b>	<b>\$ (10,210)</b>	<b>\$ (20,690)</b>	<b>\$ (3,971)</b>	<b>\$ (34,865)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.07)</b>	<b>\$ (0.16)</b>	<b>\$ (0.03)</b>	<b>\$ (0.26)</b>
<b>Shares used in computing basic and diluted net loss per common share</b>	<b>150,283</b>	<b>132,288</b>	<b>146,011</b>	<b>132,222</b>

*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>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (3,971)	\$ (34,865)
<b>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</b>		
Depreciation and amortization	3,598	3,208
Common shares contribution to 401(k) and management incentive plans	1,198	1,008
Share-based compensation expense	1,885	2,881
Accrued interest on interest bearing obligations	(122)	774
Revaluation of warrant liability	(991)	
Amortization of discount, premium and debt issuance costs of interest bearing obligations	416	1,032
Amortization of premiums on short-term investments	1	10
(Gain) loss on disposal/retirement of property and equipment	(142)	50
Impairment charge of property and equipment	27	
Other non-cash adjustments		(23)
<b>Changes in assets and liabilities:</b>		
Receivables	10,403	(394)
Prepaid expenses and other current assets	(362)	(256)
Accounts payable	(5,381)	3,267
Accrued liabilities	3,049	(1,431)
Deferred revenue	(7,268)	(1,683)
Other liabilities	(897)	
<b>Net cash provided by (used in) operating activities</b>	<b>1,443</b>	<b>(26,422)</b>
<b>Cash flows from investing activities:</b>		
Proceeds from sales of investments		9,875
Proceeds from maturities of investments	1,300	2,794
Purchase of investments		(3,199)
Transfer of restricted cash	3,484	(2,266)
Purchase of property and equipment	(232)	(5,412)
<b>Net cash provided by investing activities</b>	<b>4,552</b>	<b>1,792</b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of long-term debt		55,000
Principal payments of long-term debt		(32,284)
Principal payments of short-term debt	(8,401)	
Proceeds from issuance of common shares	20,509	148
<b>Net cash provided by financing activities</b>	<b>12,108</b>	<b>22,864</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>18,103</b>	<b>(1,766)</b>
Cash and cash equivalents at the beginning of the period	9,513	22,500

Cash and cash equivalents at the end of the period	\$ 27,616	\$ 20,734
--	-----------	-----------

*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, develops and manufactures therapeutic antibodies and other agents designed to treat inflammatory, autoimmune, infectious and oncological 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. (a wholly-owned member of the Roche Group, referred to herein as Genentech ) on LUCENTIS®, for the treatment of neovascular (wet) age-related macular degeneration. XOMA also receives royalties from UCB Celltech, a branch of UCB S.A. ( UCB ), on sales of CIMZIFOR for the treatment of Crohn's disease and moderate-to-severe rheumatoid arthritis. XOMA's pipeline includes both proprietary products and collaborative programs at various stages of preclinical and clinical development.

**Liquidity and Financial Condition**

The Company has incurred significant operating losses and negative cash flows from operations since its inception. As of June 30, 2009, the Company had cash and cash equivalents of \$27.6 million and restricted cash of \$6.1 million. Based on cash and cash equivalents on hand at June 30, 2009 and anticipated spending levels, revenues, collaborator funding, government funding and other sources of funding the Company believes to be available, the Company estimates that it has sufficient cash resources to meet its anticipated net cash needs through the next twelve months, excluding a potential acceleration of the Company's outstanding principal on a term loan facility with Goldman Sachs Specialty Lending Holdings, Inc. ( Goldman Sachs ) due to the cessation of future royalties from sales of RAPTIVA®.

The Company is currently in discussions with the lenders regarding a restructuring of the terms of this facility to address the effects of certain recent developments related to RAPTIVA®. In the first quarter of 2009, RAPTIVA® was recommended for withdrawal from the European Union, Canadian and Australian markets, and in the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA® from the U.S. market. As a result of these events, the Company is no longer in compliance with the requirements of the relevant provisions of this loan facility, and has received a notice from its lenders to this effect. As a consequence, the lenders currently have the right to accelerate payment of the full amount of the loan. The Company cannot be certain that it will reach agreement with the lenders on acceptable terms, or at all, as a result of these discussions or that the lenders will not accelerate payment of the loan at any time. If the lenders accelerate payment, currently the Company would not have the resources to pay the full amount due.

In the second quarter of 2009, the Company raised approximately \$22.0 million, before deducting placement agent fees and estimated offering expenses of approximately \$1.6 million, in two separate registered direct offerings. Certain institutional investors purchased 22.2 million units, with each unit consisting of one of the Company's common shares and a warrant to purchase 0.5 of a common share. Refer to *Note 5: Debt and Other Financing Other Equity Financings* for additional disclosure relating to these equity financing transactions.

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 attractive to it, or at all, or that any such arrangement will be permitted under the terms of the term loan facility with Goldman Sachs, as they may be revised. Furthermore, any additional equity financings may be dilutive to shareholders and debt financing, if available, may involve covenants that place substantial restrictions on the Company's business. 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 has developed contingency plans that may require the Company to delay, reduce the scope of, or eliminate one or more of its development programs. In addition, the Company may be required to reduce personnel and related costs and other discretionary expenditures that are within the Company's control.

The accompanying interim financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The interim financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

---

## **Table of Contents**

### **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, 2008, filed with the SEC on March 11, 2009 ( 2008 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 June 30, 2009, the consolidated results of the Company's operations for the three and six months ended June 30, 2009 and 2008, and the Company's cash flows for the six months ended June 30, 2009 and 2008. The condensed consolidated balance sheet amounts at December 31, 2008 have been derived from the 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.

The Company has evaluated subsequent events through August 6, 2009, the date on which the financial statements being presented were available to be issued, and not beyond that date.

### **Use of Estimates and Reclassifications**

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, liabilities, revenues and expenses, and related disclosures. On an on-going basis, management evaluates its estimates, including those related to revenue recognition, research and development expense, long-lived assets and share-based compensation. The Company bases its estimates on historical experience and on various other market-specific and other relevant assumptions that are believed 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 significantly from these estimates.

### **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. Volatility in the financial markets created liquidity problems in these types of investments in 2008, and money market fund investors were unable to retrieve the full amount of funds, even in highly-rated liquid money market accounts, upon maturity. The Company has not encountered such issues during 2009.

The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the six months ended June 30, 2009, three customers represented 61%, 14% and 13% of total revenues. As of June 30, 2009, there were receivables outstanding from two of these customers representing 48% and 33% of the accounts receivable balance. For the six months ended June 30, 2008, four customers represented 44%, 34%, 11% and 11% of total revenues.

### **Recent Accounting Pronouncements**

In June of 2009, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 168 The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162 ( SFAS 168 ). The FASB Accounting Standards Codification (the Codification ) will become the source of authoritative U.S. generally accepted accounting principles recognized by the FASB applicable to non-governmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of SFAS 168, the Codification will supersede all then-existing non-SEC accounting and reporting standards. SFAS 168 is effective for the Company for the nine-month period ended September 30, 2009 and is not expected to have a material effect on the Company's financial statements.

In May of 2009, the FASB issued Statement of Financial Accounting Standards No. 165 Subsequent Events ( SFAS 165 ). SFAS 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. In particular, SFAS 165 sets forth the period after the balance sheet date during which management should evaluate events or transactions that may

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

occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. SFAS 165 is effective for interim financial periods ending after June 15, 2009 and did not have a material effect on the Company's financial statements.

## **Table of Contents**

Effective April 1, 2009, the Company adopted FASB Staff Position No. FAS 115-2 ( FSP FAS 115-2 ). FSP FAS 115-2 amends Statement of Financial Accounting Standards No. 115 Accounting for Certain Investments in Debt and Equity Securities ( SFAS 115 ) to make previous guidance regarding other-than-temporary impairments more operational and to improve the presentation of other-than-temporary impairments in the financial statements. FSP FAS 115-2 replaces the existing requirement that management assert it has both the intent and ability to hold an impaired debt security until recovery with a requirement that management assert it does not have the intent to sell the security and it is more likely than not it will not have to sell the security before recovery of its cost basis. FSP FAS 115-2 requires increased and more frequent disclosures regarding expected cash flows, credit losses, and an aging of securities with unrealized losses. The adoption of FSP FAS 115-2 did not have a material effect on the Company's financial statements.

In December of 2007, the Emerging Issues Task Force ( EITF ) reached a consensus on EITF Issue 07-1 Accounting for Collaborative Agreements ( EITF 07-1 ). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants and third parties in a collaborative arrangement. EITF 07-1 prohibits companies from applying the equity method of accounting to activities performed outside a separate legal entity by a virtual joint venture. Instead, revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented gross or net by the collaborators based on the criteria in EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent, and other applicable accounting literature. The consensus should be applied to collaborative arrangements in existence at the date of adoption using a modified retrospective method that requires reclassification in all periods presented for those arrangements still in effect at the transition date, unless that application is impracticable. Effective January 1, 2009 the Company adopted EITF 07-1, which did not have a material effect on the Company's financial statements. As a result of the restructuring in November of 2008 of the Company's collaboration agreement with Novartis AG ( Novartis ), this collaboration agreement is no longer within the scope of EITF 07-1. As of June 30, 2009, the Company does not have any collaboration agreements that fall under the scope of EITF 07-1. See *Note 4: Collaborative and Other Arrangements*.

Effective January 1, 2009 the Company adopted EITF Issue 07-5 Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock ( EITF 07-5 ). EITF 07-5 was issued in June of 2008 to clarify how to determine whether certain instruments or features were indexed to an entity's own stock. EITF 07-5 applies to any free standing financial instrument or embedded feature that has all the characteristics of a derivative in Statement of Financial Accounting Standards No. 133 Accounting for Derivative Instruments and Hedging Activities ( SFAS 133 ). Refer to *Note 1: Business and Summary of Significant Accounting Policies - Significant Accounting Policies* for the effect this standard had on the Company's financial statements.

In February of 2008, the FASB issued FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157, Fair Value Measurements ( SFAS 157 ) for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value at least annually. Effective January 1, 2009, the Company adopted SFAS 157, as it relates to non-financial assets and non-financial liabilities. The implementation of the remaining portion of this standard did not have a material effect on the Company's financial statements.

## **Significant Accounting Policies and Other Disclosures**

### ***Accounting for Warrants***

The Company issued warrants to purchase XOMA's common shares in connection with two separate registered direct offerings completed in May and June of 2009. Refer to *Note 5: Debt and Other Financing - Other Equity Financings* for additional disclosure relating to these two transactions. The warrants issued include a provision allowing for an adjustment of the exercise price and number of warrant shares. This adjustment occurs if the Company issues or sells certain common shares in the future for a price per share less than the exercise price of the warrants in effect immediately prior to such issuance or sale. Due to this adjustment provision, the warrants do not meet the criteria set forth in EITF 07-5 and therefore are not considered indexed to the Company's own stock.

Accordingly, the Company has accounted for these warrants under SFAS 133. The fair value of the warrants at the issuance date was estimated using the Monte Carlo Simulation Model ( Simulation Model ) and recorded as a liability. The warrants were revalued at June 30, 2009 using the Simulation Model and the change in the fair value of the warrants was recognized in the other income (expense) line item in the Company's consolidated statement of operations. The Company will revalue the unexercised warrants at each reporting period over the life of the warrants using the Simulation Model, and the changes in the fair value of the warrants will be recognized in the Company's consolidated statement of operations.

**Table of Contents****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). However, certain options granted to employees vest monthly or immediately, certain options granted to directors vest monthly over one year or three years and certain options may fully vest upon a change of control of the Company or may accelerate based on performance-driven measures. 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 2009, the Board of Directors of the Company approved a company-wide grant of an aggregate of 4,730,000 share options, of which 4,568,000 were issued as part of its annual incentive compensation package. These options vest monthly over four years and include an acceleration clause based on meeting certain performance measures. As of June 30, 2009, the Company has assessed the probability of achieving the performance measures and has determined that accelerated expense recognition is not appropriate at this time. The Company will reassess the probability at each future reporting period and accelerate expense recognition accordingly.

As of June 30, 2009, the Company had approximately 9.0 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 six months ended June 30, 2009 and 2008 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Research and development	\$ 399	\$ 989	\$ 951	\$ 1,259
Selling, general and administrative	457	1,380	934	1,622
<b>Total share-based compensation expense</b>	<b>\$ 856</b>	<b>\$ 2,369</b>	<b>\$ 1,885</b>	<b>\$ 2,881</b>

There was no capitalized share-based compensation cost as of June 30, 2009 and December 31, 2008, and there were no recognized tax benefits related to our share-based compensation cost during the three and six months ended June 30, 2009 and 2008.

To estimate the value of an award, the Company uses the Black-Scholes Option Pricing Model ( the Black-Scholes Model ). This model requires inputs such as expected life, expected volatility and risk-free interest rate. The forfeiture rate also affects 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 primarily from the Company's historical data, the risk-free rate is based on the yield available on U.S. Treasury zero-coupon issues.

The fair value of share-based awards was estimated using the Black-Scholes Model with the following weighted-average assumptions for the three and six months ended June 30, 2009 and 2008:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Dividend yield	0%	0%	0%	0%
Expected volatility	79%	64%	74%	64%
Risk-free interest rate	2.66%	3.07%	1.81%	3.02%
Expected life	5.6 years	5.3 years	5.6 years	5.3 years



**Table of Contents**

Share option activity for the six months ended June 30, 2009 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2008	19,810,183	\$ 3.24		
Granted	5,026,000	0.57		
Exercised	(7,000)	0.56		
Forfeited, expired or cancelled	(2,711,030)	2.78		
Options outstanding at June 30, 2009	22,118,153	\$ 2.69	7.87	\$ 1,318
Options exercisable at June 30, 2009	10,380,398	\$ 3.57	6.66	\$ 133

Total intrinsic value of the options exercised for the six months ended June 30, 2009 was \$910.

At June 30, 2009, there was \$9.7 million of unrecognized share-based compensation expense related to unvested share options with a weighted-average remaining recognition period of 2.6 years.

**Comprehensive Loss**

Unrealized gain or (loss) on the Company's available-for-sale securities is included in accumulated comprehensive loss. Comprehensive loss and its components for the three and six months ended June 30, 2009 and 2008 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss	\$ (10,210)	\$ (20,690)	\$ (3,971)	\$ (34,865)
Unrealized gain (loss) on securities available-for-sale		(39)	2	20
Comprehensive loss	\$ (10,210)	\$ (20,729)	\$ (3,969)	\$ (34,845)

**Income Taxes**

The Company recognized \$0.1 million in income tax benefit for the three months ended June 30, 2009 relating to refundable credits, compared with no income tax expense for the same period of 2008.

The Company recognized \$5.7 million in income tax expense for the six months ended June 30, 2009, primarily related to \$5.8 million of foreign income tax expense recognized in connection with the expansion of the Company's existing collaboration with Takeda Pharmaceutical Company Limited (Takeda), which was signed in February of 2009. Refer to *Note 4: Collaborative and Other Arrangements* for additional information. This expense was partially offset by the income tax benefit recognized in the second quarter of 2009 referred to above. No income tax expense was recognized for the six months ended June 30, 2008.

**Net Loss Per Common Share**

Basic net loss per common share is based on the weighted-average number of common shares outstanding during the period. Diluted net 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 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 loss per share (in thousands):

	Three and Six Months Ended June 30,	
	2009	2008
Options for common shares	22,118	19,450
Convertible preference shares	3,818	3,818
Warrants for common shares	11,100	125

**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 June 30, 2009 and December 31, 2008, cash and cash equivalents consisted of overnight deposits, money market funds, repurchase agreements and debt securities with original maturities of 90 days or less and are reported at fair value. Cash and cash equivalent balances were as follows as of June 30, 2009 and December 31, 2008 (in thousands):

	June 30, 2009			Estimated Fair Value
	Cost Basis	Unrealized Gains	Unrealized Losses	
Cash	\$ 1,420	\$	\$	\$ 1,420
Cash equivalents	26,196			26,196
<b>Total cash and cash equivalents</b>	<b>\$ 27,616</b>	<b>\$</b>	<b>\$</b>	<b>\$ 27,616</b>

	December 31, 2008			Estimated Fair Value
	Cost Basis	Unrealized Gains	Unrealized Losses	
Cash	\$ 553	\$	\$	\$ 553
Cash equivalents	8,960			8,960
<b>Total cash and cash equivalents</b>	<b>\$ 9,513</b>	<b>\$</b>	<b>\$</b>	<b>\$ 9,513</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 loss. The estimate of fair value is based on publicly available market information. 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.

At June 30, 2009, the Company had no short-term investments. At December 31, 2008, all short-term investments had maturities of less than one year.

**Table of Contents**

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

		December 31, 2008		
	Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	\$ 1,301	\$	\$ (2)	\$ 1,299
Total short-term investments	\$ 1,301	\$	\$ (2)	\$ 1,299

The Company recognized no realized gains on short-term investments for the three and six months ended June 30, 2009. The Company recognized \$4,000 in realized gains on short-term investments in the second quarter of 2008, which represents the only realized gain recognized for the three and six months ended June 30, 2008.

**Restricted Cash**

Under the terms of its loan agreement with Goldman Sachs, as discussed in *Note 5: Debt and Other Financing – Goldman Sachs Term Loan*, the Company maintains a custodial account for the deposit of RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup> royalty revenues in addition to a standing reserve of the next semi-annual interest payment due on the loan. 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 the lenders.

At June 30, 2009, the restricted cash balance of \$6.1 million was held in the Goldman Sachs custodial account as discussed above and was invested in money market funds. At December 31, 2008, the restricted cash balance of \$9.5 million included \$8.6 million held in the Goldman Sachs custodial account and \$0.9 million related to an irrevocable letter of credit arrangement, which was released to the Company in the first quarter of 2009. The December 31, 2008 balances were invested in money market funds and a certificate of deposit, respectively.

**Receivables**

Receivables consisted of the following at June 30, 2009 and December 31, 2008 (in thousands):

	June 30, 2009	December 31, 2008
Trade receivables, net	\$ 5,751	\$ 16,274
Other receivables	532	412
Total	\$ 6,283	\$ 16,686

**Accrued Liabilities**

Accrued liabilities consisted of the following at June 30, 2009 and December 31, 2008 (in thousands):

	June 30, 2009	December 31, 2008
Accrued management incentive compensation	\$ 1,731	\$
Accrued restructuring costs	285	
Accrued payroll and other benefits	2,005	2,776
Accrued professional and other fees	2,223	514
Accrued clinical trial costs	517	438
Deferred rent	468	399

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

Other	258	311
Total	\$ 7,487	\$ 4,438

---

**Table of Contents*****Supplemental Cash Flow Information***

The following table shows the supplemental cash flow information for the six months ended June 30, 2009 and 2008 (in thousands):

	Six Months Ended June 30,	
	2009	2008
Non-cash investing and financing activities:		
Fair value of warrant liability	\$ 5,550	\$
Interest added to principal balance on Novartis note	\$ 249	\$ 704

Refer to *Note 5: Debt and Other Financing* for additional disclosures regarding the warrants liability and the Novartis note.

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

In accordance with SFAS 157, the following tables set forth the Company's fair value hierarchy for its financial assets (cash equivalents and investments) and liabilities measured at fair value on a recurring basis as of June 30, 2009 and December 31, 2008.

Financial assets carried at fair value as of June 30, 2009 and December 31, 2008 are classified as follows (in thousands):

	Fair Value Measurements at June 30, 2009 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	\$ 12,859	\$ 12,859	\$	\$
Money market funds	13,337	13,337		
Money market funds- restricted	6,061	6,061		
Total	\$ 32,257	\$ 32,257	\$	\$

	Fair Value Measurements at December 31, 2008 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	\$ 8,950	\$ 8,950	\$	\$
Certificates of deposit- restricted	952	952		
Money market funds	10	10		
Money market funds-restricted	8,593	8,593		
Corporate notes and bonds	1,299		1,299	
Total	\$ 19,804	\$ 18,505	\$ 1,299	\$

**Table of Contents**

Financial liabilities carried at fair value as of June 30, 2009 are classified as follows (in thousands):

	Total	Fair Value Measurements at June 30, 2009 Using Quoted Prices in Active Markets for Identical Assets (Level 1)		
		Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Warrants liability	\$ 5,550	\$	\$	\$ 5,550
Total	\$ 5,550	\$	\$	\$ 5,550

The fair value of the warrants liability was determined at June 30, 2009 using the Simulation Model, as discussed in *Note 1: Business and Summary of Significant Accounting Policies – Significant Accounting Policies – Accounting for Warrants*.

The Company did not have any financial liabilities carried at fair value as of December 31, 2008.

The following table provides a summary of changes in the fair value of the Company's Level 3 financial liabilities for the six month period ended June 30, 2009 (in thousands):

	Warrants Liability
Balance at December 30, 2008	\$
Initial fair value of warrants	(6,541)
Change in fair value of warrants included in other income (expense)	991
Balance at June 30, 2009	(5,550)

**Table of Contents****3. RESTRUCTURING CHARGES**

On January 15, 2009, the Company announced a workforce reduction of approximately 42%, or 144 employees, a majority of which were employed in manufacturing and related support functions. This decision was made based on the challenging economic conditions and a decline in forecasted contract manufacturing demand in 2009.

As part of this workforce reduction, the Company recorded a charge of \$3.3 million related to severance, other termination benefits and outplacement services in the first quarter of 2009. In the second quarter of 2009, the Company recorded an adjustment of \$0.2 million to reduce the outplacement services liability related to the expiration of outplacement services offered to terminated employees. Additionally during the second quarter of 2009, the Company vacated one of its leased buildings and recorded a restructuring charge of \$0.5 million primarily related to the net present value of the net future minimum lease payments at the cease-use date, less the estimated future sublease income. The Company is currently seeking a sublease tenant. These charges are included as restructuring expenses in the consolidated statement of operations for the three and six months ended June 30, 2009. The following table summarizes the restructuring charges and utilization for the six months ended June 30, 2009 (in thousands):

	Balance as of December 31, 2008	Charges	Cash Payments	Adjustments	Balance as of June 30, 2009
Employee severance and benefits	\$	\$ 3,289	\$ (2,991)	\$ (193)	\$ 105
Facilities consolidation		491	(30)		461
<b>Total</b>	<b>\$</b>	<b>\$ 3,780</b>	<b>\$ (3,021)</b>	<b>\$ (193)</b>	<b>\$ 566</b>

The remaining balance of employee severance and benefits is recorded as a current liability within the accrued liabilities balance at June 30, 2009 as payments are expected to be complete within the next three months. The Company does not expect to incur any additional restructuring charges for employee severance and other termination benefits related to the January of 2009 workforce reduction. The facilities consolidation charge is recorded as both a current accrued liability and a long-term liability at June 30, 2009 since the remaining lease term of the vacated building is approximately five years.

Also, as a result of the workforce reduction, the Company significantly reduced operations in four leased buildings in the first quarter of 2009. In the second quarter of 2009, the Company resumed operations in one of these buildings and vacated another resulting in a restructuring charge, as discussed above. The Company's leases on the remaining two buildings expire in 2011 and 2013, and total minimum lease payments due from July 1, 2009 until expiration of the leases are \$4.6 million. The Company is currently evaluating its options as to the future use of these leased spaces.

As of June 30, 2009, in accordance with Statement of Financial Accounting Standards No. 144 Accounting for Impairment or Disposal of Long-Lived Assets (SFAS 144), the Company performed an analysis of the long-lived assets related to the two remaining leased buildings, with an approximate net book value of \$9.8 million. Based on estimated undiscounted future cash inflows, the Company has determined that there is no current impairment relating to these assets, and will continue to assess for impairment at each future reporting period.

**4. COLLABORATIVE AND OTHER ARRANGEMENTS*****Termination of Target Development Programs with Schering-Plough Research Institute***

In May of 2006, the Company entered into a fully funded collaboration agreement with the Schering-Plough Research Institute (SPRI), a division of Schering-Plough Corporation, for therapeutic monoclonal antibody discovery and development. SPRI selected the initial discovery and development program at the inception of the collaboration and, in December of 2006, exercised its right to initiate additional discovery and development programs.

In the second quarter of 2009, the number of discovery and development programs under this collaboration was significantly reduced, which resulted in the accelerated recognition of \$2.6 million in May of 2009 of the remaining unamortized balance in deferred revenue pertaining to the terminated programs. The Company will continue to amortize the deferred revenue relating to its continuing efforts over the estimated remaining period of the Company's obligation.





**Table of Contents*****Expansion of Collaboration with Takeda***

In February of 2009, the Company expanded its existing collaboration with Takeda to provide Takeda with access to multiple antibody technologies, including a suite of research and development technologies and integrated information and data management systems. The Company was paid a \$29.0 million expansion fee, of which \$23.2 million was received in cash in February of 2009 and the remainder was withheld for payment to the Japanese taxing authority. After deducting an estimated \$1.5 million in costs to be incurred related to the agreement, the Company recognized \$27.5 million in revenue in February of 2009 as the terms of the expansion were fulfilled and no related continuing performance obligations exist. The Company continues to conduct multiple discovery programs through this arrangement.

***Restructuring of Collaboration with Novartis***

The Company entered into a product development collaboration with Novartis (then Chiron Corporation) in 2004 for the development and commercialization of antibody products for the treatment of cancer, which was initially a cost and profit sharing arrangement. Under this agreement, XOMA received initial payments of \$10.0 million in 2004, which were recognized from 2004 to 2007, at which point the parties mutual obligation to conduct antibody discovery, development and commercialization work in oncology exclusively with one another ended. The expiration of this mutual obligation had no effect on the existing collaboration projects which had reached the development stage and the parties continued to collaborate on a non-exclusive basis. XOMA recognized development expenses relating to the collaboration with Novartis of \$4.5 million in 2008 and \$3.8 million in 2007.

In November of 2008, the Company restructured its product development collaboration with Novartis. Under the restructured agreement, the Company recognized \$13.7 million in revenue in 2008 and may, in the future, receive milestones and double-digit royalty rates for two ongoing product programs and options to develop or receive royalties on four additional programs, in exchange for Novartis receiving control over the two ongoing programs under the original product development collaboration. In addition, as a result of the restructuring of the agreement, the Company does not expect to incur any future development expense under this collaboration agreement.

In December of 2008, the Company entered into a Manufacturing and Technology Transfer Agreement with Novartis, effective July 1, 2008. Under this agreement, the Company was engaged to perform research and development, process development, manufacturing and technology transfer activities with respect to the ongoing product programs now controlled by Novartis under the restructured product development collaboration. The Company substantially completed this work in the second quarter of 2009.

**5. DEBT AND OTHER FINANCING**

As of June 30, 2009, the Company had current debt obligations of \$42.0 million under its term loan with Goldman Sachs. The Company also had long-term debt of \$13.1 million outstanding under its note with Novartis.

***Goldman Sachs Term Loan***

In May of 2008, the Company entered into a five-year amended and restated term loan facility with Goldman Sachs, refinancing the original facility entered into in November of 2006, and borrowed the full amount thereunder. As of June 30, 2009, the interest rate was 11.5%. 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>.

The on-going requirements of this loan facility include a financial test that requires the Company to maintain a specified ratio of royalties collected to interest payable and a requirement that quarterly U.S. sales of RAPTIVA<sup>®</sup> and LUCENTIS<sup>®</sup> and outside-the-U.S. sales of RAPTIVA<sup>®</sup> exceed certain specified minimum levels. The Company's ability to comply with these requirements depends on continuing sales by Genentech, UCB and their partners of RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup> at adequate levels, and any significant reduction in such sales results in a violation or default under these provisions, providing the lenders the right to accelerate the Company's obligation to repay this debt.

As discussed in *Note 1: Business and Summary of Significant Accounting Policies - Liquidity and Financial Condition*, in the first quarter of 2009, RAPTIVA<sup>®</sup> was recommended for withdrawal from the European Union, Canadian and Australian markets, and in the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA<sup>®</sup> from the U.S. market. As a result of these events, the Company is no longer in compliance with the requirements of the relevant provisions of this loan facility, and as a consequence the lenders currently have the right to accelerate payment of the full amount of the loan. Accordingly, the outstanding principal balance under the Goldman Sachs loan facility is classified as a current obligation at June 30, 2009.



**Table of Contents**

The amount originally borrowed under the amended and restated loan facility was \$55.0 million and has since been reduced to \$42.0 million at June 30, 2009. Additionally, at June 30, 2009, the balance in restricted cash was \$6.1 million, which is available to pay interest and principal due under the facility. Debt issuance costs under the facility of \$2.0 million are being amortized on a straight-line basis over the five-year life of the loan and are classified as current debt issuance costs on the balance sheet, consistent with the classification of the loan balance.

**Novartis Note**

In May of 2005, the Company executed a secured note agreement with Novartis (then Chiron Corporation), which is due and payable in full in June of 2015. Under the note agreement, the Company borrowed semi-annually to fund up to 75% of the Company's research and development and commercialization costs under its collaboration arrangement with Novartis, not to exceed \$50.0 million in an aggregate principal amount. As of June 30, 2009, the interest rate was 3.18%. 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. The Company has made this election for all interest payments thus far. Loans under the note agreement are secured by the Company's interest in the collaboration with Novartis, including any payment owed to it thereunder. At June 30, 2009, the outstanding principal balance under this note agreement totaled \$13.1 million and, pursuant to the terms of the arrangement as restructured in November of 2008, the Company will not make any additional borrowings on the Novartis note.

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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
<b>Interest expense</b>				
Goldman Sachs term loan	\$ 1,225	\$ 1,098	\$ 2,779	\$ 1,890
Novartis note	119	342	243	692
Total interest expense	\$ 1,344	\$ 1,440	\$ 3,022	\$ 2,582
<b>Amortization of debt issuance costs</b>				
Goldman Sachs term loan	\$ 327	\$ 724	\$ 417	\$ 1,032
Total amortization of debt issuance costs	\$ 327	\$ 724	\$ 417	\$ 1,032
<b>Total interest expense</b>	\$ 1,671	\$ 2,164	\$ 3,439	\$ 3,614

**Equity Line of Credit**

In October of 2008, the Company entered into a common share purchase agreement (the "Purchase Agreement") with Azimuth Opportunity Ltd. ("Azimuth"), pursuant to which it obtained a committed equity line of credit facility (the "Facility") under which the Company may sell up to \$60 million of its registered common shares to Azimuth over a 24-month period, subject to certain conditions and limitations. The Purchase Agreement currently requires a minimum share price of \$1.00 per share to allow the Company to issue shares to Azimuth under the Facility. However, at its election, Azimuth may buy shares below the threshold price at a negotiated discount. The Company is not obligated to utilize any of the \$60 million Facility and remains free to enter other financing transactions. 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.

The Company did not sell any common shares under, or make any modifications to, this facility during the six months ended June 30, 2009, and \$52.5 million remains available under the Facility as of June 30, 2009, subject to certain conditions as discussed above.

**Other Equity Financings**

In May of 2009, the Company entered into a definitive agreement with an institutional investor to sell 11,764,706 units, with each unit consisting of one of the Company's common shares and a warrant to purchase 0.50 of a common share, for gross proceeds of approximately \$10.0 million, before deducting placement agent fees and estimated offering expenses of \$0.8 million, in a registered direct offering. The investor purchased

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

the units at a price of \$0.85 per unit. The warrants, which represent the right to acquire an aggregate of up to 5,882,353 common shares, are exercisable at any time on or after May 15, 2009 and prior to May 20, 2014 at an exercise price of \$1.02 per share.

---

**Table of Contents**

In June of 2009, the Company entered into a definitive agreement with certain institutional investors to sell 10,434,782 units, with each unit consisting of one of the Company's common shares and a warrant to purchase 0.50 of a common share, for gross proceeds of approximately \$12.0 million, before deducting placement agent fees and estimated offering expenses of \$0.8 million, in a second registered direct offering. The investors purchased the units at a price of \$1.15 per unit. The warrants, which represent the right to acquire an aggregate of up to 5,217,391 common shares, will be exercisable at any time on or after December 11, 2009 and prior to December 10, 2014 at an exercise price of \$1.30 per share.

As discussed in *Note 1: Business and Summary of Significant Accounting Policies - Significant Accounting Policies*, the Company has accounted for the warrants issued in the two separate registered direct offerings in accordance with SFAS 133. The fair value of the warrants at the issuance dates was estimated using the Simulation Model, and the Company recorded liabilities of \$2.9 million and \$3.6 million for the May and June warrant issuances, respectively. Additionally, the Company revalued the warrants at June 30, 2009 and recorded a decrease in the fair value of the warrants of \$1.0 million in the other income line item of the Company's consolidated statement of operations for the three and six months ended June 30, 2009.

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

On April 9, 2009, a complaint was filed in the Superior Court of Alameda County, California, in a lawsuit captioned Hedrick et al. v. Genentech, Inc. et al., Case No. 09-446158. The complaint asserts claims against Genentech, the Company and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraud, wrongful death and other claims based on injuries alleged to have occurred as a result of three individuals' treatment with RAPTIV<sup>®</sup>. The complaint seeks unspecified compensatory and punitive damages. On April 29, 2009 and May 22, 2009, two additional complaints were filed in the same court in lawsuits captioned Heinen et al v. Genentech, Inc., et al., Case No. 09-449804 and York et al v. Genentech, Inc., et al., Case No. 09-453932. Those complaints allege the same claims and seek the same types of damages based on injuries alleged to have occurred as a result of two individuals' treatment with RAPTIV<sup>®</sup>. The Company's agreement with Genentech provides for an indemnity of XOMA and payment of legal fees by Genentech which the Company believes is applicable to this matter. The Company believes the claims against it to be without merit and intends to defend against them vigorously.

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, 2008) during the six months ended June 30, 2009.

**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 and assumptions 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 revenue recognition, research and development expense, long-lived assets and share-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant 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 significantly from these estimates.

**Overview**

We are a leader in the discovery, development and manufacture of therapeutic antibodies and other agents designed to treat inflammatory, autoimmune, infectious and oncological diseases. Our proprietary development pipeline includes XOMA 052, an anti-IL-1 beta antibody, XOMA 3AB, a biodefense anti-botulism antibody candidate, and five antibodies in preclinical development. Our proprietary development pipeline is funded by multiple revenue streams resulting from the licensing of our antibody technologies, product royalties, development collaborations and biodefense contracts, and sales of XOMA's common shares. Our technologies and experienced team have contributed to the success of marketed antibody products, including LUCENTIS® (ranibizumab injection) for (wet) age-related macular degeneration and CIMZIA® (certolizumab pegol, CDP870) for Crohn's disease and rheumatoid arthritis.

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 technologies. Our bacterial cell expression technology is a key biotechnology for the discovery and manufacturing of antibodies and other proteins. Thus far, more than 50 pharmaceutical and biotechnology companies have signed bacterial cell expression licenses with us. We are currently in discussions with multiple companies to license our antibody technologies.

In addition to developing our own potential products, we develop products for premier pharmaceutical companies including Novartis AG (Novartis), Takeda Pharmaceutical Company Limited (Takeda) and Schering-Plough Research Institute (SPRI). In February of 2009, we announced the expansion of our collaboration agreement with Takeda under which Takeda will have access to multiple antibody technologies, including a suite of research and development technologies and integrated information and data management systems, for which we were paid a \$29.0 million expansion fee. We have a fully integrated product development infrastructure, extending from preclinical science to manufacturing.

Our ability to fund ongoing operations is dependent on the progress of our proprietary development pipeline, specifically XOMA 052 and XOMA 3AB. In April of 2009 we completed enrollment in our two Phase 1 clinical trials of XOMA 052 in Type 2 diabetes patients in the U.S. and Europe. In July of 2009, we announced positive results from the U.S. Phase 1 trial, which continued to demonstrate that XOMA 052 is well tolerated in patients. Further, a multiple dose regimen of XOMA 052 showed clinically meaningful reductions in glycosylated hemoglobin and high sensitivity C-reactive protein compared to a single dose regimen. New positive biological activity was observed with sustained improvements noted in fasting blood glucose and in standard biomarkers of systemic inflammation and cardiovascular risk. Pharmacokinetic results continue to support monthly or less frequent dosing.

These Phase 1 results support our plans to begin a Phase 2 clinical development program in Type 2 diabetes and cardiovascular disease in the third quarter of 2009. We have been approached by a number of companies offering to collaborate on our testing and development of XOMA 052 for Type 2 diabetes, and we continue to seek to enter into a collaboration arrangement by the end of 2009.

Our royalty streams are necessary to provide funding to meet the requirements under our term loan with Goldman Sachs Specialty Lending Holdings, Inc. (Goldman Sachs). These royalty streams currently include U.S. and European sales of LUCENTIS, for which Genentech, Inc. (a wholly-owned member of the Roche Group (Roche), referred to herein as Genentech) licensed our bacterial cell expression technology, and sales of CIMZIA® in the U.S. and Switzerland, for which UCB Celltech, a branch of UCB S.A. (UCB), licensed our bacterial cell expression technology. Genentech, UCB and their partners are responsible for the manufacturing, marketing and sales efforts in support of these products.

Previously, we also relied on a royalty stream from RAPTIVA®, a drug we developed under a collaboration agreement with Genentech, from which we had earned mid-single digit royalties. In the first quarter of 2009, RAPTIVA® was recommended for withdrawal from the European Union, Canadian and Australian markets, and in the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA® from the U.S. market. As a result, sales of RAPTIVA® ceased in the second quarter of 2009. These events have significant adverse consequences under our term loan with Goldman Sachs, as discussed in the *Liquidity and Capital Resources* section.



## **Table of Contents**

Our initial biodefense anti-botulism antibody candidate, XOMA 3AB, is a multi-antibody product that targets the most potent of the botulinum toxins, Type A. Our anti-botulism program was recently expanded to include additional product candidates and is the first of its kind to combine multiple human antibodies to target a broad spectrum of the most toxic botulinum toxins, including the three most toxic serotypes of botulism, Types A, B and E. The antibodies are designed to bind to each toxin and enhance the clearance of the toxin from the body. The use of multiple antibodies increases the likelihood of clearing the harmful toxins by providing specific protection against each toxin type. To date, we have been awarded three contracts, totaling nearly \$100 million, from the National Institute of Allergy and Infectious Diseases ( NIAID ), a part of the National Institutes of Health ( NIH ), to support our ongoing development of XOMA 3AB and additional product candidates toward clinical trials in the treatment of botulism poisoning.

We also have the ability to generate revenues from funded research and development and other development activities. We are developing a number of products, both proprietary and under collaboration agreements with other companies and may enter into additional arrangements. Our objective in development collaborations is to leverage our existing development infrastructure to broaden and strengthen our proprietary product pipeline thereby diversifying our development risk and gaining financial support from our collaboration partners.

In January of 2009, we announced a workforce reduction of approximately 42%, or 144 employees, a majority of which were employed in manufacturing and related support functions. This decision was made based on the challenging economic conditions and a decline in forecasted manufacturing demand in 2009. We expect an annualized reduction of approximately \$27 million in cash expenditures when changes are completed. We remain staffed with approximately 190 employees to develop XOMA 052, develop and license proprietary products and technology, and continue fully funded antibody discovery and development activities with our pharmaceutical partners in collaborations and the U.S. government in biodefense. We recorded a charge in the first quarter of 2009 of \$3.3 million for severance, other termination benefits and outplacement services in connection with the workforce reduction. In the second quarter of 2009, we recorded an adjustment of \$0.2 million to reduce the outplacement services liability upon expiration of such services offered to terminated employees.

Also, as a result of the workforce reduction, we significantly reduced operations in four leased buildings in the first quarter of 2009. In the second quarter of 2009, we resumed operations in one of these buildings and vacated another resulting in a restructuring charge of \$0.5 million primarily related to the net present value of the future minimum lease payments, less the estimated future sublease income. We are currently seeking a sublease tenant. Our leases on the remaining two buildings expire in 2011 and 2013, and total minimum lease payments due from July 1, 2009 until expiration of the leases are \$4.6 million. In addition, the net book value of fixed assets in these two buildings potentially subject to write-down is approximately \$9.8 million as of June 30, 2009. We are currently evaluating our options as to the future use of these leased spaces. We anticipate the potential for incurring further restructuring charges through the remainder of 2009 as we continue to evaluate our options as the future use of our facilities.

We incurred negative cash flow from operations in four of the past five years and expect to remain in this position until sufficient cash flow can be generated from XOMA 052 partnering agreements, technology licensing, biodefense contracts with the government and various development collaboration arrangements, or until we achieve additional regulatory approvals and commence commercial sales of additional products. The timing and likelihood of additional approvals is uncertain and there can be no assurance that approvals will be granted or that cash flow from product sales will be sufficient to fully fund operations.

## **Results of Operations**

### ***Revenues***

Total revenues for the three and six months ended June 30, 2009, and 2008, were as follows (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
License and collaborative fees	\$ 155	\$ 155	\$ 27,855	\$ 180
Contract and other revenue	7,576	5,638	14,974	12,749
Royalties	1,975	5,323	6,581	10,244
Total revenues	\$ 9,706	\$ 11,116	\$ 49,410	\$ 23,173





## **Table of Contents**

License and collaborative fee revenue includes fees and milestone payments related to the out-licensing of our products and technologies. License and collaborative fee revenue remained unchanged and increased by \$27.7 million for the three and six months ended June 30, 2009, compared to the same periods of 2008. The increase in license and collaborative fee revenue for the first half of 2009, compared to the same period of 2008, was primarily due to \$27.5 million in revenue recognized during the first quarter of 2009 related to the expansion of our collaboration agreement with Takeda to provide Takeda with access to multiple antibody technologies. In addition, we received a milestone payment of \$0.2 million from Pfizer Inc. ( Pfizer ) in the first quarter of 2009. The generation of future revenues related to license fees and other collaboration arrangements is dependent on our ability to attract new licensees to bacterial cell expression and other antibody technologies and new collaboration partners.

Contract and other revenue increased by \$1.9 million and \$2.2 million for the three and six months ended June 30, 2009, compared to the same periods of 2008. These revenues include agreements where we provide contracted research and development and manufacturing services to our collaboration partners, including Takeda, SPRI, Novartis and NIAID. The increases in contract and other revenue for the three and six months ended June 30, 2009 are primarily related to work performed under our contracts with NIAID Contract No. HHSN272200800028C ( NIAID 3 ), which was awarded in September of 2008, and Novartis, which was entered into in December of 2008. The work performed under our contract with Novartis is substantially complete as of June 30, 2009. Additionally, we accelerated the recognition of \$2.6 million of unamortized deferred revenue in the second quarter of 2009 related to the termination of certain discovery and development programs under our collaboration with SPRI.

These increases in contract revenue were partially offset by a decrease in revenue recognized for research and development activities performed under our SPRI contract in 2009 as a result of the termination of these programs. In addition, contract and other revenue decreased related to our NIAID Contract No. HHSN266200600008C/N01-A1-60008 ( NIAID 2 ) and our AVEO Pharmaceuticals, Inc. (now with SPRI and referred to herein together as SPRI/AVEO ) contract as a result of the Company nearing the end of the respective contracted service arrangements. Depending on whether and when we obtain new government and other contracts, we expect to experience a decline in contract revenues from 2008 levels.

Revenue from royalties decreased by \$3.3 million and \$3.7 million for the three and six months ended June 30, 2009, compared to the same periods of 2008. The decrease in revenue from royalties was due to the cessation of royalties earned from sales of RAPTIVA® in the second quarter of 2009 and an adjustment made to reduce royalty revenue recognized in the first quarter of 2009 by \$0.9 million to reflect actual first quarter royalty receipts that were lower than estimated as a result of sales returns. These decreases were partially offset by an increase in royalties earned from sales of LUCENTIS® of \$0.5 million and \$0.9 million for the three and six months ended June 30, 2009. During the three and six months ended June 30, 2009, royalties received from sales of CIMZIA® were immaterial.

As discussed in the *Overview* section, in the first quarter of 2009, RAPTIVA® was recommended for withdrawal from the European Union, Canadian and Australian markets, and in the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA® from the U.S. market. As a result of these events, sales of RAPTIVA® ceased in the second quarter of 2009. We earned mid-single digit royalties from sales of RAPTIVA®. These events have significant adverse consequences under our term loan with Goldman Sachs, as discussed in the *Liquidity and Capital Resources* section.

According to Roche, U.S. sales of LUCENTIS® were 573 million Swiss francs, approximately \$503 million, for the six months ended June 30, 2009 compared with \$414 million for the same period of 2008. According to Novartis, sales of LUCENTIS® outside the United States were \$523 million for the six months ended June 30, 2009 compared with \$437 million for the same period of 2008. We expect royalty revenues from sales of LUCENTIS® to continue to increase in 2009. In January of 2009, Novartis announced that LUCENTIS® was approved in Japan for the treatment of (wet) age-related macular degeneration.

Additionally, CIMZIA® was approved by the U.S. Food and Drug Administration ( FDA ) in May of 2009 for the treatment of moderate-to-severe rheumatoid arthritis in adults. We expect royalty revenues from sales of CIMZIA® to increase in 2009.

### ***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, third party costs and other expenses related to preclinical and clinical testing.



**Table of Contents**

Research and development expenses were \$13.5 million and \$30.0 million for the three and six months ended June 30, 2009, compared with \$23.5 million and \$42.7 million for the three and six months ended June 30, 2008. The decrease of \$10.0 million and \$12.7 million for the three and six months ended June 30, 2009, as compared to the same periods in 2008, is a result of our continuing focus on cost control. In addition, spending on XOMA 052 decreased in the first half of 2009, as compared to same period of 2008, due to the completion of enrollment in our two Phase 1 clinical trials in April of 2009. Additionally, spending on NIAID 2 and SPRI/AVEO related contract activities decreased in 2009 due to the Company nearing the end of contracted service arrangements, and spending on SPRI-related contract activities decreased in 2009 due to the termination of certain discovery and development programs under the collaboration. These decreases were partially offset by increased spending on the preclinical development of five antibodies, and on our contracts with Novartis, NIAID 3 and Takeda.

We recorded research and development salaries and employee-related expenses of \$6.1 million for the three months ended June 30, 2009, compared with \$9.7 million for the same period of 2008. The decrease of \$3.6 million for the second quarter of 2009 was due to decreases in salaries and benefits of \$2.9 million and accrued bonus expense of \$0.1 million primarily due to the workforce reduction announced in January of 2009. In addition, share-based compensation decreased by \$0.6 million. See *Results of Operations: Share-Based Compensation* for further discussion of our share-based compensation expense.

For the six months ended June 30, 2009, we recorded research and development salaries and employee-related expenses of \$13.8 million, compared with \$18.4 million for the same period of 2008. The decrease of \$4.6 million for the first half of 2009 was due to decreases in salaries and benefits of \$4.1 million and accrued bonus expense of \$0.2 million primarily due to the workforce reduction announced in January of 2009. In addition, share-based compensation decreased by \$0.3 million. See *Results of Operations: Share-Based Compensation* for further discussion of our share-based compensation expense.

Our research and development activities can be divided into earlier stage programs and later stage programs. Earlier stage programs include molecular biology, process development, pilot-scale production and preclinical testing. Also included in earlier stage programs are costs related to excess manufacturing capacity, which we expect will continue to decrease in 2009 as we continue to consolidate facilities. Later stage programs include clinical testing, regulatory affairs and manufacturing clinical supplies. The costs associated with these programs approximate the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Earlier stage programs	\$ 10,073	\$ 16,775	\$ 23,063	\$ 28,320
Later stage programs	3,434	6,744	6,965	14,410
<b>Total</b>	<b>\$ 13,507</b>	<b>\$ 23,519</b>	<b>\$ 30,028</b>	<b>\$ 42,730</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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Internal projects	\$ 10,350	\$ 17,009	\$ 19,933	\$ 29,663
Collaborative and contract arrangements	3,157	6,510	10,095	13,067
<b>Total</b>	<b>\$ 13,507</b>	<b>\$ 23,519</b>	<b>\$ 30,028</b>	<b>\$ 42,730</b>

For the three and six months ended June 30, 2009, our largest development program (XOMA 052) accounted for more than 20% but less than 30% of our total research and development expense. For the three months ended June 30, 2009, one development program (NIAID 3) accounted for more than 10% but less than 20% of our total research and development expense, and for the six months ended June 30, 2009, two development programs (NIAID 3 and Novartis) accounting for more than 10% but less than 20% of our total research and development expense. No development program accounted for more than 30% of our total research and development expense in the first half of 2009. For the three and

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

six months ended June 30, 2008, our largest development program (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 expense.

---

**Table of Contents**

We currently expect our research and development spending in 2009 to be reduced as compared to 2008. In the third quarter of 2009, we plan to initiate a Phase 2 clinical development program in Type 2 diabetes and cardiovascular disease and will continue to seek to enter into a collaboration arrangement by the end of 2009.

Future research and development spending may 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.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses include salaries and related personnel costs, facilities costs and professional fees. Selling, general and administrative expenses were \$5.7 million and \$11.8 million for the three and six months ended June 30, 2009, compared with \$6.4 million and \$12.3 million for the same periods of 2008. The \$0.7 million and \$0.5 million decreases for the three and six months ended June 30, 2009, as compared to the same periods of 2008, primarily relates to decreases in salaries and employee-related expenses in 2009 as discussed below. These decreases were partially offset by \$0.3 million and \$0.5 million in fees incurred for the three and six months ended June 30, 2009, related to the potential restructuring of the Goldman Sachs term loan discussed in further detail below in the *Liquidity and Capital Resources* section.

We recorded salaries and employee-related expenses of \$3.2 million for the three months ended June 30, 2009, compared with \$4.3 million for the same period of 2008. The decrease of \$1.1 million for the second quarter of 2009 was primarily due to a decrease in share-based compensation of \$0.9 million. See *Results of Operations: Share-Based Compensation* for further discussion of our share-based compensation expense. In addition, salaries and benefits and accrued bonus expense decreased by \$0.2 million primarily due to the workforce reduction announced in January of 2009.

For the six months ended June 30, 2009, we recorded salaries and employee-related expenses of \$6.4 million, compared with \$7.6 million for the same period of 2008. The decrease of \$1.2 million for the first half of 2009 was primarily due to a decrease in share-based compensation of \$0.7 million. See *Results of Operations: Share-Based Compensation* for further discussion of our share-based compensation expense. In addition, salaries and benefits and accrued bonus expense decreased by \$0.5 million primarily due to the workforce reduction announced in January of 2009.

***Restructuring Charges***

As discussed in the *Overview* section, we announced a workforce reduction of approximately 42% in January of 2009. As part of this workforce reduction, in the first quarter of 2009, we recorded a charge of \$3.3 million related to severance, other termination benefits and outplacement services. In the second quarter of 2009, we recorded an adjustment of \$0.2 million to reduce the outplacement services liability upon expiration of such services offered to terminated employees.

As a result of the workforce reduction, we significantly reduced operations in four leased buildings in the first quarter of 2009. In the second quarter of 2009, we resumed operations in one of these buildings and vacated another resulting in a restructuring charge of \$0.5 million primarily related to the net present value of the future minimum lease payments, less the estimated future sublease income. We are currently seeking a sublease tenant. Our leases on the remaining two buildings expire in 2011 and 2013, and total minimum lease payments due from July 1, 2009 until expiration of the leases are \$4.6 million. We are currently evaluating our options as to the future use of these leased spaces.

As of June 30, 2009, in accordance with Statement of Financial Accounting Standards No. 144 *Accounting for Impairment or Disposal of Long-Lived Assets* ( SFAS 144 ), we performed an analysis of the long-lived assets related to the two leased buildings, with an approximate net book value of \$9.8 million. Based on estimated undiscounted future cash inflows, we have determined that there is no current impairment relating to these assets, and will continue to assess for impairment at each future reporting period.

We anticipate the potential for incurring further restructuring charges through the remainder of 2009 as we continue to evaluate our options as to the future use of our facilities.

***Other Income (Expense)***

Investment and interest income was \$8,000 and \$38,000 for the three and six months ended June 30, 2009, compared with \$0.2 million and \$0.6 million for the same periods of 2008. Investment and interest income consists primarily of interest earned on our cash and investment balances. The differences between 2009 and 2008 balances resulted from varying average cash balances and interest rates and a decrease in the investments balance.



**Table of Contents**

Interest expense and amortization of debt issuance costs for the Goldman Sachs term loan and Novartis note are shown below for the three and six months ended June 30, 2009 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
<b>Interest expense</b>				
Goldman Sachs term loan	\$ 1,225	\$ 1,098	\$ 2,779	\$ 1,890
Novartis note	119	342	243	692
Total interest expense	\$ 1,344	\$ 1,440	\$ 3,022	\$ 2,582
<b>Amortization of debt issuance costs</b>				
Goldman Sachs term loan	\$ 327	\$ 724	\$ 417	\$ 1,032
Total amortization of debt issuance costs	\$ 327	\$ 724	\$ 417	\$ 1,032
<b>Total interest expense</b>	\$ 1,671	\$ 2,164	\$ 3,439	\$ 3,614

The decrease in interest expense in 2009, as compared to the same periods of 2008, was due to a decrease in the amortization of debt issuance costs in 2009 related to the restructuring of the Goldman Sachs term loan in May of 2008, at which point the debt issuance costs related to the original term loan facility were fully amortized. Partially offsetting this decrease was an increase in interest expense related to the Goldman Sachs term loan due to a higher average principal balance for the six month period of 2009, as compared to the same period of 2008. Refer to the *Liquidity and Capital Resources: Goldman Sachs Term Loan* section for additional disclosure regarding this term loan. In addition, interest expense related to the Novartis note decreased for the three and six months ended June 30, 2009, as compared to the same periods of 2008, due to a decrease in the principal balance of this note.

Other income (expense) was \$1.1 million for both the three and six months ended June 30, 2009, compared with \$42,000 and \$(49,000) for the same periods of 2008. The increase in this balance primarily relates to the revaluation of our warrant liability at June 30, 2009. See *Results of Operations: Warrants Revaluation* below for additional disclosure.

**Warrants Revaluation**

We issued warrants to purchase XOMA's common shares in connection with two separate registered direct offerings completed in May and June of 2009. Refer to *Liquidity and Capital Resources: Other Equity Financings* for additional disclosure relating to these financing transactions.

The warrants issued include a provision allowing for an adjustment of the exercise price and number of warrant shares. This adjustment occurs if we issue or sell certain common shares in the future for a price per share less than the exercise price of the warrants in effect immediately prior to such issuance or sale. Due to this adjustment clause, these warrants are not considered indexed to our stock and are therefore subject to the liability and fair value re-measurement provisions under Statement of Financial Accounting Standards No. 133 *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133). The fair value of the warrants at the issuance dates were estimated using the Monte Carlo Simulation Model (Simulation Model) and we recorded liabilities of \$2.9 million and \$3.6 million for the May and June warrant issuances, respectively. We revalued the warrants at June 30, 2009 and recorded a decrease in the fair value of the warrants of \$1.0 million for the three and six months ended June 30, 2009. We will revalue the warrants at each reporting period using the Simulation Model and changes in the fair values of the warrants will continue to be recognized in our consolidated statement of operations throughout the life of the unexercised warrants.

**Income Taxes**

We recognized \$0.1 million in income tax benefit for the three months ended June 30, 2009 relating to refundable credits, compared with no income tax expense for the same period of 2008.

We recognized \$5.7 million in income tax expense for the six months ended June 30, 2009, primarily related to \$5.8 million of foreign income tax expense recognized in connection with the expansion of our existing collaboration with Takeda signed in February of 2009. We were paid a



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

\$29.0 million expansion fee, of which \$5.8 million was withheld for payment to the Japanese taxing authority. This expense was partially offset by the income tax benefit recognized in the second quarter of 2009 referred to above. No income tax expense was recognized for the six months ended June 30, 2008.

---

**Table of Contents**

Statement of Financial Accounting Standards No. 109 Accounting for Income Taxes ( SFAS 109 ) provides for the recognition of deferred tax assets if realization of such assets is more likely than not. Based upon the weight of available evidence, which includes our historical operating performance and carryback potential, we have determined that total deferred tax assets should be fully offset by a valuation allowance.

We did not have unrecognized tax benefits as of June 30, 2009 and do not expect this to change significantly over the next twelve months. In connection with the adoption of FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes ( FIN 48 ), we will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of June 30, 2009, we have not accrued interest or penalties related to uncertain tax positions.

**Share-Based Compensation**

In February of 2009, our Board of Directors approved a company-wide grant of 4,730,000 share options, of which 4,568,000 were issued as part of our annual incentive compensation package. These options vest monthly over four years and include an acceleration clause based on meeting certain performance measures. As of June 30, 2009, we have assessed the probability of achieving the performance measures and have determined that accelerated expense recognition is not appropriate at this time. We will reassess the probability at each future reporting period and accelerate expense recognition accordingly.

During the three and six months ended June 30, 2009, we recognized \$0.9 million and \$1.9 million in share-based compensation expense, compared to \$2.4 million and \$2.9 million for the same periods of 2008. The decrease in share-based compensation expense for the three and six months ended June 30, 2009, as compared to the same periods of 2008, was primarily due to increased expense recognized in the second quarter of 2008 related to 8.7 million options granted in February of 2008 and October of 2007 that were not deemed granted for accounting purposes until shareholder approval was obtained in May of 2008. In addition, share-based compensation for the first half of 2009 decreased due to a decline in outstanding options as a result of the workforce reduction in January of 2009.

As of June 30, 2009, there was \$9.7 million of unrecognized share-based compensation expense related to unvested shares with a weighted-average remaining recognition period of 2.6 years.

**Liquidity and Capital Resources**

Cash, cash equivalents and short-term investments at June 30, 2009 were \$27.6 million compared with \$10.8 million at December 31, 2008. Net cash provided by operating activities was \$1.4 million for the six months ended June 30, 2009, compared with net cash used in operating activities of \$26.4 million for the same period in 2008. The \$27.8 million increase in cash provided by operations for the six months ended June 30, 2009, as compared to same period of 2008, was primarily due to the receipt of \$23.2 million in the first quarter of 2009 related to the expansion of our existing collaboration with Takeda.

In addition, receivables decreased by \$10.4 million for the six months ended June 30, 2009 due to a decline in contract and royalty revenues, and accrued liabilities increased in the first half of 2009 by \$3.0 million related to restructuring charges, accrual of the 2009 employee bonus and costs accrued relating to the expansion of our existing collaboration with Takeda. These increases in cash were partially offset by a decrease in deferred revenue of \$7.3 million at June 30, 2009 related to a decline in advance billings and the recognition of the remaining deferred revenue related to upfront fees received for terminated programs with SPRI. In addition, the accounts payable balance decreased by \$5.4 million at June 30, 2009 related to the pay down of the balance in the period.

Comparatively, for the six months ended June 30, 2008, accrued liabilities decreased by \$1.4 million primarily related to the payment of 2007 bonuses in the first quarter of 2008, and deferred revenue decreased by \$1.7 million due to the timing of advance billings. Offsetting these decreases was an increase in accounts payable of \$3.3 million due to increased research and development and expenses in the period.

Net cash provided by investing activities was \$4.6 million for the six months ended June 30, 2009, compared with net cash provided by investing activities of \$1.8 million for the same period of 2008. Cash provided by investing activities in the first half of 2009 primarily consisted of a decrease in the restricted cash balance of \$3.5 million due to a principal and interest payment made in April of 2009 on our loan facility with Goldman Sachs, offset by funds received from our royalty streams. Cash received from our royalty streams is held in a restricted cash account for payment of interest due on our Goldman Sachs loan facility on April 1 and October 1 of each year. In addition, we received proceeds from maturities of investments in the period of \$1.3 million.

Net cash provided by investing activities for the six months ended June 30, 2008 consisted of \$9.5 million in net proceeds from investment transactions. Offsetting this cash inflow was an increase in restricted cash of \$2.3 million related to funds held in the restricted account due to the refinancing of the Goldman Sachs loan facility in May of 2008, and purchases of property and equipment of \$5.4 million in the first half of

2008.

**Table of Contents**

Net cash provided by financing activities was \$12.1 million for the six months ended June 30, 2009, compared with net cash provided by financing activities of \$22.9 million in the same period of 2008. Cash provided by financing activities in the first half of 2009 relates to proceeds received from the issuance of common shares of \$20.5 million, offset by principal repayments of our loan with Goldman Sachs of \$8.4 million. Cash provided by financing activities in the first half of 2008 represents net proceeds of \$22.7 million related to the refinancing of our loan facility with Goldman Sachs.

***Goldman Sachs Term Loan***

In May of 2008, we entered into a five-year amended and restated term loan facility with Goldman Sachs, refinancing our original facility entered into in November of 2006, and borrowed the full amount thereunder. As of June 30, 2009, the interest rate on the new facility was 11.5%. 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>. 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 the lenders. We may prepay indebtedness under the facility at any time, subject to certain prepayment premiums if prepaid during the first four years.

The on-going requirements of this loan facility include a financial test that requires us to maintain a specified ratio of royalties collected to interest payable and a requirement that quarterly U.S. sales of RAPTIVA<sup>®</sup> and LUCENTIS<sup>®</sup> and outside-the-U.S. sales of RAPTIVA<sup>®</sup> exceed certain specified minimum levels. Our ability to comply with these requirements depends on continuing sales by Genentech, UCB and their partners of RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup> at adequate levels, and any significant reduction in such sales results in a violation or default under these provisions, providing the lenders the right to accelerate our obligation to repay this debt.

As discussed in the *Overview* section, in the first quarter of 2009, RAPTIVA<sup>®</sup> was recommended for withdrawal from the European Union, Canadian and Australian markets, and in the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA<sup>®</sup> from the U.S. market. As a result of these events, we are no longer in compliance with the requirements of the relevant provisions of this loan facility, and as a consequence the lenders currently have the right to accelerate payment of the full amount of the loan. We have received a notice from our lenders to this effect and are currently in discussions with the lenders regarding a restructuring of the terms of this facility to address the effects of these developments, but we cannot be certain that we will reach agreement with the lenders on acceptable terms, or at all, as a result of these discussions or that the lenders will not accelerate payment of the loan at any time. If the lenders accelerate payment, currently we would not have the resources to pay the full amount due. Accordingly, the outstanding principal balance under the Goldman Sachs loan facility is classified as a current obligation at June 30, 2009.

The amount originally borrowed under the amended and restated loan facility was \$55.0 million and has since been reduced to \$42.0 million at June 30, 2009. Additionally, at June 30, 2009, the balance in restricted cash was \$6.1 million, which is available to pay interest and principal due under the facility.

***Novartis Note***

In May of 2005, we executed a secured note agreement with Novartis (then Chiron Corporation), which is due and payable in full in June of 2015. Under the note agreement, we borrowed semi-annually to fund up to 75% of our research and development and commercialization costs under our collaboration arrangement with Novartis, not to exceed \$50.0 million in aggregate principal amount. As of June 30, 2009, the interest rate was 3.18%. 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 all interest payments thus far. Loans under the note agreement are secured by our interest in the collaboration with Novartis, including any payments owed to us thereunder.

In November of 2008, we restructured our product development collaboration with Novartis. Pursuant to this restructuring, we will not make any additional borrowings on our Novartis note.

At June 30, 2009, the outstanding principal balance under this note agreement totaled \$13.1 million.

---

**Table of Contents*****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. The Purchase Agreement currently requires a minimum share price of \$1.00 per share to allow us to issue shares to Azimuth under the Facility. However, at its election, Azimuth may buy shares below the threshold price at a negotiated discount. We are not obligated to utilize any of the \$60 million Facility and remain free to enter other financing transactions. 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.

We did not sell any common shares under, or make any modifications to, this facility during the three or six months ended June 30, 2009, and \$52.5 million remains available under the Facility as of June 30, 2009, subject to certain conditions as discussed above.

***Other Equity Financings***

In May of 2009, we entered into a definitive agreement with an institutional investor to sell 11,764,706 units, with each unit consisting of one of our common shares and a warrant to purchase 0.50 of a common share, for gross proceeds of approximately \$10.0 million, before deducting placement agent fees and estimated offering expenses of \$0.8 million, in a registered direct offering. The investor purchased the units at a price of \$0.85 per unit. The warrants, which represent the right to acquire an aggregate of up to 5,882,353 common shares, are exercisable at any time on or after May 15, 2009 and prior to May 20, 2014 at an exercise price of \$1.02 per share.

In June of 2009, we entered into a definitive agreement with certain institutional investors to sell 10,434,782 units, with each unit consisting of one of our common shares and a warrant to purchase 0.50 of a common share, for gross proceeds of approximately \$12.0 million, before deducting placement agent fees and estimated offering expenses of \$0.8 million, in a second registered direct offering. The investor purchased the units at a price of \$1.15 per unit. The warrants, which represent the right to acquire an aggregate of up to 5,217,391 common shares, will be exercisable at any time on or after December 11, 2009 and prior to December 10, 2014 at an exercise price of \$1.30 per share.

We intend to use the \$20.4 million of net proceeds from these offerings to continue development of our XOMA 052 product candidate and for other working capital and general corporate purposes.

We have incurred significant operating losses and negative cash flows from operations since our inception. At June 30, 2009, we had cash and cash equivalents of \$27.6 million and restricted cash of \$6.1 million. During 2009, we expect to continue using our cash and cash equivalents to fund ongoing operations. Additional licensing, antibody discovery collaboration agreements, government funding and financing arrangements may positively impact our cash balances. Based on anticipated spending levels, revenues, collaborator funding 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 the next twelve months, excluding a potential acceleration of our loan from Goldman Sachs, as discussed above in this section. 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 addition, as a result of recent events, the lenders under our loan from Goldman Sachs currently have the right to accelerate payment of the full amount of the loan. In the event the lenders accelerate full payment of this loan or we are not able to restructure the terms of the loan and otherwise maintain at least twelve months of cash resources, there will 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. We continue to engage in a rigorous cost-saving program, which includes decreasing activity levels and related expenses in certain of our product development programs. If adequate funds are not available, we have developed contingency plans that may require us to delay, reduce the scope of, or eliminate one or more of our product development programs and further reduce personnel-related costs.

Our independent registered public accounting firm included in their report for our fiscal year ended December 31, 2008 a qualification with respect to our ability to continue as a going concern. Our interim financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we would have to liquidate our assets and the values we receive for our assets in liquidation could be significantly lower than the values at which they are carried on our consolidated financial statements. The inclusion of a going concern qualification in our independent registered public accounting firm's audit opinion for the year ended December 31, 2008 may materially adversely affect our share price and our ability to raise new capital.

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 *Item 1A: Risk Factors*.



## **Table of Contents**

### **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, research and development expense, long-lived assets and share-based compensation to be critical policies. There have been no significant changes in our critical accounting policies during the six months ended June 30, 2009, except as noted below, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 11, 2009 ( 2008 Form 10-K ).

#### ***Long-Lived Assets***

In accordance with SFAS 144, we record impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. At June 30, 2009, we have determined there is no material impairment relating to our long-lived assets, and will continue to assess for impairment at each future reporting period.

#### ***Accounting for Warrant Liability***

We issued warrants to purchase XOMA's common shares in connection with two separate registered direct offerings completed in May and June of 2009. The warrants issued include a provision allowing for an adjustment of the exercise price and number of warrant shares. This adjustment occurs if we issue or sell certain common shares in the future for a price per share less than the exercise price of the warrants in effect immediately prior to such issuance or sale. Due to this adjustment provision, the warrants do not meet the criteria set forth by the Emerging Issues Task Force ( EITF ) of the Financial Accounting Standards Board ( FASB ) in EITF Issue 07-5 Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock ( EITF 07-5 ) and therefore are not considered indexed to the Company's own stock.

Accordingly, we have accounted for these warrants under SFAS 133. The fair value of the warrants at the issuance date was estimated using the Simulation Model and recorded as a liability. The warrants were revalued at June 30, 2009 using the Simulation Model and the change in the fair value of the warrants was recognized in other income (expense) in our statement of operations. We will revalue the unexercised warrants on each reporting date over the life of the warrants using the Simulation Model, and the changes in the fair value of the warrants will be recognized in other income (expense) in our statement of operations.

#### ***Accrued Restructuring Costs***

In the second quarter of 2009, we vacated one of our leased buildings and are currently seeking a sublease tenant. In accordance with Statement of Financial Accounting Standards No. 146 Accounting for Costs Associated with Exit or Disposal Activities ( SFAS 146 ), we recorded a restructuring charge in the second quarter of 2009 for the net present value of the future minimum lease payments, offset by potential future sublease payments. These charges are shown as restructuring expense in our consolidated statement of operations for the three and six months ended June 30, 2009. If the amount of sublease income changes in the future based on changes in our estimates, we will adjust the related liability for the estimated net present value of the lease.

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

Certain statements contained herein related to discussions with our lenders regarding our Goldman Sachs loan, the sufficiency of our cash resources, and our efforts to enter into a collaborative arrangement with respect to XOMA 052, 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, discussions with our lenders may not result in an agreement to restructure our loan facility on acceptable terms, or at all, and our lenders could accelerate payment of the loan at any time; the period for which our cash resources are sufficient could be shortened if our lenders accelerate payment of our loan from Goldman Sachs, if expenditures are made earlier or in larger amounts than anticipated or are unanticipated, if anticipated revenues or cost sharing arrangements do not materialize, or if funds are not otherwise available on acceptable terms; and, we may not be able to enter into a collaborative arrangement with respect to XOMA 052 on acceptable terms by the end of 2009, or at all. These and other risks, including those related to the results of preclinical testing; the timing or results of pending and future clinical trials (including the design and progress of clinical trials; safety and efficacy of the products being tested; action, inaction or delay by the FDA, European or other regulators or their advisory bodies; and analysis or interpretation by, or submission to, these entities or others of scientific data); changes in the status of existing collaborative relationships; the ability of collaborators and other partners to meet their obligations; our ability to meet the demand of the United States government agency with which we have entered our government contracts; 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 twelve months. However, if the need arose to liquidate such securities before maturity, we may experience losses on liquidation. We do not invest in derivative financial instruments.

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-average interest rates of our cash and investments at June 30, 2009 and December 31, 2008 (in thousands, except interest rates):

	<b>Maturity</b>	<b>Carrying Amount (in thousands)</b>	<b>Fair Value (in thousands)</b>	<b>Average Interest Rate</b>
<b>June 30, 2009</b>				
Cash and cash equivalents	Daily to 90 days	\$ 27,616	\$ 27,616	0.38%
<b>December 31, 2008</b>				
Cash and cash equivalents	Daily to 90 days	\$ 9,513	\$ 9,513	2.67%
Short-term investments	91 days to less than 12 months	1,301	1,299	4.64%

In May of 2008, we entered into a five-year, \$55.0 million amended and restated term loan facility with Goldman Sachs, refinancing our original facility entered into in November of 2006, and borrowed the full amount thereunder. As of June 30, 2009, \$42.0 million remains outstanding under the new facility, which is classified as a current obligation. Interest on the new facility is charged at a rate of the greater of (x) six-month LIBOR or (y) 3.0%, plus 8.5%, which was 11.5% at June 30, 2009.





## **Table of Contents**

As of June 30, 2009, we have an outstanding principal balance on our note with Novartis of \$13.1 million, which is due in 2015. The interest rate on this note is charged at a rate of six-month LIBOR plus 2%, which was 3.18% at June 30, 2009. No further borrowing is 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 \$559,000 on an annualized basis.

## **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 Vice President, Finance and Chief Financial 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 Vice President, Finance and Chief Financial 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**

On April 9, 2009, a complaint was filed in the Superior Court of Alameda County, California, in a lawsuit captioned Hedrick et al. v. Genentech, Inc. et al., Case No. 09-446158. The complaint asserts claims against Genentech, XOMA Ltd. ( the Company ) and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraud, wrongful death and other claims based on injuries alleged to have occurred as a result of three individuals' treatment with RAPTIVA<sup>®</sup>. The complaint seeks unspecified compensatory and punitive damages. On April 29, 2009 and May 22, 2009, two additional complaints were filed in the same court in lawsuits captioned Heinen et al v. Genentech, Inc., et al., Case No. 09-449804 and York et al v. Genentech, Inc., et al., Case No. 09-453932. Those complaints allege the same claims and seek the same types of damages based on injuries alleged to have occurred as a result of two individuals' treatment with RAPTIVA<sup>®</sup>. The Company's agreement with Genentech provides for an indemnity of XOMA and payment of legal fees by Genentech which the Company believes is applicable to this matter. The Company believes the claims against it to be without merit and intends to defend against them vigorously.

There were no developments material to the Company in the United States Bankruptcy Court proceedings involving Apton Corporation (described in the Company's Annual Report on Form 10-K for the year ended December 31, 2008) during the quarter ended June 30, 2009.

**Table of Contents****ITEM 1a. RISK FACTORS**

The following risk factors and other information included in this annual 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.

**As a result of the recent cessation of sales of RAPTIVA<sup>®</sup>, we are no longer in compliance with the requirements of the relevant provisions of our loan facility with Goldman Sachs, and as a consequence the lenders currently have the right to accelerate payment of the full amount of the loan.**

Our loan agreement with Goldman Sachs Specialty Lending Holdings, Inc. ( Goldman Sachs ) includes provisions that allow the lenders to accelerate our obligation to repay the debt or to pursue other remedies against us in certain circumstances. For example, the terms of this debt include a financial test that requires us to maintain a specified ratio of royalties collected to interest payable and another requirement that quarterly U.S. sales of RAPTIVA<sup>®</sup> and LUCENTIS<sup>®</sup> and outside-the-U.S. sales of RAPTIVA<sup>®</sup> exceed certain specified minimum levels. This means that our ability to comply with these requirements depends on continuing sales by Genentech, Inc. (a wholly-owned member of the Roche Group ( Roche ), referred to herein as Genentech ), UCB Celltech, a branch of UCB S.A ( UCB ) and their partners of RAPTIVA<sup>®</sup> and CIMZIA<sup>®</sup> at adequate levels, and any significant reduction in such sales results in a violation or default under these provisions, providing the lenders the right to accelerate our obligation to repay this debt.

In February of 2009, the European Medicines Agency ( EMEA ) announced that it had recommended suspension of the marketing authorization of RAPTIVA<sup>®</sup> in the European Union and EMD Serono Inc., the company that markets RAPTIVA<sup>®</sup> in Canada ( EMD Serono ) announced that, in consultation with Health Canada, the Canadian health authority ( Health Canada ), it will suspend marketing of RAPTIVA<sup>®</sup> in Canada. In March of 2009, Merck Serono Australia Pty Ltd, the company that markets RAPTIVA<sup>®</sup> in Australia ( Merck Serono Australia ), following a recommendation from the Therapeutic Goods Administration, the Australian health authority ( TGA ), announced that it was withdrawing RAPTIVA<sup>®</sup> from the Australian market. In the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA<sup>®</sup> from the U.S. market, based on the association of RAPTIVA<sup>®</sup> with an increased risk of progressive multifocal leukoencephalopathy ( PML ). As a result of these events, we are no longer in compliance with the requirements of the relevant provisions of our loan from Goldman Sachs, and as a consequence the lenders currently have the right to accelerate payment of the full amount of the loan. We have received a notice from our lenders to this effect and are currently in discussions with the lenders regarding a restructuring of the terms of this facility to address the effects of these developments, but we cannot be certain that we will reach agreement with the lenders on acceptable terms, or at all, as a result of these discussions or that the lenders will not accelerate payment of the loan at any time. If the lenders accelerate payment, currently we would not have the resources to pay the full amount due.

**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.**

While our refocused business strategy will reduce capital expenditures and other operating expenses, we will need to commit substantial funds to continue development of our product candidates and we may not be able to obtain sufficient funds on acceptable terms, or at all. 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,

various human clinical trials, and

protection of our intellectual property.

We finance our operations primarily through our multiple revenue streams resulting from the licensing of our antibody technologies, product royalties, development collaborations and biodefense contracts, and sales of XOMA's common shares. Based on anticipated spending levels, revenues, collaborator funding and other sources of funding we believe to be available, we estimate that we have sufficient cash resources to

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

meet our anticipated net cash needs through the next twelve months, excluding a potential acceleration of payment under our loan with Goldman Sachs. Any significant revenue shortfalls, increases in planned spending on

---

**Table of Contents**

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 addition, as a result of the recent cessation of sales of RAPTIVA<sup>®</sup>, we are no longer in compliance with the requirements of the relevant provisions of our loan from Goldman Sachs, and as a consequence the lenders under this loan currently have the right to accelerate payment of the full amount of the loan. In the event the lenders accelerate full payment of this loan or we are not able to restructure the terms of the loan and otherwise maintain at least twelve months of cash resources, there will be substantial doubt as to our ability to continue as a going concern. If adequate funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our product development programs and further reduce personnel-related costs. 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,

royalties will be sufficient to meet debt covenants,

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.

**Our independent registered public accountants have indicated there is substantial doubt as to our ability to continue as a going concern.**

Our independent registered public accounting firm has included in their report for our fiscal year ended December 31, 2008 a qualification with respect to our ability to continue as a going concern. Our interim financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we would have to liquidate our assets and the values we receive for our assets in liquidation could be significantly lower than the values at which they are carried on our consolidated financial statements. The inclusion of a going concern qualification in our independent registered public accounting firm's audit opinion for the year ended December 31, 2008 may materially adversely affect our share price and our ability to raise new capital.

**Global credit and financial market conditions may reduce our ability to access capital and cash and could negatively impact the value of our current portfolio of cash equivalents or short-term investments and our ability to meet our financing objectives.**

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 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 in the past been unable to retrieve the full amount of funds, even in highly-rated liquid money market accounts, upon maturity. Although as of June 30, 2009, we have received the full amount of proceeds from money market fund investments, an inability to retrieve funds from money market and similar short-term investments as they mature in the future could have a material and adverse impact on our business, results of operations and cash flows.

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments since June 30, 2009, no assurance can be given that further deterioration in conditions of

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

the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments or our ability to meet our financing objectives.

---

**Table of Contents**

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

As of June 30, 2009, we had approximately \$55.1 million of indebtedness outstanding, including \$13.1 million with Novartis AG ( Novartis ) classified as long-term debt, and \$42.0 million with Goldman Sachs classified as a current obligation. 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 original collaboration with Novartis, Novartis extended a loan to us (through our U.S. subsidiary) to fund up to 75% of our expenses thereunder. The loan bears interest at an annual rate of six-month LIBOR plus 2%, which was equal to 3.18% at June 30, 2009, and any unpaid principal amount together with accrued and unpaid interest is due and payable in full in June of 2015. This loan is secured on a first priority basis by a pledge of our interest in the collaboration. Although the collaboration was restructured in November of 2008 and we may not draw any additional funds under the loan facility, we remain liable for amounts previously borrowed under this facility.

In November of 2006, our U.S. subsidiary entered into a five-year, \$35.0 million term royalty-based loan facility with Goldman Sachs and borrowed the full amount thereunder. In May of 2008, this term loan facility was replaced with a new five-year term royalty-based loan facility. The loan bears interest at an annual rate equal to the greater of six-month LIBOR or 3%, plus a margin of 8.5%. As of June 30, 2009, the interest rate on this loan was 11.5%.

The Goldman Sachs loan is guaranteed by XOMA and secured on a first priority basis 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 without the consent of the lenders.

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.**

NASDAQ-listed companies are subject to delisting for, among other things, failure to maintain a minimum closing bid price per share of \$1.00 for 30 consecutive business days. The closing price per share of our common shares has been below \$1.00 for all but six days since December 9, 2008. Although NASDAQ temporarily suspended the minimum bid price requirement in response to current market conditions, this suspension expired on July 31, 2009, and there can be no assurance that any such suspension will be granted in the future.



---

**Table of Contents**

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.

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.

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 June 30, 2009, we had an accumulated deficit of \$789.1 million.

For the quarter ended June 30, 2009, we had a net loss of approximately \$10.2 million or \$0.07 per common share (basic and diluted). For the quarter ended June 30, 2008, we had a net loss of approximately \$20.7 million or \$0.16 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 August 3, 2009, 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 164,593,517 were issued and outstanding as of August 3, 2009. 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. Through August 3, 2009, we have sold 7,932,432 common shares under this facility for aggregate gross proceeds of \$7.5 million.

**Table of Contents**

**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, 2009 through August 3, 2009, our share price has ranged from a high of \$1.34 to a low of \$0.37. Factors contributing to such volatility include, but are not limited to:

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

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, including XOMA 052 and XOMA 3AB, 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.

---

## **Table of Contents**

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.

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 BLA 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, BLA, 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. 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, and such data may have a material impact on the FDA product approval process.

**Even once approved, a product may be subject to additional testing or significant marketing restrictions, its approval may be withdrawn or it may be voluntarily taken off the market.**

Even if the FDA, the European Commission or another regulatory agency approves a product candidate for marketing, the approval may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials, and the FDA, European Commission or other regulatory agency may subsequently withdraw approval based on these additional trials.

Even for approved products, the FDA, European Commission or other regulatory agency may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product.

Furthermore, a marketing approval of a product may be withdrawn by the FDA, the European Commission or another regulatory agency or such a product may be voluntarily withdrawn by the company marketing it based, for example, on subsequently-arising safety concerns. In February of 2009, the EMEA announced that it had recommended suspension of the marketing authorization of RAPTIVA® in the European Union and that its Committee for Medicinal Products for Human Use ( CHMP ) had concluded that the benefits of RAPTIVA® no longer outweigh its risks because of safety concerns, including the occurrence of PML in patients taking the medicine. In the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA® from the U.S. market, based on the association of RAPTIVA® with an increased risk of PML.

The FDA, European Commission and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

---

**Table of Contents**

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

Our potential products, including XOMA 052 and XOMA 3AB, 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. In the fourth quarter of 2008, we decided to curtail all spending on XOMA 629 in response to current economic conditions and to focus our financial resources on XOMA 052.

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 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. Preclinical 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 preclinical studies for some compounds in a particular research and development program may occur in

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

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,

---

## **Table of Contents**

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 bacterial cell expression 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.

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

Currently, our revenues rely significantly upon sales of LUCENTIS<sup>®</sup>, in which we have only a royalty interest. 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<sup>®</sup> in the U.S. and Switzerland for the treatment of moderate-to-severe Crohn's disease and in the U.S. for the treatment of moderate-to-severe rheumatoid arthritis, in which we only have a royalty interest. 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 CHMP of the EMEA had rejected UCB's appeal following CHMP's previously-announced refusal of UCB's marketing authorization application for CIMZIA<sup>®</sup> in the treatment of Crohn's disease. CIMZIA<sup>®</sup> was approved by the FDA in May of 2009 for the treatment of moderate-to-severe rheumatoid arthritis in adults. 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, Novartis and UCB do not have an express contractual obligation to us regarding the marketing or sales of LUCENTIS<sup>®</sup> or CIMZIA<sup>®</sup>.

Successful commercialization of LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup> is subject to a number of risks, including, but not limited to:

Genentech'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 age-related macular degeneration, Crohn's disease and rheumatoid arthritis;

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

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

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

pricing and reimbursement issues; and

expiration of patents and royalties.



---

## **Table of Contents**

According to Roche, U.S. sales of LUCENTIS<sup>®</sup> were 573 million Swiss francs, approximately \$503 million, for the first six months of 2009 compared with \$414 million for the first six months of 2008. According to Novartis, sales of LUCENTIS<sup>®</sup> outside the United States were \$523 million for the first six months of 2009 compared with \$437 million for the first six months of 2008.

Given our current reliance on LUCENTIS<sup>®</sup> as a principal source of revenues, any material adverse developments with respect to the commercialization of LUCENTIS<sup>®</sup> may cause our revenues to decrease and may cause us to incur additional 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 LUCENTIS<sup>®</sup> was approved in the United States in June of 2006, in the European Union in January of 2007 and in Japan in January of 2009, its acceptance in the marketplace may not continue. Although CIMZIA<sup>®</sup> was approved in the United States in April of 2008 and in Switzerland in September of 2007 for the treatment of Crohn's disease, and in the United States in May of 2009 for the treatment of rheumatoid arthritis, 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 LUCENTIS<sup>®</sup> or CIMZIA<sup>®</sup>, 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, in February of 2009, the EMEA announced that it had recommended suspension of the marketing authorization of RAPTIVA<sup>®</sup> in the European Union and EMD Serono announced that, in consultation with Health Canada, it will suspend marketing of RAPTIVA<sup>®</sup> in Canada. In March of 2009, Merck Serono Australia, following a recommendation from the TGA, announced that it is withdrawing RAPTIVA<sup>®</sup> from the Australian market. In the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA<sup>®</sup> from the U.S. market, based on the association of RAPTIVA<sup>®</sup> with an increased risk of PML. As a result, sales of RAPTIVA<sup>®</sup> ceased in the second quarter of 2009.

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 LUCENTIS<sup>®</sup>. UCB is responsible for manufacturing or arranging for the manufacturing of commercial quantities of CIMZIA<sup>®</sup>. Should Genentech or UCB 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.

**Table of Contents**

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 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 entitled us to a royalty interest on worldwide net sales. In February of 2009, the EMEA announced that it had recommended suspension of the marketing authorization of RAPTIVA® in the European Union and EMD Serono announced that, in consultation with Health Canada, it would suspend marketing of RAPTIVA® in Canada. In March of 2009, Merck Serono Australia, following a recommendation from the TGA, announced that it was withdrawing RAPTIVA® from the Australian market. In the second quarter of 2009, Genentech announced and carried out a phased voluntary withdrawal of RAPTIVA® from the U.S. market, based on the association of RAPTIVA® with an increased risk of PML. As a result, sales of RAPTIVA® ceased in the second quarter of 2009.

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 chronic lymphocytic leukemia. 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 HCD122 program. In exchange for cash and debt reduction on our existing loan facility with Novartis, Novartis has control over the HCD122 program and the additional ongoing program, as well as the right to expand the development of these programs into additional indications outside of oncology. We may, in the future, receive milestones of up to \$14.0 million and double-digit royalty rates for two ongoing product programs, including HCD122. The agreement also provides us with options to develop or receive royalties on four additional programs.

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 awarded 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 bacterial cell expression 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 June 30, 2009, 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 and rheumatoid arthritis.

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 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, 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 arrangement 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 Pharmaceuticals, Inc. ( 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.

---

**Table of Contents**

In September of 2006, we entered into an agreement with Taligen Therapeutics, Inc. ( Taligen ) which formalized an earlier letter agreement, which was signed in May of 2006, for the development and 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 which provided that we would 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 provided that we would conduct and complete the technical transfer of the process to Avecia Biologics Limited or its designated affiliate ( Avecia ). The letter agreement also provided that, subject to payment by Taligen of approximately \$1.7 million, we would grant to Avecia a non-exclusive, worldwide, paid-up, non-transferable, non-sublicensable, perpetual license under our owned project innovations. We received \$0.6 million as the first installment under the payment terms of the letter agreement but not the two additional payments totaling approximately \$1.1 million to which we were entitled upon fulfillment of certain obligations. In May of 2009, the matter was resolved by agreement of the parties in a manner that had no further impact on the Company's financial position.

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*

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

XOMA has initiated clinical testing of XOMA 052, a potent anti-inflammatory monoclonal antibody targeting IL-1 beta, 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 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 rheumatoid arthritis. AMG 108 showed statistically significant improvement in the signs and symptoms of rheumatoid arthritis and was well tolerated. Amgen announced it is focusing on other opportunities for the antibody.

---

**Table of Contents**

In 2008, Biovitrum AB obtained a worldwide exclusive license to Amgen Inc.'s Kineret® (anakinra) for its current approved indication. Kineret® is an IL-1 receptor antagonist (IL-1ra) currently marketed to treat rheumatoid arthritis and 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.

In June of 2009, Novartis announced it had received marketing approval for Ilaris® (canakinumab), a fully human monoclonal antibody targeting IL-1 beta, to treat children and adults with Cryopyrin-Associated Periodic Syndromes ( CAPS ). In July of 2009, Novartis announced that Ilaris® was recommended for approval in the European Union for CAPS. Canakinumab is also in clinical trials in Type 2 diabetes, chronic obstructive pulmonary disorder, certain forms of gout and systemic juvenile rheumatoid arthritis.

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 CAPS, 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.

*XOMA 3AB*

In May of 2006, the U.S. Department of Health & Human Services 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 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.

*LUCENTIS®*

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

In February of 2008, the National Eye Institute ( NEI ) of the National Institutes of Health announced the start of a multicenter clinical trial to compare the relative safety and effectiveness of LUCENTIS® and Avastin®, which targets the same protein as LUCENTIS® and, according to NEI, has been widely used to treat the same indication as LUCENTIS® even though Avastin® is not approved for that indication. Avastin® is currently priced lower than LUCENTIS® and, according to NEI, may remain in the eye longer than LUCENTIS®, possibly allowing for less frequent injections. The study is expected to enroll 1,200 patients and include 57 centers. Final data collection for the primary outcome measure is expected by February of 2010, and the study is expected to be completed by February of 2011. Results of this trial favoring Avastin® could have a material adverse effect on sales of LUCENTIS® and, consequently, on our subsequent royalty payments based thereon.

---

## **Table of Contents**

### *CIMZIA®*

In addition to CIMZIA®, there are four other FDA-approved anti-TNF therapies to treat moderate-to-severe rheumatoid arthritis: Amgen's Enbrel® (etanercept), Johnson & Johnson's Remicade® (infliximab), Simponi (golimumab) and Abbott Laboratories' Humira® (adalimumab), with two of them, infliximab and adalimumab, also approved for moderate-to-severe active Crohn's disease in adults.

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

To the extent we continue to provide manufacturing services for our own benefit or to third parties, we are subject to manufacturing risks. Additionally, unanticipated fluctuations in customer requirements have led and may continue to lead to manufacturing inefficiencies. We must utilize our manufacturing operations 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, product modification or customer or to meet changing regulatory or third party requirements, and this work may not be successfully or efficiently completed. In addition, to the extent we continue to provide manufacturing services, our fixed costs, such as facility costs, would be expected to increase, as would necessary capital investment in equipment and facilities.

Manufacturing and quality problems may arise in the future to the extent we continue to perform these services for our own benefit or for third parties. Consequently, our development goals or milestones may not be achieved in a timely manner or at a commercially reasonable cost, or at all. In addition, to the extent we continue to make investments to improve our manufacturing operations, our efforts may not yield the improvements that we expect.

### **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 bacterial cell expression 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 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,

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.



---

## Table of Contents

**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:

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.

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 bacterial cell expression 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 bacterial cell expression 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

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

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.

---

## **Table of Contents**

### **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.

### **We are exposed to an increased risk of product liability claims, and one such case is currently pending against us.**

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.

On April 9, 2009, a complaint was filed in the Superior Court of Alameda County, California, in a lawsuit captioned Hedrick et al. v. Genentech, Inc. et al., Case No. 09-446158. The complaint asserts claims against Genentech, us and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraud, wrongful death and other claims based on injuries alleged to have occurred as a result of three individuals' treatment with RAPTIV<sup>®</sup>. The complaint seeks unspecified

---

## **Table of Contents**

compensatory and punitive damages. On April 29, 2009 and May 22, 2009, two additional complaints were filed in the same court in lawsuits captioned Heinen et al v. Genentech, Inc., et al, Case No. 09-449804 and York et al v. Genentech, Inc., et al, Case No. 09-453932. Those complaints allege the same claims and seek the same types of damages based on injuries alleged to have occurred as a result of two individuals treatment with RAPTIVA®. Even though Genentech has agreed to indemnify us, there can be no assurance that this or other products liability lawsuits will not result in liability to us or that our insurance or contractual arrangements will provide us with adequate protection against such liabilities.

### **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; Fred Kurland, our Vice President, Finance and Chief Financial Officer; Patrick J. Scannon, M.D., Ph.D., our Executive Vice President and Chief Medical Officer; and Christopher J. Margolin, our Vice President, General Counsel and Secretary. We currently have no key person insurance on any of our employees.

### **We may not realize the expected benefits of our initiatives to reduce costs across our operations, and we may incur significant charges or write-downs as part of these efforts.**

We are pursuing and may continue to pursue a number of initiatives to reduce costs across our operations. In January of 2009, we implemented a workforce reduction of approximately 42% in order to improve our cost structure. We expect an annualized reduction of approximately \$27 million in cash expenditures when changes are completed. We recorded charges during the first six months of 2009 of \$3.1 million for severance, other employee benefits and outplacement services related to the workforce reduction. In the second quarter of 2009, we vacated one of our leased buildings and recorded a restructuring charge of \$0.5 million primarily related to the net present value of the net future minimum lease payments, less the estimated future sublease income. We anticipate that we will incur some level of restructuring charges through the remainder of 2009 as we continue to consolidate facilities.

As a result of the workforce reduction, we significantly reduced operations in four leased buildings in the first quarter of 2009. In the second quarter of 2009, we resumed operations in one of these buildings and vacated another resulting in a restructuring charge. The net book value of fixed assets in two remaining buildings potentially subject to write-down is approximately \$9.8 million as of June 30, 2009. Although we have determined that there was no impairment of these assets as of June 30, 2009, there can be no assurance that we will not determine otherwise as of a future date and as a consequence write down these assets as impaired, and any such write-down may be significant.

We may not realize some or all of the expected benefits of our current and future initiatives to reduce costs. In addition to restructuring or other charges, we may experience disruptions in our operations as a result of these initiatives and write-downs.

### **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 190 employees as of August 3, 2009. 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.



---

**Table of Contents**

**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.

**It may be difficult to enforce a judgment obtained 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 bye-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 bye-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 bye-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.

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

As a result of the recent cessation of sales of RAPTIVA<sup>®</sup>, the Company has been notified by the lenders under its loan facility with Goldman Sachs that it is no longer in compliance with the provisions of the loan facility requiring quarterly sales of RAPTIVA<sup>®</sup> to exceed certain specified minimum levels and that, as a consequence, the lenders currently have the right (among others) to accelerate payment of the full amount of the loan. The notice also states that it does not constitute an exercise by the lenders of any remedies but that the lenders reserve their right to do so at any time. If the lenders accelerate payment, currently the Company would not have the resources to pay the full amount due. See *Note 1 to Condensed Consolidated Financial Statements in Part I, Item 1* above under Liquidity and Financial Condition, and *Part I, Item 2* above under Liquidity and Capital Resources Goldman Sachs Term Loan.

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

On May 21, 2009, the Company held its 2009 annual general meeting of shareholders. The following persons (the only nominees) were elected as the Company's directors, having received the indicated votes:

<i>Name</i>	<i>Votes For</i>	<i>Votes Withheld</i>
Steven B. Engle	106,055,362	10,044,513
Patrick J. Scannon, M.D., Ph.D.	106,133,234	9,966,641
William K. Bowes, Jr.	98,998,529	17,101,346
Charles J. Fisher, Jr., M.D.	99,545,729	16,554,146
Peter Barton Hutt	105,935,037	10,164,838
W. Denman Van Ness	99,146,127	16,953,748
John Varian	106,257,992	9,841,883
Patrick J. Zenner	106,029,381	10,070,494

The proposal to appoint Ernst & Young LLP to act as the Company's independent auditors for the 2009 fiscal year and authorize the Board to agree to such auditors' fee was approved, having received 107,989,143 votes for, 7,190,509 votes against, 920,223 abstentions and zero broker non-votes.

The proposal to approve an increase of the Company's authorized share capital by the creation of an additional 190,000,000 common shares was approved, having received 86,923,718 votes for, 24,815,606 votes against, 4,360,551 abstentions and zero broker non-votes.

The proposal to approve an amendment to the Company's 1981 Share Option Plan to increase the number of shares issuable over the term of the plan by 6,500,000 shares to 32,100,000 shares in the aggregate was approved, having received 38,943,295 votes for, 9,297,847 votes against, 3,913,120 abstentions and 63,945,613 broker non-votes.

The proposal to approve an amendment to the Company's 1992 Directors Share Option Plan to, effective as of July 1, 2008, (a) increase the number of shares automatically granted under such plan to non-employee directors (other than the Lead Independent Director) to 35,000 per year, (b) change the number of shares automatically granted to non-employee directors who serve in the capacity of Lead Independent Director to 45,000 per year, and (c) increase the number of shares granted to non-employee directors as an initial grant on first becoming a director to 70,000 was approved, having received 41,691,763 votes for, 6,493,007 votes against, 3,969,492 abstentions and 63,945,613 broker non-votes.

The proposal to approve an amendment to the Company's 1992 Directors Share Option Plan to extend the vesting of options granted under such plan on or after July 1, 2008 to (a) monthly over three years, in the case of initial awards and (2) monthly over one year, in the case of annual awards was approved, having received 42,395,089 votes for, 5,784,547 votes against, 3,974,626 abstentions and 63,945,613 broker non-votes.



**Table of Contents**

The proposal to approve an increase in the number of shares issuable over the term of the Company's 1992 Directors Share Option Plan by 250,000 shares to 1,600,000 shares was approved, having received 41,962,487 votes for, 6,337,759 votes against, 3,854,016 abstentions and 63,945,613 broker non-votes.

**ITEM 5. OTHER INFORMATION**

None.

**Table of Contents**

**ITEM 6. EXHIBITS**

**Exhibit  
Number**

31.1	Certification of Steven B. Engle, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Fred Kurland, 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 Fred Kurland, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1	Press Release dated August 6, 2009, 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: August 6, 2009

By: /s/ STEVEN B. ENGLE  
Steven B. Engle

Chairman, Chief Executive Officer and President

Date: August 6, 2009

By: /s/ FRED KURLAND  
Fred Kurland

Vice President, Finance and Chief Financial Officer