

XOMA LTD /DE/  
Form 10-Q  
May 06, 2010  
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 March 31, 2010

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 0-14710

**XOMA Ltd.**

(Exact name of registrant as specified in its charter)

**Bermuda**  
(State or other jurisdiction of  
incorporation or organization)

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

**2910 Seventh Street, Berkeley,**

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

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

including zip code)

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 May 4, 2010
Common Shares, U.S. \$0.0005 par value	261,247,750

---

**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 March 31, 2010 and December 31, 2009</u>	1
<u>Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2010 and 2009</u>	2
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2010 and 2009</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>	15
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	23
Item 4. <u>Controls and Procedures</u>	24
<b><u>PART II OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	24
Item 1A. <u>Risk Factors</u>	24
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	41
Item 3. <u>Defaults Upon Senior Securities</u>	41
Item 4. <u>Reserved</u>	41
Item 5. <u>Other Information</u>	41
Item 6. <u>Exhibits</u>	42
<u>Signatures</u>	43

**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)

	March 31, 2010 (unaudited)	December 31, 2009 (Note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 28,417	\$ 23,909
Trade and other receivables, net	7,792	7,231
Prepaid expenses and other current assets	1,219	1,012
Total current assets	37,428	32,152
Property and equipment, net	18,865	20,270
Other assets	402	402
Total assets	\$ 56,695	\$ 52,824
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,176	\$ 2,942
Accrued liabilities	6,146	8,639
Deferred revenue	1,582	2,114
Warrant liabilities	7,788	4,760
Other current liabilities	104	223
Total current liabilities	19,796	18,678
Deferred revenue long-term	1,865	2,894
Interest bearing obligation long-term	13,341	13,341
Other long-term liabilities	360	385
Total liabilities	35,362	35,298
Shareholders equity:		
Preference shares, \$0.05 par value, 1,000,000 shares authorized		
Series A, 210,000 designated, no shares issued and outstanding at March 31, 2010 and December 31, 2009		
Series B, 8,000 designated, 2,959 shares issued and outstanding at March 31, 2010 and December 31, 2009 (aggregate liquidation preference of \$29.6 million)	1	1
Common shares, \$0.0005 par value, 400,000,000 shares authorized, 261,247,750 and 203,042,194 shares outstanding at March 31, 2010 and December 31, 2009, respectively	131	101
Additional paid-in capital	827,540	801,978
Accumulated deficit	(806,339)	(784,554)
Total shareholders equity	21,333	17,526

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

Total liabilities and shareholders' equity	\$ 56,695	\$ 52,824
--	-----------	-----------

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

*(Note 1) The condensed consolidated balance sheet as of December 31, 2009 has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.*

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

	<b>Three months ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Revenues:</b>		
License and collaborative fees	\$ 189	\$ 27,700
Contract and other revenue	6,811	7,398
Royalties	202	4,606
<b>Total revenues</b>	<b>7,202</b>	<b>39,704</b>
<b>Operating expenses:</b>		
Research and development (including contract related of \$3,901 and \$7,436, respectively, for the three months ended March 31, 2010 and 2009)	17,587	16,521
Selling, general and administrative	5,553	6,120
Restructuring		3,289
<b>Total operating expenses</b>	<b>23,140</b>	<b>25,930</b>
<b>Income (loss) from operations</b>	<b>(15,938)</b>	<b>13,774</b>
<b>Other income (expense):</b>		
Investment and interest income	3	30
Interest expense	(87)	(1,768)
Other income (expense)	(5,763)	3
<b>Net income (loss) before taxes</b>	<b>(21,785)</b>	<b>12,039</b>
<b>Provision for income tax expense</b>		<b>5,800</b>
<b>Net income (loss)</b>	<b>\$ (21,785)</b>	<b>\$ 6,239</b>
<b>Basic and diluted net income (loss) per common share</b>	<b>\$ (0.09)</b>	<b>\$ 0.04</b>
Shares used in computing basic net income (loss) per common share	239,493	141,772
Shares used in computing diluted net income (loss) per common share	239,493	145,596

*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>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ (21,785)	\$ 6,239
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>		
Depreciation and amortization	1,511	1,816
Common shares contribution to 401(k) and management incentive plans	905	1,198
Share-based compensation expense	961	1,029
Accrued interest on interest bearing obligations	81	1,677
Revaluation of warrant liabilities	1,261	
Amortization of discount, premium and debt issuance costs of interest bearing obligations		90
Warrant modification expense	4,500	
Other non-cash adjustments	1	1
<b>Changes in assets and liabilities:</b>		
Receivables	(561)	7,397
Prepaid expenses and other assets	(207)	318
Accounts payable and accrued liabilities	(1,340)	(2,097)
Deferred revenue	(1,561)	(2,237)
Other liabilities	(144)	(92)
Net cash (used in) provided by operating activities	(16,378)	15,339
<b>Cash flows from investing activities:</b>		
Proceeds from maturities of investments		1,300
Transfer of restricted cash		(4,453)
Purchase of property and equipment	(107)	(179)
Net cash used in investing activities	(107)	(3,332)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common shares	25,493	41
Payment for modification of warrants	(4,500)	
Net cash provided by financing activities	20,993	41
Net increase in cash and cash equivalents	4,508	12,048
Cash and cash equivalents at the beginning of the period	23,909	9,513
Cash and cash equivalents at the end of the period	\$ 28,417	\$ 21,561
<b>Supplemental Cash Flow Information:</b>		
<b>Cash paid during the quarter for:</b>		
Income taxes, including foreign withholding taxes	\$	\$ 5,800

Non-cash investing and financing activities:

Issuance and extinguishment of warrant liabilities	\$	1,767	\$
--	----	-------	----

*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. Description of Business**

XOMA Ltd. ( XOMA or the Company ), a Bermuda company, is a biopharmaceutical company focused on the discovery, development and manufacture of therapeutic antibodies 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.

**2. Basis of Presentation and Significant Accounting Policies**

**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, 2009, filed with the U.S. Securities and Exchange Commission on March 11, 2010, as amended on April 30, 2010.

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 March 31, 2010, the consolidated results of the Company's operations for the three months ended March 31, 2010 and 2009, and the Company's cash flows for the three months ended March 31, 2010 and 2009. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year or future periods.

**Liquidity and Financial Condition**

The Company has incurred significant operating losses and negative cash flows from operations since its inception. As of March 31, 2010, the Company had an accumulated deficit of \$806.3 million, cash and cash equivalents of \$28.4 million and working capital of \$17.6 million. Based on cash and cash equivalents on hand at March 31, 2010 and anticipated spending levels, funding from collaborators including a XOMA 052 corporate partnership, licensing transactions or biodefense contracts 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.

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. Furthermore, any additional equity financings may be dilutive to shareholders and debt financing, if available, may involve restrictive covenants. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue business strategies. If adequate funds are not available, the Company 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 further reduce personnel-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**

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an on-going basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, long-lived assets, warrant liabilities 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 and receivables are financial instruments, which potentially subject the Company to concentrations of credit risk, as well as liquidity risk for certain cash equivalents such as money market funds. The Company has not encountered such issues during 2010.

The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the three months ended March 31, 2010, two customers represented 49% and 38% of total revenue and as of March 31, 2010, there were receivables outstanding from three customers representing 34%, 28% and 28% of the accounts receivable balance. For the three months ended March 31, 2009, two customers represented 73% and 11% of total revenues.

### **Recent Accounting Pronouncements**

In March of 2010, Accounting Standards Codification Topic 605, *Revenue Recognition* ( ASC 605 ) was amended to define a milestone and clarify that the milestone method of revenue recognition is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, a Company can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The Company will adopt this guidance in the third quarter of 2010 on a prospective basis. The Company is assessing the impact of this guidance on its consolidated results of operations and financial condition.

Accounting Standards Update No. 2009-13, Revenue Recognition Topic 605: *Multiple Deliverable Revenue Arrangements – A Consensus of the FASB Emerging Issues Task Force* ( ASU 2009-13 ) provides application guidance on whether multiple deliverables exist, how the deliverables should be separated and how the consideration should be allocated to one or more units of accounting. This update establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. The Company will adopt this guidance from January 1, 2011. The Company is assessing the impact of this guidance on its consolidated results of operations and financial condition.

In February of 2010, Accounting Standards Codification Topic 855, *Subsequent Events* ( ASC 855 ) was amended by Accounting Standards Update No. 2010-09 ( ASU 2010-09 ) which removed the requirement that a public entity disclose the date through which it evaluated subsequent events in the financial statements. ASU 2010-09 was effective upon issuance in February of 2010 and did not have a material effect on the Company's financial statements.

### **Significant Accounting Policies**

#### ***Warrant Liabilities***

In February of 2010, the Company issued warrants to purchase XOMA's common shares in connection with an underwritten offering. Refer to *Note 7: Long-term Debt and Other Financings – Other Financings* for additional disclosure relating to this transaction. The Company has accounted for the warrants issued in February of 2010 as a liability at fair value, due to a provision included in the warrant agreement that allows the warrant holders an option to require the Company (or its successor) to purchase their warrants for cash in an amount equal to their Black-Scholes Option Pricing Model (the Black-Scholes Model) value, in the event of a change in control of the Company (the Change in Control Provisions). The fair value of the warrant liability is estimated using the Black-Scholes Model which requires inputs such as the expected term of the warrants, share price volatility and risk-free interest rate. These assumptions are reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants are recognized in the other income (expense) line of the condensed consolidated statements of operations.



**Table of Contents**

Also in February of 2010, the holders of warrants issued in May and June of 2009 agreed to amend the terms of their warrants to remove the provisions that would have required a reduction of the warrant exercise price and an increase in the number of shares issuable on exercise of the warrants each time the Company sold common shares at a price less than the exercise price of such warrants (the Eliminated Adjustment Provisions). Refer to *Note 7: Long-term Debt and Other Financings - Other Financings* for additional disclosures relating to these warrants. Prior to amendment, the Company recorded the warrants issued in May and June of 2009 as liabilities at fair value due to the Change in Control Provisions and the Eliminated Adjustment Provisions. These liabilities were estimated using the Monte Carlo Simulation Model (Simulation Model), which, in addition to the Black-Scholes Model inputs referred to above, required the Company to consider the probability and timing of future equity financings in the estimation to reflect the value of the Eliminated Adjustment Provisions. These assumptions were reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants were recognized in the other income (expense) line.

After amendment on February 2, 2010, the Company continued to account for the warrants issued in May and June of 2009 as liabilities at fair value, due to the Change in Control Provisions. With the removal of the Eliminated Adjustment Provisions, the fair value of the warrants is now estimated using the Black-Scholes Model. The assumptions used in the Black-Scholes Model are reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants are recognized in the other income (expense) line. As of March 31, 2010, all warrants issued in May of 2009 had been exercised and the related liability was fully extinguished and reclassified to additional paid-in capital in the Company's condensed consolidated balance sheet.

**3. Condensed Consolidated Financial Statement Detail****Comprehensive Income (Loss)**

Unrealized gain on the Company's available-for-sale securities is included in accumulated comprehensive income (loss). Comprehensive income (loss) and its components for the three months ended March 31, 2010 and 2009 was as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Net income (loss)	\$ (21,785)	\$ 6,239
Unrealized gain on securities available-for-sale		2
<b>Comprehensive income (loss)</b>	<b>\$ (21,785)</b>	<b>\$ 6,241</b>

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

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Options for common shares	18,359	21,222
Convertible preference shares	3,818	
Warrants for common shares	24,117	
<b>Total</b>	<b>46,294</b>	<b>21,222</b>



**Table of Contents**

For the three months ended March 31, 2009, the following is a reconciliation of the numerators and denominators of the basic and diluted net income per share (in thousands):

	<b>Three Months Ended March 31, 2009</b>
<b>Numerator</b>	
Net income used for diluted net income per share	\$ 6,239
<b>Denominator</b>	
Weighted average shares outstanding used for basic net income per share	141,772
Effect of dilutive share options	6
Effect of convertible preference shares	3,818
 Weighted average shares outstanding and dilutive securities used for diluted net income per share	 145,596

For the three months ended March 31, 2010, all outstanding securities were considered anti-dilutive, and therefore the calculation of basic and diluted net loss per share was the same.

**Cash and Cash Equivalents**

At March 31, 2010 and December 31, 2009, cash equivalents consisted of overnight deposits, money market funds and repurchase agreements with maturities of less than 90 days at the date of purchase. Cash and cash equivalent balances were recorded at fair value as follows as of March 31, 2010 and December 31, 2009 (in thousands):

	<b>March 31, 2010</b>			<b>Estimated Fair Value</b>
	<b>Cost Basis</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	
Cash	\$ 3,175	\$	\$	\$ 3,175
Cash equivalents	25,242			25,242
<b>Total cash and cash equivalents</b>	<b>\$ 28,417</b>	<b>\$</b>	<b>\$</b>	<b>\$ 28,417</b>

	<b>December 31, 2009</b>			<b>Estimated Fair Value</b>
	<b>Cost Basis</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	
Cash	\$ 3,065	\$	\$	\$ 3,065
Cash equivalents	20,844			20,844
<b>Total cash and cash equivalents</b>	<b>\$ 23,909</b>	<b>\$</b>	<b>\$</b>	<b>\$ 23,909</b>

**Receivables**

Receivables consisted of the following at March 31, 2010 and December 31, 2009 (in thousands):

<b>March 31, 2010</b>	<b>December 31, 2009</b>
---------------------------	------------------------------

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

Trade receivables, net	\$ 7,232	\$ 6,391
Other receivables	560	840
<b>Total</b>	<b>\$ 7,792</b>	<b>\$ 7,231</b>

Trade receivables at March 31, 2010 and December 31, 2009 includes \$2 million related to an antibody discovery collaboration entered into in September of 2009 with Arana Therapeutics Limited, a wholly-owned subsidiary of Cephalon, Inc. ( Arana ), which is due in September of 2010, and \$2 million related to an antibody discovery collaboration entered into in October of 2009 with The Chemo-Sero-Therapeutic Research Institute, a Japanese research foundation known as Kaketsuken, which is due in October of 2010.

**Table of Contents****Accrued Liabilities**

Accrued liabilities consisted of the following at March 31, 2010 and December 31, 2009 (in thousands):

	March 31, 2010	December 31, 2009
Accrued payroll and other benefits	\$ 2,252	\$ 2,691
Accrued management incentive compensation	1,046	3,681
Accrued clinical trial costs	1,043	609
Accrued professional fees	769	767
Accrued restructuring costs	139	155
Other	897	736
<b>Total</b>	<b>\$ 6,146</b>	<b>\$ 8,639</b>

**4. Licensing, Collaborative and Other Arrangements****Takeda**

In November of 2006, the Company entered into a fully-funded collaboration agreement with Takeda Pharmaceutical Company Limited ( Takeda ) for therapeutic monoclonal antibody discovery and development, which was expanded in the first quarter of 2009 to include access to multiple antibody technologies. In the first quarter of 2010, the Company received a \$1 million payment from Takeda for achieving a pre-established, pre-clinical milestone under one of the Company's discovery and development programs with Takeda. The Company recognized this milestone payment in revenue in the first quarter of 2010 as the milestone was achieved.

Separately, another discovery and development program with Takeda under this collaboration was discontinued following the analysis of research data. The termination resulted in the recognition of the remaining unamortized balance in deferred revenue of \$1.1 million pertaining to the discontinued program as no continuing performance obligations exist.

**5. Restructuring Charges**

On January 15, 2009, the Company announced a workforce reduction of approximately 42%. As part of this workforce reduction, the Company recorded a charge of \$3.3 million related to severance, other termination benefits and outplacement services, which were fully paid in 2009. The Company does not expect to incur any additional employee-related restructuring charges in connection with this workforce reduction.

As a result of the workforce reduction, in 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. The remaining liability related to this restructuring charge was \$0.3 million and \$0.4 million at March 31, 2010 and December 31, 2009, respectively.

Additionally, as a result of the workforce reduction, the Company has temporarily vacated a building in order to optimize its facility usage. As manufacturing demand increases in the future, the Company plans to resume operations at this facility. As of March 31, 2010, the Company performed an analysis of the long-lived assets related to the vacant building, with an approximate net book value of \$4.0 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 these assets for impairment at each future reporting period.

**6. Fair Value Measurements**

The following tables set forth the Company's fair value hierarchy for its financial assets (cash equivalents) and liabilities measured at fair value on a recurring basis as of March 31, 2010 and December 31, 2009.





**Table of Contents**

Financial assets carried at fair value as of March 31, 2010 and December 31, 2009 were classified as follows (in thousands):

	Fair Value Measurements at March 31, 2010 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	\$ 12,895	\$ 12,895	\$	\$
Money market funds	12,347	12,347		
<b>Total</b>	<b>\$ 25,242</b>	<b>\$ 25,242</b>	<b>\$</b>	<b>\$</b>

	Fair Value Measurements at December 31, 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	\$ 6,504	\$ 6,504	\$	\$
Money market funds	14,340	14,340		
<b>Total</b>	<b>\$ 20,844</b>	<b>\$ 20,844</b>	<b>\$</b>	<b>\$</b>

Financial liabilities carried at fair value as of March 31, 2010 and December 31, 2009 were classified as follows (in thousands):

	Fair Value Measurements at March 31, 2010 Using			
	Total	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liabilities	\$ 7,788	\$	\$	\$ 7,788
<b>Total</b>	<b>\$ 7,788</b>	<b>\$</b>	<b>\$</b>	<b>\$ 7,788</b>

	Fair Value Measurements at December 31, 2009 Using			
	Total	Quoted Prices in Active Markets for Identical Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liabilities	\$ 4,760	\$	\$	\$ 4,760
<b>Total</b>	<b>\$ 4,760</b>	<b>\$</b>	<b>\$</b>	<b>\$ 4,760</b>



**Table of Contents**

As discussed in *Note 2: Basis of Presentation and Significant Accounting Policies – Significant Accounting Policies*, the fair value of the warrant liabilities was determined at March 31, 2010 using the Black-Scholes Model and at December 31, 2009 using the Simulation Model, both of which require inputs such as the expected term of the warrants, share price volatility and risk-free interest rate. These inputs are subjective and generally require significant analysis and judgment to develop.

The fair value of the warrant liabilities was estimated using the following range of assumptions at March 31, 2010 and December 31, 2009:

	March 31, 2010	December 31, 2009
Expected volatility	78.2 - 78.6%	77.0 - 77.7%
Risk-free interest rate	2.6%	2.4 - 2.7%
Expected term	4.7 - 4.9 years	4.4 - 5.0 years

The following table provides a summary of changes in the fair value of the Company's Level 3 financial liabilities for the three month period ended March 31, 2010 (in thousands):

	Warrant Liabilities
Balance at December 31, 2009	\$ 4,760
Initial fair value of warrants issued in February 2010	4,382
Reclassification of warrant liability to equity upon exercise of warrants	(2,615)
Net increase in fair value of warrant liabilities on revaluation	1,261
Balance at March 31, 2010	\$ 7,788

The net increase in the estimated fair value of the warrant liabilities was recognized as an expense in the other income (expense) line of the condensed consolidated statements of operations.

The Company had long-term debt with a carrying amount of \$13.3 million at March 31, 2010 and December 31, 2009, as further discussed below in *Note 7: Long-Term Debt and Other Financings*. The fair value of the Company's debt approximated \$6 million and \$4.7 million at March 31, 2010 and December 31, 2009, respectively, based on the net present value of future payments discounted at interest rates consistent with then current borrowing rates offered to the Company.

**7. Long-Term Debt and Other Financings****Long-Term Debt***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 million in aggregate principal amount. Interest on the principal amount of the loan accrues at six-month LIBOR plus 2%, which was equal to 2.44% at March 31, 2010, and is payable semi-annually in June and December of each year. At the Company's election, the semi-annual interest payments can be added to the outstanding principal amount, in lieu of a cash payment, as long as the aggregate principal amount does not exceed \$50 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 payments owed to it thereunder.

At March 31, 2010 and December 31, 2009, the outstanding principal balance under this note agreement was \$13.3 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.



**Table of Contents**

Interest expense and amortization of debt issuance costs for the Novartis note and Goldman Sachs Specialty Lending Holdings, Inc. ( Goldman Sachs ) term loan, which was repaid in September of 2009, are shown below (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Interest expense</b>		
Goldman Sachs term loan	\$	\$ 1,554
Novartis note	81	124
Other	6	
<b>Total interest expense</b>	<b>\$ 87</b>	<b>\$ 1,678</b>
<b>Amortization of debt issuance costs</b>		
Goldman Sachs term loan	\$	\$ 90
Total amortization of debt issuance costs	\$	\$ 90
<b>Total interest expense</b>	<b>\$ 87</b>	<b>\$ 1,768</b>

**Other Financings***Underwritten Offering*

In February of 2010, the Company completed an underwritten offering of 42 million units, with each unit consisting of one of the Company's common shares and a warrant to purchase 0.45 of a common share, for gross proceeds of approximately \$21 million, before deducting underwriting discounts and commissions and estimated offering expenses of \$1.7 million. The warrants, which represent the right to acquire an aggregate of up to 18.9 million common shares, are exercisable beginning six months and one day after issuance and have a five-year term and an exercise price of \$0.70 per share.

As discussed in *Note 2: Basis of Presentation and Significant Accounting Policies Significant Accounting Policies*, the fair value of the warrants at the issuance date was estimated using the Black-Scholes Model, and the Company recorded a warrant liability of \$4.4 million. The Company revalued the warrant liability at March 31, 2010 and recorded an increase in the fair value of the warrant liability of \$2.0 million in the other income (expense) line of the Company's condensed consolidated statement of operations.

*Modification of May 2009 Warrants*

In May of 2009, the Company issued warrants to an institutional investor as part of a registered direct offering. The warrants represented the right to acquire an aggregate of up to 5,882,353 common shares over a five year period beginning May 15, 2009 at an exercise price of \$1.02 per share. In February of 2010, the holders of these warrants agreed to amend the terms of their warrants to remove the Eliminated Adjustment Provisions and the exercise price of these warrants was reduced from \$1.02 per share to \$0.001 per share.

As discussed in *Note 2: Basis of Presentation and Significant Accounting Policies Significant Accounting Policies*, these warrants were recorded as a warrant liability at fair value, which, prior to amendment of the warrants, was estimated using the Simulation Model. The fair value of the warrant liability using the Simulation Model was \$2.9 million on February 1, 2010, prior to amendment of the warrants, resulting in the Company recording an increase in the fair value of the warrant liability of \$0.5 million in the other income (expense) line of the Company's condensed consolidated statement of operations. Subsequent to amendment of the warrant terms, on February 2, 2010, the fair value of the warrant liability using the Black-Scholes Model was \$2.6 million, resulting in the Company recording a decrease in the fair value of the warrant liability of \$0.3 million in the other income (expense) line.

The holders of these warrants subsequently exercised all their warrants, acquiring 5,882,353 common shares for an aggregate exercise price of \$5,882. As of March 31, 2010, none of the warrants issued in May of 2009 remained outstanding and the related liability was fully extinguished and reclassified to additional paid-in capital in the Company's condensed consolidated balance sheet.

*Modification of June 2009 Warrants*

In June of 2009, the Company issued warrants to certain institutional investors as part of a separate registered direct offering. The warrants represent the right to acquire an aggregate of up to 5,217,391 common shares over a five year period beginning December 11, 2009 at an exercise price of \$1.30 per share. In February of 2010, the holders of these warrants agreed to amend the

**Table of Contents**

terms of their warrants to remove the Eliminated Adjustment Provisions and the Company made a cash payment of \$4.5 million to these warrant holders, which was recorded in the other income (expense) line of the Company's condensed consolidated statement of operations. The exercise price of these warrants remained unchanged at \$1.30 per share.

As discussed in *Note 2: Basis of Presentation and Significant Accounting Policies - Significant Accounting Policies*, the warrants are recorded as a warrant liability at fair value, which, prior to amendment of the warrants, was estimated using the Simulation Model. The fair value of the warrant liability using the Simulation Model was \$3.3 million on February 1, 2010, prior to amendment of the warrants, resulting in the Company recording an increase in the fair value of the warrant liability of \$0.9 million in the other income (expense) line. The Company revalued the warrants at March 31, 2010 using the Black-Scholes Model and recorded a decrease in the fair value of the warrant liability of \$1.9 million in the other income (expense) line.

***ATM Agreement***

In the third quarter of 2009, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement"), with Wm Smith & Co. (Wm Smith), under which the Company may sell up to 25 million of its common shares from time to time through Wm Smith, as the agent for the offer and sale of the common shares. Wm Smith may sell these common shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act of 1933, including but not limited to sales made directly on The NASDAQ Global Market, on any other existing trading market for the common shares or to or through a market maker. Wm Smith may also sell the common shares in privately negotiated transactions, subject to the Company's approval. The Company pays Wm Smith a commission equal to 3% of the gross proceeds of all common shares sold through it as sales agent under the ATM Agreement but in no event less than \$0.02 per share. Shares sold under the ATM Agreement are sold pursuant to a prospectus which forms a part of a registration statement declared effective by the Securities and Exchange Commission on May 29, 2008. From the inception of the ATM Agreement through March 31, 2010, the Company sold a total of 12,990,842 common shares through Wm Smith for aggregate gross proceeds of \$9.3 million, including 8,940,225 common shares sold in the first quarter of 2010 for aggregate gross proceeds of \$6.4 million. Total offering expenses incurred related to sales under the ATM Agreement from inception to March 31, 2010 were \$0.3 million.

**8. Income Taxes**

No income tax expense was recognized for three months ended March 31, 2010. The Company recognized \$5.8 million in foreign income tax expense for the three months ended March 31, 2009, in connection with the expansion of the Company's existing collaboration with Takeda, which was signed in February of 2009. The Company's effective tax rate will fluctuate from period to period due to several factors inherent in the nature of the Company's operations and business transactions. The factors that most significantly impact this rate include the variability of licensing transactions in foreign jurisdictions.

**9. Share-Based Compensation**

In March of 2010, the Board of Directors of the Company approved a company-wide grant of an aggregate of 12,987,100 share options. This grant included 12,840,100 options that were issued as part of the Company's annual incentive compensation review, of which 8,950,000 options were granted subject to shareholder approval of an increase in the number of shares available under the Company's existing share option plans. These options are not included in the options outstanding or granted disclosures or in share-based compensation expense as they are not deemed granted for accounting purposes until the foregoing shareholder approval is obtained. The Company will record a cumulative adjustment for share-based compensation expense based on the fair value of these options at the date of approval. The options granted as part of this annual incentive compensation review will vest monthly over four years.

As previously disclosed, the options granted in February of 2009 as part of the annual incentive compensation review include an acceleration clause based on meeting certain performance measures. In the third quarter of 2009, management determined that it was probable that the performance measures would be achieved. The Company accelerated expense recognition related to these options, with an estimated implicit service period of two years from the grant date.

As of March 31, 2010, the Company had approximately 5.0 million common shares reserved for future grant under its share option plans and Employee Share Purchase Plan (ESPP), excluding the 9.0 million options granted subject to shareholder approval, as discussed above.



**Table of Contents**

The following table shows total share-based compensation expense included in the condensed consolidated statements of operations for the three months ended March 31, 2010 and 2009 (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Research and development	\$ 457	\$ 553
Selling, general and administrative	504	476
<b>Total share-based compensation expense</b>	<b>\$ 961</b>	<b>\$ 1,029</b>

There was no capitalized share-based compensation cost as of March 31, 2010 or December 31, 2009, and there were no recognized tax benefits related to the Company's share-based compensation expense during the three months ended March 31, 2010 or 2009.

The valuation of share-based compensation awards is determined at the date of grant using the Black-Scholes Model. This model requires inputs such as the expected term of the option, expected volatility and risk-free interest rate. Further, 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 the expected term, volatility and forfeiture rate are derived primarily from the Company's historical data, the risk-free rate is based on the yield available on United States Treasury zero-coupon issues. The fair value of share-based awards was estimated based on the following weighted average assumptions for the three months ended March 31, 2010 and 2009:

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Dividend yield	0%	0%
Expected volatility	79%	73%
Risk-free interest rate	2.60%	1.76%
Expected term	5.6 years	5.6 years

Share option activity for the three months ended March 31, 2010 was as follows:

	<b>Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (in years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Options outstanding at December 31, 2009	22,801,533	\$ 2.56		
Granted	4,037,100	0.49		
Exercised	(292)	0.56		
Forfeited, expired or cancelled	(870,767)	4.01		
<b>Options outstanding at March 31, 2010</b>	<b>25,967,574</b>	<b>\$ 2.19</b>	<b>7.74</b>	<b>\$ 362</b>
<b>Options exercisable at March 31, 2010</b>	<b>12,994,574</b>	<b>\$ 3.06</b>	<b>6.59</b>	<b>\$ 13</b>

The total intrinsic value of the options exercised for the three months ended March 31, 2010 was not material.

At March 31, 2010, there was \$6.8 million of unrecognized share-based compensation expense related to unvested share options with a weighted average remaining recognition period of 2.7 years.

**10. Legal Proceedings, Commitments and Contingencies**

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

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, fraudulent concealment, 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. Since then, additional complaints have been filed in the same court, bringing the total number of pending cases to twenty-eight. All of the complaints allege the same claims and seek the same types of damages

**Table of Contents**

based on injuries alleged to have occurred as a result of the plaintiffs' treatment with RAPTIVA®. 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 Apton Corporation (described in XOMA's Annual Report on Form 10-K for the fiscal year ended December 31, 2009) during the three months ended March 31, 2010.

**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 are 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, but not limited to, those related to terms of revenue recognition, long-lived assets, warrant liabilities 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 designed to treat inflammatory, autoimmune, infectious and oncological diseases. Our proprietary development pipeline includes XOMA 052, an anti-interleukin-1 beta ( IL-1 beta ) antibody, XOMA 3AB, a biodefense anti-botulism antibody candidate, and preclinical antibody discovery programs in several indications. We have a fully-integrated product development platform, extending from preclinical science to development and manufacturing. We have multiple revenue streams resulting from the licensing of our antibody technologies, biodefense contracts and discovery and development collaborations and product royalties. Our technologies have contributed to the success of marketed antibody products, including LUCENTIS® (ranibizumab injection) for wet age-related macular degeneration and CIMZIA® (certolizumab pegol) for rheumatoid arthritis and Crohn's disease.

We have established on-going technology licensing programs for certain of our proprietary technologies, which have attracted numerous significant licensees including Bayer Healthcare AG, Johnson & Johnson (formerly Centocor, Inc.), Merck & Co., Inc. ( Merck ), Pfizer Inc. and Takeda Pharmaceutical Company Limited ( Takeda ). We have a premier antibody discovery and development platform that includes multiple antibody discovery or phage display libraries that increase our ability and that of our collaboration partners to discover new therapeutic antibodies. Once an antibody is discovered, we use a number of proprietary technologies including our Human Engineering , affinity maturation, bacterial cell expression and manufacturing technologies to enhance and improve the qualities of the antibodies for efficacy, safety, stability, productivity and cost. Some of XOMA's technologies are used widely across the industry and have generated significant revenues for the company. For example, bacterial cell expression technology is a key biotechnology for the discovery and manufacture of antibodies and other proteins. Thus far, more than 50 pharmaceutical and biotechnology companies have signed bacterial cell expression licenses with us, and a number of licensed product candidates are in clinical development.

Our biodefense initiatives currently include a \$65 million multiple-year contract funded by the National Institute of Allergy and Infectious Diseases ( NIAID ), a part of the National Institutes of Health ( NIH ), to support our ongoing development of drug candidates toward clinical trials in the treatment of botulism poisoning. This contract is the third that NIAID has awarded us for the development of botulinum antitoxins and brings the program's total awards to nearly \$100 million. We also develop products with premier pharmaceutical companies including Novartis AG ( Novartis ), Schering-Plough Research Institute, a division of Schering Corporation, which is now a subsidiary of Merck (referred to herein as Merck/Schering-Plough ), and Takeda.

**Significant Developments in 2010*****Proprietary Pipeline***

In February of 2010, we announced that enrollment had begun in a 325-patient Phase 2b dose-ranging clinical trial of XOMA 052 in Type 2 diabetes patients. The clinical trials are designed to further evaluate the use of multiple dose regimens on the safety, pharmacodynamics and efficacy of XOMA 052 in cardiometabolic and other diseases, and based on positive results, to select doses for pivotal Phase 3 studies.

In March of 2010, we announced the initiation of a Phase 2 clinical trial of XOMA 052 in Type 1 diabetes patients funded by the Juvenile Diabetes Research Foundation.

**Table of Contents**

In April of 2010, we announced the issuance of two new U.S. patents, one covering methods of treating Type 2 diabetes with high affinity IL-1 beta antibodies and antibody fragments including XOMA 052, and one covering methods of treating IL-1 related inflammatory diseases including rheumatoid arthritis and osteoarthritis with XOMA 052 and other antibodies and antibody fragments with similar binding properties for human IL-1 beta.

**Collaboration Revenue**

In the first quarter of 2010, we received a \$1 million payment from Takeda for achieving a pre-established, pre-clinical milestone under our collaboration agreement.

**Financings**

In February of 2010, we completed an underwritten offering of 42 million units, with each unit consisting of one of our common shares and a warrant to purchase 0.45 of a common share, for gross proceeds of approximately \$21 million.

Also in February of 2010, the holders of the warrants issued in May and June of 2009 agreed to amend their warrants to remove the provisions that would have required a reduction of the warrant exercise price and an increase in the number of shares issuable on exercise of the warrants each time we sold common shares at a price less than the exercise price of such warrants (the Eliminated Adjustment Provisions) and the exercise price of the warrants issued in May of 2009 was reduced from \$1.02 per share to \$0.001 per share and we made a \$4.5 million payment to holders of the warrants issued in June of 2009. The exercise price of the warrants issued in June of 2009 remains unchanged at \$1.30 per share. The holders of the warrants issued in May of 2009 subsequently exercised all their warrants, acquiring 5,882,353 common shares for an aggregate exercise price of \$5,882.

In the first quarter of 2010, we sold 8,940,225 common shares through Wm Smith & Co. (Wm Smith), under our At Market Issuance Sales Agreement dated July 14, 2009 (the ATM Agreement), for aggregate gross proceeds of \$6.4 million.

**Other**

In March of 2010, we received a Staff Determination letter from The NASDAQ Stock Market LLC (NASDAQ) indicating that we have not regained compliance with the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market, pursuant to NASDAQ Listing Rule 5450(a)(1). As a result, our common shares would have been subject to delisting from The NASDAQ Global Market unless we requested a hearing before a NASDAQ Listing Qualifications Panel (the Panel) to present our plan for regaining compliance, which we have done. The delisting of our common shares has therefore been stayed pending the issuance of the Panel's decision following the hearing.

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

Total revenues for the three months ended March 31, 2010, and 2009, were as follows (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
License and collaborative fees	\$ 189	\$ 27,700
Contract and other revenue	6,811	7,398
Royalties	202	4,606
Total revenues	\$ 7,202	\$ 39,704

License and collaborative fee revenue includes fees and milestone payments related to the out-licensing of our products and technologies. The decrease in license and collaborative fee revenue for the three months ended March 31, 2010, as compared to the same period of 2009, was entirely due to \$27.5 million in revenue recognized in the first quarter of 2009 related to the expansion of our collaboration agreement with Takeda to provide Takeda with access to multiple antibody technologies. The generation of future revenue related to license fees and other collaborative arrangements is dependent on our ability to attract new licensees to our antibody and bacterial cell expression technologies and new collaboration partners. Depending on whether and when we obtain new licensees and collaboration partners, we expect to experience a decline in these revenues for 2010 from 2009 levels.

**Table of Contents**

Contract and other revenue decreased by \$0.6 million for the three months ended March 31, 2010, as compared to the same period of 2009. This revenue includes agreements where we provide contracted research and development and manufacturing services to our collaboration partners, including Takeda, Merck/Schering-Plough and NIAID. The decrease in contract and other revenue for the three months ended March 31, 2010 was primarily due to a decrease in revenue on our Merck/Schering-Plough contract of \$2.1 million, as a result of the termination of certain programs in 2009, and a decrease in revenue on our Novartis contract of \$2.1 million, due to the completion of work under this agreement in the third quarter of 2009.

These decreases were partially offset by increases in contract revenue related to work performed under our contract with NIAID Contract No. HHSN272200800028C ( NIAID 3 ) of \$2.4 million. In addition, contract revenue from our collaboration with Takeda increased by \$1.5 million in the first quarter of 2010, primarily related to a \$1 million payment for achieving a pre-established, pre-clinical milestone under one of our discovery and development programs with Takeda. We also recognized the remaining unamortized balance of \$1.1 million in deferred revenue pertaining to another discovery and development program with Takeda that was discontinued. These increases were partially offset by a decrease in other work performed under the Takeda collaboration.

Based on expected increases in revenue related to our NIAID 3 contract and our subcontract awards from SRI International, partially offset by decreases in contract revenue from other collaboration partners, we expect contract and other revenue in 2010 to remain comparable to 2009 levels or to slightly increase, depending on the timing and level of revenue generating activity.

Revenue from royalties decreased by \$4.4 million for the three months ended March 31, 2010, compared to the same period of 2009, primarily due to the sale of our LUCENTIS<sup>®</sup> royalty interest to Genentech, Inc., a wholly-owned member of the Roche Group (referred to herein as Genentech ) in the third quarter of 2009. Royalties earned from sales of LUCENTIS<sup>®</sup> during the first quarter of 2009 were \$2.4 million. Also contributing to the decrease in royalty revenue was the cessation of royalties earned from sales of RAPTIVA<sup>®</sup> in the second quarter of 2009. RAPTIVA<sup>®</sup> was withdrawn from the commercial drug markets in the first half of 2009. Royalties earned from sales of RAPTIVA<sup>®</sup> during the first quarter of 2009 were \$2.2 million.

Royalties earned from sales of CIMZIA<sup>®</sup> were \$0.2 million for the three months ended March 31, 2010. We receive royalties on U.S. sales of CIMZIA<sup>®</sup> for the treatment of Crohn's disease and on U.S. and Canadian sales of CIMZIA<sup>®</sup> for the treatment of moderate-to-severe rheumatoid arthritis in adults. Royalties earned from sales of CIMZIA<sup>®</sup> in the first quarter of 2009 were immaterial. We expect royalty revenue from sales of CIMZIA<sup>®</sup> to increase in 2010.

**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.

Research and development expenses were \$17.6 million for the three months ended March 31, 2010, compared with \$16.5 million for the same period of 2009. The increase of \$1.1 million for the three months ended March 31, 2010, as compared to the same period in 2009, was primarily due to increased spending on XOMA 052 related to the initiation of the Phase 2 clinical program. In addition, spending on NIAID 3 increased in the first quarter of 2010 due to increased activity under the contract. Partially offsetting these increases in spending were decreases in spending on Novartis-related contract activities, due to the completion of work under this agreement in the third quarter of 2009, and on Merck/Schering-Plough-related contract activities, due to the termination of certain programs in 2009.

Salaries and related personnel costs are a significant component of research and development expenses. We recorded \$7.0 million in research and development salaries and employee-related expenses for the three months ended March 31, 2010, as compared with \$7.6 million for the same period of 2009. The decrease of \$0.6 million for the first quarter of 2010 was primarily due to a decrease in salaries and benefits of \$0.6 million related to the workforce reduction in the first quarter of 2009. See *Results of Operations: Share-Based Compensation* for discussion of our share-based compensation expense.

**Table of Contents**

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 decrease in 2010 due to the consolidation of facilities. Later stage programs include clinical testing, regulatory affairs and manufacturing clinical supplies. The costs associated with these programs approximate the following (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Earlier stage programs	\$ 11,174	\$ 12,603
Later stage programs	6,413	3,918
<b>Total</b>	<b>\$ 17,587</b>	<b>\$ 16,521</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):

	<b>Three Months Ended March 31,</b>	
	<b>2010</b>	<b>2009</b>
Internal projects	\$ 13,686	\$ 9,084
Collaborative and contract arrangements	3,901	7,437
<b>Total</b>	<b>\$ 17,587</b>	<b>\$ 16,521</b>

For the three months ended March 31, 2010, our largest development program (XOMA 052) accounted for more than 30% but less than 40% of our total research and development expense, and one other development program (NIAID) accounted for more than 10% but less than 20% of our total research and development expense. All remaining development programs accounted for less than 10% of our total research and development expense for the three months ended March 31, 2010. For the three months ended March 31, 2009, our largest development program (XOMA 052) accounted for more than 20% but less than 30%, and two other development programs (NIAID and Novartis) each accounted for more than 10% but less than 20% of our total research and development expenses.

We expect our research and development spending in 2010 will increase due to the initiation of our Phase 2 clinical program for XOMA 052 in Type 2 diabetes and cardiovascular disease and in support of our biodefense contracts. We continue ongoing discussions with a number of companies for a corporate partnership to develop and commercialize XOMA 052.

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 \$5.6 million for the three months ended March 31, 2010, compared with \$6.1 million for the same period of 2009. The \$0.5 million decrease for the first quarter of 2010, as compared to the same period of 2009, relates to a decrease in salaries and related personnel costs of \$0.2 million, primarily related to the workforce reduction in the first quarter of 2009, and other decreases due to our continued focus on cost control.

***Restructuring Charges***

On January 15, 2009, we announced a workforce reduction of approximately 42%. As part of this workforce reduction, we recorded a charge of \$3.3 million related to severance, other termination benefits and outplacement services, which were fully paid in 2009. We do not expect to incur any additional employee-related restructuring charges in connection with this workforce reduction.



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

As a result of the workforce reduction, we temporarily vacated a building in order to optimize our facility usage. As manufacturing demand increases in the future, we plan to resume operations at this facility. As of March 31, 2010, we performed an analysis of the long-lived assets related to the vacant building, with an approximate net book value of \$4.0 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 these assets for impairment at each future reporting period.

## **Table of Contents**

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

Interest expense was \$0.1 million and \$1.8 million for the three months ended March 31, 2010 and 2009, respectively. The decrease in interest expense of \$1.7 million for the three months ended March 31, 2010, as compared to the same period of 2009, was primarily due to the repayment in full of the term loan facility with Goldman Sachs Specialty Lending Holdings, Inc. ( Goldman Sachs ) in September of 2009.

Other income (expense) was (\$5.8 million) and \$3,000 for the three months ended March 31, 2010 and 2009, respectively. The increase in other expense in 2010 primarily related to \$4.5 million paid in the first quarter of 2010 to the holders of warrants issued in June of 2009, upon modification of the terms. In addition, other expense includes losses of \$1.3 million recognized relating to the revaluation of our warrant liabilities during the period. See *Results of Operations: Warrant Liabilities* below for additional disclosure.

### ***Warrant Liabilities***

In February of 2010, we issued warrants to purchase XOMA's common shares in connection with an underwritten offering, as further discussed below in *Liquidity and Capital Resources: Underwritten Offering*. We have accounted for the warrants issued in February of 2010 as a liability at fair value as further discussed below in *Critical Accounting Estimates: Warrant Liabilities*. The fair value of the warrant liability at issuance date was estimated using the Black-Scholes Option Pricing Model (the Black-Scholes Model ) and we recorded a warrant liability of \$4.4 million. We revalued the warrant liability at March 31, 2010 and recorded an increase in the fair value of the warrant liability of \$2.0 million in other income (expense) in our condensed consolidated statement of operations.

In May of 2009, we issued warrants to an institutional investor as part of a registered direct offering. The warrants represented the right to acquire an aggregate of up to 5,882,353 common shares over a five year period beginning May 15, 2009 at an exercise price of \$1.02 per share. In February of 2010, the holders of these warrants agreed to amend the terms of their warrants to remove the Eliminated Adjustment Provisions and the exercise price of these warrants was reduced from \$1.02 per share to \$0.001 per share.

Prior to amendment, we recorded the warrants issued in May of 2009 as a liability at fair value due to the Eliminated Adjustment Provisions and certain other provisions as further discussed below in *Critical Accounting Estimates: Warrant Liabilities*, which was estimated using the Monte Carlo Simulation Model ( Simulation Model ). The fair value of the warrant liability was \$2.9 million on February 1, 2010, prior to amendment of the warrants, resulting in an increase in the fair value of the warrant liability of \$0.5 million which we recorded in other income (expense). Subsequent to amendment of the warrant terms, on February 2, 2010, the fair value of the warrant liability using the Black-Scholes Model was \$2.6 million, resulting in a decrease in the fair value of the warrant liability of \$0.3 million which we recorded in other income (expense). The holders of these warrants subsequently exercised all their warrants, acquiring 5,882,353 common shares for an aggregate exercise price of \$5,882. As of March 31, 2010, none of the warrants issued in May of 2009 remained outstanding and the related liability was fully extinguished and reclassified to additional paid-in capital.

In June of 2009, we issued warrants to certain institutional investors as part of a separate registered direct offering. The warrants represent the right to acquire an aggregate of up to 5,217,391 common shares over a five year period beginning December 11, 2009 at an exercise price of \$1.30 per share. In February of 2010, the holders of these warrants agreed to amend the terms of their warrants to remove the Eliminated Adjustment Provisions and we made a cash payment of \$4.5 million to these warrant holders, which was recorded in other income (expense). The exercise price of these warrants remained unchanged at \$1.30 per share.

Prior to amendment, we recorded the warrants issued in June of 2009 as a liability at fair value due to the Eliminated Adjustment Provisions and certain other provisions as further discussed below in *Critical Accounting Estimates: Warrant Liabilities*, which was estimated using the Simulation Model. The fair value of the warrant liability was \$3.3 million on February 1, 2010, prior to amendment of the warrants, resulting in an increase in the fair value of the warrant liability of \$0.9 million which we recorded in other income (expense). We revalued the warrants at March 31, 2010 using the Black-Scholes Model and recorded a decrease in the fair value of the warrant liability of \$1.9 million in other income (expense).

### ***Income Taxes***

No income tax expense was recognized for the three months ended March 31, 2010. We recognized \$5.8 million in foreign income tax expense for the three months ended March 31, 2009, in connection with the expansion in February of 2009 of our existing collaboration with Takeda. We were paid a \$29 million expansion fee, of which \$5.8 million was withheld for payment to the Japanese taxing authority.

Accounting Standards Codification Topic 740, *Income Taxes* ( ASC 740 ) 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 carry-back

potential, we have determined that total deferred tax assets should be fully offset by a valuation allowance.

---

## **Table of Contents**

We did not have unrecognized tax benefits as of March 31, 2010 and do not expect this to change significantly over the next twelve months. In accordance with ASC 740, we will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of March 31, 2010, we have not accrued interest or penalties related to uncertain tax positions.

### ***Share-Based Compensation***

In March of 2010, our Board of Directors approved a company-wide grant of an aggregate of 12,987,100 share options. This grant included 12,840,100 options that were issued as part of our annual incentive compensation review, of which 8,950,000 options were granted subject to shareholder approval of an increase in the number of shares available under our existing share option plans. These options are not included in the options outstanding or granted disclosures or in share-based compensation expense as they are not deemed granted for accounting purposes until the foregoing shareholder approval is obtained. We will record a cumulative adjustment for share-based compensation expense based on the fair value of these options at the date of approval. The options granted as part of this annual incentive compensation review will vest monthly over four years.

For the three months ended March 31, 2010, we recognized \$1.0 million in share-based compensation expense, compared with the same amount for the first quarter of 2009. As of March 31, 2010, there was \$6.8 million of unrecognized share-based compensation expense related to unvested share options with a weighted average remaining recognition period of 2.7 years.

### **Liquidity and Capital Resources**

Cash and cash equivalents at March 31, 2010 were \$28.4 million compared with \$23.9 million at December 31, 2009. Net cash used in operating activities was \$16.4 million for the three months ended March 31, 2010, compared with net cash provided by operations of \$15.3 million for the same period in 2009. The decrease in cash provided by operations for the three months ended March 31, 2010, as compared to same period of 2009, was primarily due to a decrease in revenue receipts for license and collaborative fees and royalties. In the first quarter of 2009, we received \$23.2 million related to the expansion of our existing collaboration with Takeda, and recognized royalty revenue from sales of LUCENTIS® and RAPTIVA® of \$4.6 million.

In addition, in the first quarter of 2010, net accounts payable and accrued liabilities decreased by \$1.3 million primarily related to the payment in the period of employee bonuses for 2009, and deferred revenue decreased by \$1.6 million primarily due to the accelerated recognition of the remaining \$1.1 million of the unamortized balance in deferred revenue pertaining to a discontinued discovery and development program under our collaboration with Takeda.

Comparatively, for the three months ended March 31, 2009, the decrease in receivables of \$7.4 million was primarily due to a decline in contract and royalty revenues. In addition, accrued interest on interest bearing obligations increased by \$1.7 million related to the interest payment due on the Goldman Sachs loan facility on April 1, 2009. These increases in cash were partially offset by a net decrease in the accounts payable and accrued liabilities balance of \$2.1 million related to the pay down of the accounts payable balance in the quarter, partially offset by restructuring charges in the period and an increase in clinical trial costs and costs accrued related to the expansion of our existing collaboration with Takeda.

Net cash used in investing activities was \$0.1 million for the three months ended March 31, 2010, compared with \$3.3 million for the same period of 2009. Cash used in investing activities for the three months ended March 31, 2010 consisted of purchases of fixed assets. Net cash used in investing activities of \$3.3 million for the three months ended March 31, 2009 primarily consisted of an increase in restricted cash of \$4.5 million relating to the receipt of royalties held in a restricted account under our Goldman Sachs term loan facility. This cash outflow was partially offset by proceeds from maturities of investments in the period of \$1.3 million.

Net cash provided by financing activities was \$21.0 million for the three months ended March 31, 2010, compared with \$41,000 for the same period of 2009. Cash provided by financing activities in the first quarter of 2010 related to proceeds received from the issuance of common shares of \$25.5 million, partially offset by \$4.5 million paid to the holders of warrants issued in June of 2009 upon modification of the terms.

### ***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. Interest on the principal amount of the loan accrues at six-month LIBOR plus 2%, which was equal to 2.44% at March 31,



**Table of Contents**

2010, and is payable semi-annually in June and December of each year. At our election, the semi-annual interest payments can be added to the outstanding principal amount, in lieu of a cash payment, as long as the aggregate principal amount does not exceed \$50 million. 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.

At March 31, 2010 and December 31, 2009, the outstanding principal balance under this note agreement was \$13.3 million and, pursuant to the terms of the arrangement as restructured in November of 2008, we will not make any additional borrowings on the Novartis note.

***Underwritten Offering***

In February of 2010, we completed an underwritten offering of 42 million units, with each unit consisting of one of XOMA's common shares and a warrant to purchase 0.45 of a common share, for gross proceeds of approximately \$21 million, before deducting underwriting discounts and commissions and estimated offering expenses of \$1.7 million. The warrants, which represent the right to acquire an aggregate of up to 18.9 million common shares, are exercisable beginning six months and one day after issuance and have a five-year term and an exercise price of \$0.70 per share. Refer to *Results of Operations: Warrant Liabilities* above for further discussion of the warrants.

***ATM Agreement***

In the third quarter of 2009, we entered into the ATM Agreement, under which we may sell up to 25 million of our common shares from time to time through Wm Smith, as the agent for the offer and sale of the common shares. Wm Smith may sell these common shares by any method permitted by law deemed to be an at the market offering as defined in Rule 415 of the Securities Act of 1933, including but not limited to sales made directly on The NASDAQ Global Market, on any other existing trading market for the common shares or to or through a market maker. Wm Smith may also sell the common shares in privately negotiated transactions, subject to our approval. We pay Wm Smith a commission equal to 3% of the gross proceeds of all common shares sold through it as sales agent under the ATM Agreement but in no event less than \$0.02 per share. Shares sold under the ATM Agreement are sold pursuant to a prospectus which forms a part of a registration statement declared effective by the Securities and Exchange Commission on May 29, 2008. From the inception of the ATM Agreement through March 31, 2010, we sold a total of 12,990,842 common shares through Wm Smith for aggregate gross proceeds of \$9.3 million, including 8,940,225 common shares sold in the first quarter of 2010 for aggregate gross proceeds of \$6.4 million. Total offering expenses related to these sales from inception to March 31, 2010 were \$0.3 million.

Net proceeds from the underwritten offering and sales under the ATM Agreement were used to make a \$4.5 million payment to holders of the June 2009 warrants and are being used 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 March 31, 2010, we had an accumulated deficit of \$806.3 million, cash and cash equivalents of \$28.4 million and working capital of \$17.6 million. During the remainder of 2010, we expect to continue using our cash and cash equivalents to fund ongoing operations. Additional licensing, antibody discovery and development collaboration agreements, government funding and financing arrangements may positively impact our cash balances. Based on our cash reserves and anticipated spending levels, funding from collaborators including a XOMA 052 corporate partnership, licensing transactions or biodefense contracts 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. 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. 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.

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 *Part II Item 1A: Risk Factors*.

## **Table of Contents**

### **Critical Accounting Estimates**

Critical accounting estimates 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 including, but not limited to, revenue recognition, long-lived assets, warrant liabilities and share-based compensation to be critical policies. There have been no significant changes in our critical accounting estimates during the three months ended March 31, 2010, except as noted below, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the U.S. Securities and Exchange Commission (the "SEC") on March 11, 2010, as amended on April 30, 2010.

### ***Warrant Liabilities***

In February of 2010, we issued warrants to purchase XOMA's common shares in connection with an underwritten offering, as discussed in *Liquidity and Capital Resources: Underwritten Offering* above. We have accounted for the warrants issued in February of 2010 as a liability at fair value, due to a provision included in the warrant agreement that allows the warrant holders an option to require us (or our successor) to purchase their warrants for cash in an amount equal to their Black-Scholes Model value, in the event of a change in control of the Company (the "Change in Control Provisions"). The fair value of the warrant liability is estimated using the Black-Scholes Model. The Black-Scholes Model requires inputs such as the expected term of the warrants, share price volatility and risk-free interest rate. These assumptions are reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants are recognized in other income (expense).

Also in February of 2010, the holders of warrants issued in May and June of 2009 agreed to amend the terms of their warrants to remove the Eliminated Adjustment Provisions, as discussed in *Significant Developments in 2010: Financings* and *Results of Operations: Warrant Liabilities* above. Prior to amendment, we recorded the warrants issued in May and June of 2009 as liabilities at fair value due to the Change of Control Provisions and the Eliminated Adjustment Provisions. These liabilities were estimated using the Simulation Model, which, in addition to the Black-Scholes Model inputs referred to above, required us to consider the probability and timing of future equity financings in the estimation to reflect the value of the Eliminated Adjustment Provisions. These assumptions were reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants were recognized in other income (expense).

After amendment, we continue to account for the warrants issued in May and June of 2009 as liabilities at fair value, due to the Change of Control Provisions. With the removal of the Eliminated Adjustment Provisions, the fair value of the warrants is now estimated using the Black-Scholes Model. The assumptions used in the Black-Scholes Model are reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants are recognized in other income (expense). As of March 31, 2010, all warrants issued in May of 2009 had been exercised and the related liability was fully extinguished and reclassified to additional paid-in capital.

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

Certain statements contained herein related to the sufficiency of our cash resources 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, the period for which our cash resources are sufficient could be shortened if expenditures are made earlier or in larger amounts than anticipated or are unanticipated, if anticipated revenue 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 within the timeframes anticipated or at all. These and other risks, including those related to inability to comply with NASDAQ's continued listing requirements; the generally unstable nature of current economic conditions; the results of discovery research and 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 *Part II 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 secured note agreement. 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 and cash equivalents. 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 cash equivalents at March 31, 2010 and December 31, 2009 (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>March 31, 2010</b>				
Cash and cash equivalents	Daily to 90 days	\$ 28,417	\$ 28,417	0.04%
<b>December 31, 2009</b>				
Cash and cash equivalents	Daily to 90 days	\$ 23,909	\$ 23,909	0.38%

As of March 31, 2010, we have an outstanding principal balance on our note with Novartis of \$13.3 million, which is due in 2015. The interest rate on this note is charged at a rate of USD six-month LIBOR plus 2%, which was 2.44% at March 31, 2010. No further borrowing is available under this facility.



---

## **Table of Contents**

The variable interest rate related to our long-term debt instrument is based on LIBOR. We estimate that a hypothetical 100 basis point change in interest rates could increase or decrease our interest expense by approximately \$0.1 million 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, the Company and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraudulent concealment, 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. Since then, additional complaints have been filed in the same court, bringing the total number of pending cases to twenty-eight. All of the complaints allege the same claims and seek the same types of damages based on injuries alleged to have occurred as a result of the plaintiffs' 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 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, 2009) during the three months ended March 31, 2010.

### **ITEM 1A. RISK FACTORS**

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

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

While our refocused business strategy has reduced 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,

---

**Table of Contents**

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, discovery and development collaborations, product royalties and biodefense contracts, and sales of our common shares.

Based on our cash reserves and anticipated spending levels, revenue from collaborations including a XOMA 052 corporate partnership, licensing transactions or biodefense contracts and other sources of funding we believe to be available, we believe that we have sufficient cash resources to meet our anticipated net cash needs through the next twelve months. Any significant revenue shortfalls, increases in planned spending on development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. 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,

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.

**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 March 31, 2010, 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 since March 31, 2010, no assurance can be given that further deterioration in conditions of 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.

**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.**

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

Companies listed on The NASDAQ Stock Market ( NASDAQ ) 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 eight days since December 9, 2008. Although NASDAQ temporarily suspended the minimum bid price requirement in response to market conditions, this suspension expired on July 31, 2009.

---

**Table of Contents**

On September 21, 2009, we received a letter from NASDAQ indicating that for the 30 consecutive business days preceding September 15, 2009, the bid price of our common shares closed below the minimum \$1.00 per share requirement pursuant to NASDAQ Listing Rule 5450(a)(1) for continued inclusion on The NASDAQ Global Market. In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we had a period of 180 calendar days, or until March 15, 2010, to regain compliance with the minimum bid price requirement.

In March of 2010, we received a Staff Determination letter from The NASDAQ Stock Market LLC (NASDAQ) indicating that we have not regained compliance with the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market, pursuant to NASDAQ Listing Rule 5450(a)(1). As a result, our common shares would have been subject to delisting from The NASDAQ Global Market unless we requested a hearing before a NASDAQ Listing Qualifications Panel (the Panel) to present our plan for regaining compliance, which we have done. The delisting of our common shares has therefore been stayed pending the issuance of the Panel's decision following the hearing. Although the Panel has authority to grant us up to an additional 180 days from the date of the NASDAQ notice (i.e., until September 13, 2010) to regain compliance, there can be no assurance that the Panel will grant our request for continued listing. Furthermore, we cannot be sure that our share price will comply with the requirements for continued listing of our common shares on The NASDAQ Global Market in the future. 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 March 31, 2010, we had an accumulated deficit of \$806.3 million.

For the three months ended March 31, 2010, we had a net loss of approximately \$21.8 million or \$0.09 per common share (basic and diluted). For the three months ended March 31, 2009, we had a net income of approximately \$6.2 million or \$0.04 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 May 4, 2010, 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 400,000,000 common shares, of which 261,247,750 were issued and outstanding as of May 4, 2010. If we issue additional equity securities, the price of our common shares may be materially and adversely affected.

---

**Table of Contents**

As announced in the third quarter of 2009, we have entered into an At Market Issuance Sales Agreement, with Wm Smith & Co. ( Wm Smith ), under which we may sell up to 25 million of our common shares from time to time through Wm Smith, as the agent for the offer and sale of the common shares. Wm Smith may sell these common shares by any method permitted by law deemed to be an at the market offering as defined in Rule 415 of the Securities Act of 1933, including but not limited to sales made directly on The NASDAQ Global Market, on any other existing trading market for the common shares or to or through a market maker. Wm Smith may also sell the common shares in privately negotiated transactions, subject to our approval. From the inception of this agreement through March 31, 2010, we sold a total of 12,990,842 common shares through Wm Smith for aggregate gross proceeds of \$9.3 million.

In addition, in February of 2010, we completed an underwritten offering of 42 million units, with each unit consisting of one of our common shares and a warrant to purchase 0.45 of a common share, for gross proceeds of approximately \$21 million, before deducting underwriting discounts and commissions and estimated offering expenses of \$1.7 million. The investors purchased the units at a price of \$0.50 per unit. The warrants, which represent the right to acquire an aggregate of up to 18.9 million common shares, are exercisable beginning six months and one day after issuance and have a five-year term and an exercise price of \$0.70 per share.

**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, 2010 through May 4, 2010, our share price has ranged from a high of \$0.84 to a low of \$0.40. 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,

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

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,

---

**Table of Contents**

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.

In the United States, the Food and Drug Administration ( 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 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



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

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.

---

**Table of Contents**

**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 European Medicines Agency ( 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 progressive multifocal leukoencephalopathy ( 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.

**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. 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.

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

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

## **Table of Contents**

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

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

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

We license technologies from third parties. These technologies include but are not limited to phage display technologies licensed to us in connection with our 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.

### **To the extent our present and future revenue consist of royalties on product sales, our revenue will rely on sales of products marketed and sold by others.**

We have only a royalty interest in CIMZIA<sup>®</sup> and receive revenue from sales of CIMZIA<sup>®</sup> in the U.S. for the treatment of moderate-to-severe Crohn's disease and in the U.S. and Canada for the treatment of moderate-to-severe rheumatoid arthritis. CIMZIA<sup>®</sup> was approved in the United States in April of 2008 for the treatment of Crohn's disease. In May of 2009, CIMZIA<sup>®</sup> was approved by the FDA for the treatment of moderate-to-severe rheumatoid arthritis in adults and in Canada in September of 2009. UCB is responsible for the marketing and sales effort in support of this product. We have no role in marketing and sales efforts, and UCB does not have an express contractual obligation to us regarding the marketing or sales of CIMZIA<sup>®</sup>.

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

UCB's willingness and ability to implement their marketing and sales effort and achieve sales;

---

**Table of Contents**

the strength of competition from other products being marketed or developed to treat Crohn's disease and rheumatoid arthritis;

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

physicians' and patients' acceptance of 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.

**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 CIMZIA<sup>®</sup> was approved in the United States in April of 2008 for the treatment of Crohn's disease, and in the United States in May of 2009 and in Canada in September 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 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 Inc., the company that marketed RAPTIVA<sup>®</sup> in Canada (EMD Serono) announced that, in consultation with Health Canada, the Canadian health authority (Health Canada), it would suspend marketing of RAPTIVA<sup>®</sup> in Canada. In March of 2009, Merck Serono Australia Pty Ltd, the company that marketed 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 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.**

UCB is responsible for manufacturing or arranging for the manufacturing of commercial quantities of CIMZIA<sup>®</sup>. Should UCB have difficulty in providing manufacturing capacity to produce this product in sufficient quantities, we do not know whether they will be able to meet market demand. If not, we will not realize revenue from the sales of this product. 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.

---

## **Table of Contents**

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

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

In April of 1996, we entered into an agreement with Genentech whereby we agreed to co-develop Genentech's humanized monoclonal antibody product RAPTIVA®. In April of 1999, March of 2003, and January of 2005, the companies amended the agreement. In October of 2003, RAPTIVA® was approved by the FDA for the treatment of adults with chronic moderate-to-severe 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 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 the National Institute of Allergy and Infectious Diseases ( 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 March 31, 2010, 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. In the third quarter of 2009, we sold our LUCENTIS® royalty interest to Genentech.

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.

---

**Table of Contents**

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 Aphton Corporation ( Aphton ) for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In January of 2006, Aphton announced that its common stock had been delisted from NASDAQ. In May of 2006, Aphton filed for bankruptcy protection under Chapter 11, Title 11 of the United States Bankruptcy Code.

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 our 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

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

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.

---

**Table of Contents**

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*

We have initiated clinical testing of XOMA 052, a potent anti-inflammatory monoclonal antibody targeting IL-1 beta, in Type 2 diabetes patients and cardiovascular disease patients. Other companies are developing other products based on the same or similar therapeutic targets as XOMA 052 and these products may prove more effective than XOMA 052. We are aware that:

In June of 2009, Novartis announced it had received U.S. marketing approval for Ilaris<sup>®</sup> (canakinumab), a fully-human monoclonal antibody targeting IL-1 beta, to treat children and adults with Cryopyrin-Associated Periodic Syndromes ( CAPS ). In October of 2009, Novartis announced that Ilaris<sup>®</sup> had been approved 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.

Eli Lilly and Company ( Lilly ) is developing LY2189102, an investigational IL-1 beta antibody, for bi-weekly subcutaneous injection for the treatment of Type 2 diabetes. Lilly announced the initiation of a Phase 2 study in the third quarter of 2009.

In 2008, Biovitrum AB (now called Swedish Orphan Biovitrum) obtained a worldwide exclusive license to Amgen Inc. ( Amgen ) s Kineret<sup>®</sup> (canakinra) for its current approved indication. Kineret<sup>®</sup> 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 addition to other on-going studies, a proof-of-concept clinical trial in the United Kingdom investigating Kineret<sup>®</sup> in patients with a certain type of myocardial infarction, or heart attack, was recently completed.

In February of 2008, Regeneron Pharmaceuticals, Inc. ( Regeneron ) announced it had received marketing approval from the FDA for ARCALYST<sup>®</sup> (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 March of 2009, Regeneron announced the initiation of a Phase 3 program with rilonacept in gout, which includes four clinical trials. In September of 2009, Regeneron announced that rilonacept was approved in the European Union for CAPS.

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.

In June of 2009, Cytos Biotechnology AG announced the initiation of an ascending dose Phase 1 study of CYT013-IL1bQb, a therapeutic vaccine targeting IL-1 beta, in Type 2 diabetes and that this study is expected to be completed in the first quarter of 2011.

*XOMA 3AB*

In May of 2006, the U.S. Department of Health & Human Services awarded Cangene Corporation ( Cangene ) 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. In May

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

of 2008, Cangene announced significant product delivery under this contract. In March of 2010, this contract was extended for an additional two years, until May of 2013.

Emergent BioSolutions, Inc. ( Emergent ) 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, Inc. and Human Genome Sciences, Inc. are developing anti-anthrax antibodies. Cangene and Emergent 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.

*CIMZIA*<sup>®</sup>

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

---

**Table of Contents**

**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 biotechnology 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.**

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our business. In March of 2010, the U.S. Congress enacted and President Obama signed into law the Patient Protection and Affordable Care Act, which includes a number of healthcare reform provisions. The reforms imposed by the new law will significantly impact the pharmaceutical industry, most likely in the area of pharmaceutical product pricing; however, the full effects of new law cannot be known until these provisions are implemented and the relevant federal and state agencies issue applicable regulations or guidance.

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 has considered 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 a series of related cases 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.

---

**Table of Contents**

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, fraudulent concealment, 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. Since then, additional complaints have been filed in the same court, bringing the total number of pending cases to twenty-eight. All of the complaints allege the same claims and seek the same types of damages based on injuries alleged to have occurred as a result of the plaintiffs' treatment with RAPTIVA<sup>®</sup>. 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; Patrick J. Scannon, M.D., Ph.D., our Executive Vice President and Chief Medical Officer; Fred Kurland, our Vice President, Finance and Chief Financial 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 have pursued 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 recorded charges in 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.

In addition, as a result of the workforce reduction, we temporarily vacated another building. As manufacturing demand increases in the future, we plan to resume operations at this facility. The net book value of fixed assets in the vacant building potentially subject to write-down is approximately \$4.0 million as of March 31, 2010. Although we have determined that there was no impairment of the assets as of March 31, 2010, 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.

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.

**U.S. holders of our common shares and warrants could be subject to material adverse U.S. federal income tax consequences if we were considered to be a PFIC currently or in the future.**

A non-U.S. corporation generally will be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in any taxable year in which, after applying the relevant look-through rules with respect to the income and assets of its subsidiaries, either 75% or more of its gross income is passive income (generally including (without limitation) dividends, interest, annuities and certain royalties and rents not derived in the active conduct of a business) or the average value of its assets that produce passive income or are held for the production of passive income is at least 50% of the total value of its assets. In determining whether we meet the 50% test, cash is considered a passive asset and the total value of our assets generally will be treated as equal to the sum of the aggregate fair market value of our outstanding common shares plus our liabilities. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC tests, as owning our proportionate share of the other corporation's assets and receiving our proportionate share of the other corporation's income.

We believe that we were not a PFIC for the 2009 taxable year. However, because PFIC status is determined annually and depends on the composition of a company's income and assets and the fair market value of its assets (including goodwill), which may be volatile in our industry, there can be no assurance that we will not be considered a PFIC for 2010 or any subsequent year. For example, taking into account our existing cash balances, if the value of our common shares were to decline materially, it is possible that we could become a PFIC in 2010 or a subsequent year. Additionally, due to the complexity of the PFIC provisions and the limited authority available to interpret such provisions, there can be no assurance that our determination regarding our PFIC status could not be successfully challenged by the Internal Revenue Service ( IRS ).



## **Table of Contents**

If we were found to be a PFIC for any taxable year in which a U.S. holder (as defined below) held common shares or warrants, certain adverse U.S. federal income tax consequences could apply to such U.S. holder, including a recharacterization of any capital gain recognized on a sale or other disposition of common shares or warrants as ordinary income, ineligibility for any preferential tax rate otherwise applicable to any qualified dividend income, a material increase in the amount of tax that such U.S. holder would owe and the possible imposition of interest charges, an imposition of tax earlier than would otherwise be imposed and additional tax form filing requirements.

For purposes of this discussion, the term "U.S. holder" means a beneficial owner of common shares or warrants that is, for U.S. federal income tax purposes, (i) an individual who is a U.S. citizen or resident, (ii) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (iii) an estate the income of which is includable in gross income for U.S. income tax purposes regardless of its source, or (iv) a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. fiduciaries have the authority to control all substantial decisions of the trust, or if the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

A U.S. holder owning shares in a PFIC (or a corporation that might become a PFIC) might be able to mitigate the adverse tax consequences of PFIC status by making certain elections, including qualified electing fund (a QEF) or mark-to-market elections, if deemed appropriate based on guidance provided by its tax advisor. However, it should be noted that (1) the beneficial effect of a QEF election or a mark-to-market election may be substantially diminished if such election is not made from the inception of a U.S. holder's holding period (a Year One Election), (2) neither a QEF election nor a mark-to-market election can be made with respect to the warrants, (3) a Year One Election generally cannot be made for any common shares received upon exercise of the warrants (Warrant Shares) because the holding period of Warrant Shares is deemed, for QEF election and mark-to-market election purposes, to include the holding period of the underlying warrants but the QEF election or a mark-to-market election will not be effective until the taxable year in which the underlying warrants are exercised, and (4) a QEF election or a mark-to-market election is made on a shareholder-by-shareholder basis and, once made, can only be revoked with the consent of the IRS.

The PFIC rules are very complex, as are the requirements and effects of the various elections designed to mitigate the adverse consequences of the PFIC rules. A prospective U.S. holder should consult its own tax advisor regarding the PFIC rules, including the foregoing limitations on the ability to make a QEF election or a mark-to-market election (or to qualify either such election as a Year One Election), the timing requirements with respect to the various elections and the irrevocability of certain elections (absent the consent of the IRS).

A U.S. Holder may be required to file IRS Form 8621 if the U.S. Holder holds our common shares in any taxable year in which we are classified as a PFIC (whether or not a QEF or mark-to-market election is made).

### **Our ability to use our net operating loss carry-forwards and other tax attributes will be substantially limited by Section 382 of the Internal Revenue Code.**

Section 382 of the Internal Revenue Code of 1986, as amended, generally limits the ability of a corporation that undergoes an ownership change to utilize its net operating loss carry-forwards (NOLs) and certain other tax attributes against any taxable income in taxable periods after the ownership change. The amount of taxable income in each taxable year after the ownership change that may be offset by pre-change NOLs and certain other pre-change tax attributes is generally equal to the product of (a) the fair market value of the corporation's outstanding shares immediately prior to the ownership change and (b) the long-term tax exempt rate (i.e., a rate of interest established by the IRS that fluctuates from month to month). In general, an ownership change occurs whenever the percentage of the shares of a corporation owned, directly or indirectly, by 5-percent shareholders (within the meaning of Section 382 of the Internal Revenue Code) increases by more than 50 percentage points over the lowest percentage of the share of such corporation owned, directly or indirectly, by such 5-percent shareholders at any time over the preceding three years.

In 2009, we experienced an ownership change under Section 382, which subjects the amount of NOLs and other tax credit carry-forwards that can be utilized to an annual limitation, which will substantially limit the future use of our pre-change NOLs and certain other pre-change tax attributes per year.

### **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 215 employees as of May 4, 2010. We anticipate that we will require additional experienced



---

**Table of Contents**

executive, accounting, research and development, legal, administrative and other personnel in the future. There is intense competition for the services of these personnel, especially in California. Moreover, we expect that the high cost of living in the San Francisco Bay Area, where our headquarters and manufacturing facilities are located, may impair our ability to attract and retain employees in the future. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to implement our current initiatives or grow effectively.

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

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

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

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

blacklisting of our common shares by certain pension funds,

legislation restricting certain types of transactions, and

punitive tax legislation.

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

**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:

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

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;



**Table of Contents**

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.

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. RESERVED**

**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 May 6, 2010, 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: May 6, 2010

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

Chairman, Chief Executive Officer and President

Date: May 6, 2010

By: /s/ FRED KURLAND  
Fred Kurland

Vice President, Finance and Chief Financial Officer