

XOMA LTD /DE/  
Form 10-Q  
May 07, 2009  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2009

or

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

Commission File No. 0-14710

**XOMA Ltd.**

(Exact name of registrant as specified in its charter)

**Bermuda**  
(State or other jurisdiction)

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

of incorporation or organization)

**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

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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, 2009
Common Shares, U.S. \$0.0005 par value	142,326,493

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**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, 2009 (unaudited)	December 31, 2008
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 21,561	\$ 9,513
Short-term investments		1,299
Restricted cash	13,998	9,545
Trade and other receivables, net	9,289	16,686
Prepaid expenses and other current assets	978	1,296
Debt issuance costs	1,499	365
<b>Total current assets</b>	<b>47,325</b>	<b>38,704</b>
Property and equipment, net	25,206	26,843
Debt issuance costs long-term		1,224
Other assets	402	402
<b>Total assets</b>	<b>\$ 72,933</b>	<b>\$ 67,173</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>(NET CAPITAL DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$ 5,054	\$ 9,977
Accrued liabilities	7,264	4,438
Accrued interest	3,265	1,588
Deferred revenue	7,951	9,105
Interest bearing obligations current	50,394	
Other current liabilities	1,692	1,884
<b>Total current liabilities</b>	<b>75,620</b>	<b>26,992</b>
Deferred revenue long-term	7,025	8,108
Interest bearing obligations long-term	12,880	63,274
Other long-term liabilities	300	200
<b>Total liabilities</b>	<b>95,825</b>	<b>98,574</b>
Commitments and contingencies		
Shareholders equity (net capital deficiency):		
Preference shares, \$0.05 par value, 1,000,000 shares authorized		
Series A, 210,000 designated, no shares issued and outstanding at March 31, 2009 and December 31, 2008		
	1	1

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Series B, 8,000 designated, 2,959 shares issued and outstanding at March 31, 2009 and December 31, 2008  
(aggregate liquidation preference of \$29.6 million)

Common shares, \$0.0005 par value, 210,000,000 shares authorized, 142,326,493 and 140,467,529 shares  
outstanding at March 31, 2009 and December 31, 2008, respectively

Additional paid-in capital	71	70
Additional paid-in capital	755,901	753,634
Accumulated comprehensive loss		(2)
Accumulated deficit	(778,865)	(785,104)
Total shareholders' equity (net capital deficiency)	(22,892)	(31,401)
Total liabilities and shareholders' equity (net capital deficiency)	\$ 72,933	\$ 67,173

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

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

	<b>Three months ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Revenues:</b>		
License and collaborative fees	\$ 27,700	\$ 25
Contract and other revenue	7,398	7,111
Royalties	4,606	4,921
<b>Total revenues</b>	<b>39,704</b>	<b>12,057</b>
<b>Operating expenses:</b>		
Research and development (including contract related of \$7,436 and \$5,387, respectively, for the three months ended March 31, 2009 and 2008)	16,521	19,211
Selling, general and administrative	6,120	5,872
Restructuring	3,289	
<b>Total operating expenses</b>	<b>25,930</b>	<b>25,083</b>
<b>Income (loss) from operations</b>	<b>13,774</b>	<b>(13,026)</b>
<b>Other income (expense):</b>		
Investment and interest income	30	392
Interest expense	(1,768)	(1,450)
Other income (expense)	3	(91)
<b>Net income (loss) before taxes</b>	<b>12,039</b>	<b>(14,175)</b>
<b>Provision for income tax expense</b>	<b>5,800</b>	
<b>Net income (loss)</b>	<b>\$ 6,239</b>	<b>\$ (14,175)</b>
<b>Basic net income (loss) per common share</b>	<b>\$ 0.04</b>	<b>\$ (0.11)</b>
<b>Diluted net income (loss) per common share</b>	<b>\$ 0.04</b>	<b>\$ (0.11)</b>
<b>Shares used in computing basic net income (loss) per common share</b>	<b>141,772</b>	<b>132,156</b>
<b>Shares used in computing diluted net income (loss) per common share</b>	<b>145,596</b>	<b>132,156</b>

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ 6,239	\$ (14,175)
<b>Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</b>		
Depreciation and amortization	1,816	1,613
Common shares contribution to 401(k) and management incentive plans	1,198	1,008
Share-based compensation expense	1,029	511
Accrued interest on interest bearing obligations	1,677	(476)
Amortization of discount, premium and debt issuance costs of interest bearing obligations	90	309
Amortization of premiums on short-term investments	1	8
Loss on disposal/retirement of property and equipment		92
Other non-cash adjustments		(3)
<b>Changes in assets and liabilities:</b>		
Receivables	7,397	4,434
Prepaid expenses and other current assets	318	(386)
Accounts payable	(4,923)	(1,332)
Accrued liabilities	2,826	(2,720)
Deferred revenue	(2,237)	(3,255)
Other liabilities	(92)	
<b>Net cash provided by (used in) operating activities</b>	<b>15,339</b>	<b>(14,372)</b>
<b>Cash flows from investing activities:</b>		
Proceeds from sales of investments		7,900
Proceeds from maturities of investments	1,300	1,200
Purchase of investments		(3,199)
Transfer of restricted cash	(4,453)	5,116
Purchase of property and equipment	(179)	(2,248)
<b>Net cash (used in) provided by investing activities</b>	<b>(3,332)</b>	<b>8,769</b>
<b>Cash flows from financing activities:</b>		
Principal payments of long-term debt		(8,160)
Proceeds from issuance of common shares	41	78
<b>Net cash provided by (used in) financing activities</b>	<b>41</b>	<b>(8,082)</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>12,048</b>	<b>(13,685)</b>
Cash and cash equivalents at the beginning of the period	9,513	22,500
<b>Cash and cash equivalents at the end of the period</b>	<b>\$ 21,561</b>	<b>\$ 8,815</b>

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





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**XOMA Ltd.**

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

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

**Business**

XOMA Ltd. ( XOMA or the Company ), a Bermuda company, is a biopharmaceutical company that discovers, develops and manufactures therapeutic antibodies and other agents designed to treat inflammatory, autoimmune, infectious and oncological diseases. The Company's products are presently in various stages of development and most are subject to regulatory approval before they can be commercially launched. The Company receives royalties from Genentech, Inc. (a wholly-owned member of the Roche Group, referred to herein as Genentech ) on LUCENTIS<sup>®</sup>, for the treatment of neovascular (wet) age-related macular degeneration. XOMA also receives royalties from UCB Celltech, a branch of UCB S.A. ( UCB ), on sales of CIMZIA<sup>®</sup> for the treatment of Crohn's disease. XOMA's pipeline includes both proprietary products and collaborative programs at various stages of preclinical and clinical development.

**Liquidity and Financial Condition**

The Company has incurred significant operating losses and negative cash flows from operations since its inception. As of March 31, 2009, the Company had cash and cash equivalents of \$21.6 million and restricted cash of \$14.0 million. Based on cash and cash equivalents on hand at March 31, 2009 and anticipated spending levels, revenues, collaborator funding, government funding and other sources of funding the Company believes to be available, the Company estimates that it has sufficient cash resources to meet its anticipated net cash needs through the next twelve months, excluding a potential acceleration of the Company's outstanding principal on a term loan facility with Goldman Sachs Specialty Lending Holdings, Inc. ( Goldman Sachs ) due to an anticipated cessation of future royalties from sales of RAPTIVA<sup>®</sup>.

The Company is currently in discussions with the lenders regarding a restructuring of the terms of this facility to address the effects of certain recent developments related to RAPTIVA<sup>®</sup>. In the first quarter of 2009, RAPTIVA<sup>®</sup> was recommended for withdrawal from the European Union, Canadian and Australian markets, and in April of 2009, Genentech announced a phased voluntary withdrawal of RAPTIVA<sup>®</sup> from the U.S. market. As a voluntary action not mandated by the U.S. Food and Drug Administration ( FDA ), the U.S. market withdrawal was particularly unexpected. As a result of RAPTIVA<sup>®</sup> sales levels in the first quarter, the Company is no longer in compliance with the requirements of the relevant provisions of this loan facility, and has received a notice from its lender to this effect. As a consequence, the lenders currently have the ability to accelerate payment of the full amount of the loan. The Company cannot be certain that it will reach agreement with the lenders on acceptable terms, or at all, as a result of these discussions or that the lenders will not accelerate payment of the loan at any time. If the lenders accelerate payment, the Company currently would not have the resources to pay the full amount due.

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 covenants that place substantial restrictions on the Company's business. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue business strategies. If adequate funds are not available, the Company has developed contingency plans that may require the Company to delay, reduce the scope of, or eliminate one or more of its development programs. In addition, the Company may be required to reduce personnel and related costs and other discretionary expenditures that are within the Company's control.

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

**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

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audited Consolidated Financial Statements and related Notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 11, 2009 ( 2008 Form 10-K ).

In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which are necessary to present fairly the Company's consolidated financial position as of March 31, 2009, the consolidated results of the Company's operations for the three months ended March 31, 2009 and 2008, and the

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Company's cash flows for the three months ended March 31, 2009 and 2008. The condensed consolidated balance sheet amounts at December 31, 2008 have been derived from audited consolidated financial statements. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year or future periods.

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

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an on-going basis, management evaluates its estimates, including those related to revenue recognition, research and development expense, long-lived assets and share-based compensation. The Company bases its estimates on historical experience and on various other market-specific and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates.

To conform to the current period presentation, prior period disclosures have been expanded in our consolidated statements of cash flows, to provide proceeds from sales and maturities of investments separately, and in *Note 1: Accrued Liabilities*, to provide additional disclosure of accrued liabilities. These presentation changes had no impact on previously reported net earnings/losses, financial position or cash flows.

### **Concentration of Risk**

Cash equivalents, short-term investments, restricted cash and receivables are financial instruments, which potentially subject the Company to concentrations of credit risk. The Company maintains money market funds and short-term investments that were previously thought to bear a minimal risk. Recent volatility in the financial markets created liquidity problems in these types of investments in 2008, and money market fund investors were unable to retrieve the full amount of funds, even in highly-rated liquid money market accounts, upon maturity.

The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the three months ended March 31, 2009, two customers represented 73% and 11% of total revenues. As of March 31, 2009, there were receivables outstanding from one of these customers representing 51% and two additional customers representing 24% and 17% of the accounts receivable balance. For the three months ended March 31, 2008, four customers represented 41%, 37%, 11% and 10% of total revenues.

### **Significant Accounting Policies**

#### ***Accounting for Collaborative Agreements***

In December of 2007, the Emerging Issues Task Force ( EITF ) of the Financial Accounting Standards Board ( FASB ) reached a consensus on EITF Issue 07-1 Accounting for Collaborative Agreements ( EITF 07-1 ). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants and third parties in a collaborative arrangement. EITF 07-1 prohibits companies from applying the equity method of accounting to activities performed outside a separate legal entity by a virtual joint venture. Instead, revenues and costs incurred with third parties in connection with the collaborative arrangement should be presented gross or net by the collaborators based on the criteria in EITF Issue No. 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent , and other applicable accounting literature. The consensus should be applied to collaborative arrangements in existence at the date of adoption using a modified retrospective method that requires reclassification in all periods presented for those arrangements still in effect at the transition date, unless that application is impracticable. The consensus is effective for fiscal years beginning after December 15, 2008.

Effective January 1, 2009 the Company adopted EITF 07-1, which did not have a material impact on the Company's financial statements. Refer to *Note 4: Collaborative and Other Arrangements* for additional disclosure relating to the Company's collaboration agreement with Novartis AG ( Novartis ). This collaboration agreement was restructured in November of 2008 and is no longer within the scope of EITF 07-1. As of March 31, 2009, the Company does not have any collaboration agreements that fall under the scope of EITF 07-1.

#### ***Fair Value of Non-Financial Instruments***

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



**Table of Contents****Share-Based Compensation**

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

In February of 2009, the Board of Directors of the Company approved a company-wide grant of an aggregate of 4,730,000 share options, of which 4,568,000 were issued as part of its annual incentive compensation package. These options vest monthly over four years and include an acceleration clause based on meeting certain performance measures. As of March 31, 2009, the Company has assessed the probability of achieving the performance measures and has determined that accelerated expense recognition is not appropriate at this time. The Company will reassess the probability at each future reporting period and accelerate expense recognition accordingly.

As of March 31, 2009, the Company had approximately 1.0 million common shares reserved for future grant under its share option plans and ESPP.

The following table shows total share-based compensation expense included in the condensed consolidated statements of operations for the three months ended March 31, 2009 and 2008 (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Research and development	\$ 553	\$ 270
General and administrative	476	241
<b>Total share-based compensation expense</b>	<b>\$ 1,029</b>	<b>\$ 511</b>

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

To estimate the value of an award, the Company uses the Black-Scholes option pricing model. This model requires inputs such as expected life, expected volatility and risk-free interest rate. The forfeiture rate also impacts the amount of aggregate compensation. These inputs are subjective and generally require significant analysis and judgment to develop. While estimates of expected life, volatility and forfeiture rate are derived primarily from the Company's historical data, the risk-free rate is based on the yield available on U.S. Treasury zero-coupon issues.

The fair value of share-based awards was estimated using the Black-Scholes model with the following weighted-average assumptions for the three months ended March 31, 2009 and 2008:

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Dividend yield	0%	0%
Expected volatility	73%	66%
Risk-free interest rate	1.76%	2.58%
Expected life	5.6 years	5.3 years

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Share option activity for the three months ended March 31, 2009 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2008	19,810,183	\$ 3.24		
Granted	4,730,000	0.56		
Exercised				
Forfeited, expired or cancelled	1,172,771	3.27		
Options outstanding at March 31, 2009	23,367,412	\$ 2.69	8.08	\$
Options exercisable at March 31, 2009	9,863,355	\$ 3.70	6.60	\$

No options were exercised for the three months ended March 31, 2009.

At March 31, 2009, there was \$11.3 million of unrecognized share-based compensation expense related to unvested share options with a weighted-average remaining recognition period of 2.9 years.

**Comprehensive Income (Loss)**

Unrealized gain 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, 2009 and 2008 was as follows (in thousands):

	Three Months Ended March 31,	
	2009	2008
Net income (loss)	\$ 6,239	\$ (14,175)
Unrealized gain on securities available-for-sale	2	59
Comprehensive income (loss)	\$ 6,241	\$ (14,116)

**Income Taxes**

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 Pharmaceutical Company Limited (Takeda), signed in February of 2009. Refer to Note 4: *Collaborative and Other Arrangements* for additional information.

No income tax expense was recognized for the three months ended March 31, 2008.

**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.

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Options for common shares	21,222	11,312
Convertible preference shares		3,818
Warrants for common shares <sup>(1)</sup>		125

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

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 (loss) 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
<b>Weighted average shares outstanding and dilutive securities used for diluted net income per share</b>	<b>145,596</b>

For the three months ended March 31, 2008, all outstanding securities were considered antidilutive, and therefore the calculation of basic and diluted net loss per share was the same.

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

The Company considers all highly liquid debt instruments with maturities of three months or less at the time the Company acquires them to be cash equivalents. At March 31, 2009 and December 31, 2008, cash and cash equivalents consisted of overnight deposits, money market funds, repurchase agreements and debt securities with original maturities of 90 days or less and are reported at fair value. Cash and cash equivalent balances were as follows as of March 31, 2009 and December 31, 2008 (in thousands):

	March 31, 2009			
	Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash	\$ 1,619	\$	\$	\$ 1,619
Cash equivalents	19,942			19,942
<b>Total cash and cash equivalents</b>	<b>\$ 21,561</b>	<b>\$</b>	<b>\$</b>	<b>\$ 21,561</b>

	December 31, 2008			
	Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash	\$ 553	\$	\$	\$ 553
Cash equivalents	8,960			8,960
<b>Total cash and cash equivalents</b>	<b>\$ 9,513</b>	<b>\$</b>	<b>\$</b>	<b>\$ 9,513</b>

**Short-term Investments**

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

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

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

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

For the three months ended March 31, 2009 and 2008, the Company recognized no realized gains on short-term investments.

**Restricted Cash**

Under the terms of its loan agreement with Goldman Sachs, as discussed in *Note 5: Debt and Other Financing*, the Company maintains a custodial account for the deposit of RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup> royalty revenues in addition to a standing reserve of the next



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semi-annual interest payment due on the loan. This cash account and the interest earned thereon can be used solely for the payment of the semi-annual interest amounts due on April 1 and October 1 of each year and, at that time, amounts in excess of the interest reserve requirement may be used to pay down principal or be distributed back to the Company, at the discretion of Goldman Sachs. At March 31, 2009 and December 31, 2008, the restricted cash balance of \$14.0 million and \$9.5 million, respectively, was invested in money market funds.

**Table of Contents****Receivables**

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

	March 31, 2009	December 31, 2008
Trade receivables, net	\$ 8,891	\$ 16,274
Other receivables	398	412
<b>Total</b>	<b>\$ 9,289</b>	<b>\$ 16,686</b>

**Accrued Liabilities**

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

	March 31, 2009	December 31, 2008
Accrued management incentive compensation	\$ 906	\$
Accrued restructuring costs	1,003	
Accrued payroll and other benefits	1,753	2,776
Accrued professional and other fees	2,126	514
Accrued clinical trial costs	897	438
Deferred rent	449	399
Other	130	311
<b>Total</b>	<b>\$ 7,264</b>	<b>\$ 4,438</b>

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

In accordance with SFAS 157, the following tables represent the Company's fair value hierarchy for its financial assets (cash equivalents and investments) measured at fair value on a recurring basis as of March 31, 2009 and December 31, 2008 (in thousands):

	Fair Value Measurements at March 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	\$ 10,609	\$ 10,609	\$	\$
Money market funds	9,333	9,333		
Money market funds-restricted	13,998	13,998		
Total	\$ 33,940	\$ 33,940	\$	\$

	Fair Value Measurements at December 31, 2008 Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Repurchase agreements	\$ 8,950	\$ 8,950	\$	\$
Certificates of deposit- restricted	952	952		
Money market funds	10	10		
Money market funds- restricted	8,593	8,593		
Corporate notes and bonds	1,299		1,299	
Total	\$ 19,804	\$ 18,505	\$ 1,299	\$

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

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

As part of the January of 2009 workforce reduction, the Company recorded a charge of \$3.3 million related to severance, other termination benefits and outplacement services, shown as Restructuring in the statement of operations for the three months ended March 31, 2009. The following table summarizes the restructuring charge and utilization for the three months ended March 31, 2009 (in thousands):

	Balance as of December 31, 2008	Charges	Cash Payments	Balance as of March 31, 2009
Employee Severance and Benefits	\$	\$ 3,289	\$ (2,286)	\$ 1,003
Total	\$	\$ 3,289	\$ (2,286)	\$ 1,003

The remaining balance is recorded as a current liability within the accrued liabilities balance at March 31, 2009 as the Company expects to pay this balance within the next six months. The Company does not expect to incur any additional restructuring charges for employee severance and other termination benefits related to the January of 2009 workforce reduction.

As a result of the workforce reduction, the Company has significantly reduced operations in four of its leased buildings. The Company has plans to consolidate these operations in phases during the remainder of 2009. The Company's leases on the four buildings expire at times varying from 2011 to 2014, and total minimum lease payments due from April 1, 2009 until expiration of the leases are \$6.8 million. In addition, the net book value of fixed assets in these four buildings potentially subject to write-down is approximately \$11.7 million as of March 31, 2009. The Company is currently evaluating its options as to the future use of these leased spaces.

As of March 31, 2009, the Company performed an analysis of the long-lived assets related to the four leased buildings in accordance with Statement of Financial Accounting Standards No. 144 Accounting for Impairment or Disposal of Long-Lived Assets (SFAS 144). Based on estimated undiscounted future cash inflows, the Company has determined that there is no current impairment relating to these assets, and will continue to assess for impairment at each future reporting period.

**4. COLLABORATIVE AND OTHER ARRANGEMENTS*****Expansion of Collaboration with Takeda***

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

***Restructuring of Collaboration with Novartis***

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

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

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**5. DEBT AND OTHER FINANCING**

As of March 31, 2009, the Company reclassified \$50.4 million of its outstanding debt under the Goldman Sachs term loan as a current obligation, as discussed below. The Company also has long-term debt of \$12.9 million outstanding under the Company's note with Novartis.

***Goldman Sachs Term Loan***

In May of 2008, the Company entered into a five-year, \$55.0 million amended and restated term loan facility with Goldman Sachs, refinancing the original facility entered into in November of 2006, and borrowed the full amount thereunder. As of March 31, 2009, the interest rate was 12.3%. The debt is secured by all rights to receive payments due to the Company relating to RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup>.

The on-going requirements of this loan facility include a financial test that requires the Company to maintain a specified ratio of royalties collected to interest payable and a requirement that quarterly U.S. sales of RAPTIVA<sup>®</sup> and LUCENTIS<sup>®</sup> and outside-the-U.S. sales of RAPTIVA<sup>®</sup> exceed certain specified minimum levels. The Company's ability to comply with these requirements is dependent on continued sales by Genentech, UCB and their partners of RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup> at adequate levels, and any significant reduction in such sales could cause the Company to violate or be in default under these provisions, which could result in acceleration of the Company's obligation to repay this debt.

As discussed in *Note 1: Business and Summary of Significant Accounting Policies*, in the first quarter of 2009, RAPTIVA<sup>®</sup> was recommended for withdrawal from the European Union, Canadian and Australian markets, and in April of 2009, Genentech announced a phased voluntary withdrawal of RAPTIVA<sup>®</sup> from the U.S. market. As a result of RAPTIVA<sup>®</sup> sales levels in the first quarter, the Company is no longer in compliance with the requirements of the relevant provisions of this loan facility, and as a consequence the lenders currently have the right to accelerate payment of the full amount of the loan. Accordingly, the outstanding principal balance under the Goldman Sachs loan facility of \$50.4 million has been reclassified as a current obligation at March 31, 2009.

At March 31, 2009, the related balance in restricted cash was \$14.0 million. For the three months ended March 31, 2009 and 2008, the Company incurred interest expense of \$1.6 million and \$0.8 million, respectively, in connection with this loan. Debt issuance costs under the facility of \$2.0 million are being amortized on a straight-line basis over the five-year life of the loan and have been reclassified as current debt issuance costs on the balance sheet, consistent with the reclassification of the loan balance. For the three months ended March 31, 2009 and 2008, the Company incurred amortization expense related to the debt issuance costs of \$0.1 million and \$0.3 million, respectively.

***Novartis Note***

In May of 2005, the Company executed a secured note agreement with Chiron Corporation (now Novartis), which is due and payable in full in June of 2015. Under the note agreement, the Company borrowed semi-annually to fund up to 75% of the Company's research and development and commercialization costs under its collaboration arrangement with Novartis, not to exceed \$50.0 million in an aggregate principal amount. As of March 31, 2009, the interest rate was 3.85%. At the Company's election, the semi-annual interest payments can be added to the outstanding principal amount, in lieu of a cash payment, as long as the aggregate principal amount does not exceed \$50.0 million. The Company has made this election for all interest payments thus far. Loans under the note agreement are secured by the Company's interest in the collaboration with Novartis, including any payment owed to it thereunder.

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

At March 31, 2009, the outstanding principal balance under this note agreement totaled \$12.9 million and for the three months ended March 31, 2009 and 2008, the Company incurred, and added to the principal balance of the note, interest expense of \$0.1 million and \$0.4 million, respectively, in connection with this loan.

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

In October of 2008, the Company entered into a common share purchase agreement (the *Purchase Agreement*) with Azimuth Opportunity Ltd. (*Azimuth*), pursuant to which it obtained a committed equity line of credit facility (the *Facility*) under which the Company may sell up to \$60 million of its registered common shares to Azimuth over a 24-month period, subject to certain conditions and limitations. The *Purchase Agreement* currently requires a minimum share price of \$1.00 per share to allow the Company to issue shares to Azimuth under the *Facility*. However, at its election, Azimuth may buy shares below the threshold price at a negotiated discount. The Company is not obligated to utilize any of the \$60 million *Facility* and remains free to enter other financing transactions. Shares under the *Facility* are sold pursuant to a prospectus which forms a part of a registration statement declared effective by the Securities and Exchange Commission on May 29, 2008.

The Company did not sell any common shares under, or make any modifications to, this facility for the three months ended March 31, 2009, and \$52.5 million remains available under the *Facility*.

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

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, 2008) during the three months ended March 31, 2009.

In April of 2009, a lawsuit was filed against Genentech, XOMA and others seeking financial compensation on behalf of three individuals who took RAPTIVA®, as discussed in *Note 7: Subsequent Events*.

### **7. SUBSEQUENT EVENTS**

#### ***Withdrawal of RAPTIVA® from U.S. Market***

In April of 2009, Genentech announced a phased voluntary withdrawal of RAPTIVA® from the U.S. market based on the association of RAPTIVA® with an increased risk of progressive multifocal leukoencephalopathy (*PML*). As a voluntary action not mandated by the FDA, the U.S. market withdrawal was particularly unexpected. XOMA earned mid-single digit royalties from sales of RAPTIVA®, which was approved by the FDA for the treatment of chronic moderate-to-severe plaque psoriasis. As a result of this announcement and other related events, the Company expects sales of RAPTIVA® to cease in the second quarter of 2009. This and other related events have significant adverse consequences under the Company's term loan with Goldman Sachs, as discussed in *Note 5: Debt and Other Financing*.

#### ***Lawsuit Alleging RAPTIVA® Injuries***

In April of 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, asserting claims against Genentech, the Company and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraud, wrongful death and other claims based on injuries alleged to have occurred as a result of three individuals' treatment with RAPTIVA®. The complaint seeks unspecified compensatory and punitive damages. The Company's agreement with Genentech provides for an indemnity of XOMA 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.

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

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

#### **Overview**

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

We have a premier antibody discovery and development platform that includes six antibody phage display libraries and our proprietary Human Engineering and bacterial cell expression technologies. Our bacterial cell expression technology is a key biotechnology for the discovery and manufacturing of antibodies and other proteins. Thus far, more than 50 pharmaceutical and biotechnology companies have signed bacterial cell expression licenses with us. We are currently in discussions with multiple companies to license our antibody technologies.

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

Our ability to fund ongoing operations is dependent on the progress of our proprietary development pipeline, specifically XOMA 052 and XOMA 3AB. We are currently conducting two Phase 1 clinical trials of XOMA 052 in Type 2 diabetes patients, one in the U.S. and one in Europe. In April of 2009, we completed enrollment of our Phase 1 clinical trials of XOMA 052. We plan to complete our Phase 1 clinical testing of XOMA 052 in Type 2 diabetes and initiate a major Phase 2 Type 2 diabetes study in the third quarter of 2009. We have been approached by a number of companies offering to collaborate on our testing and development of XOMA 052 for Type 2 diabetes, and we will seek to enter into a collaboration arrangement by the end of 2009.

We have received promising results from our testing of XOMA 052 for use in other indications. Based on these results, we initiated a Phase 2a pharmacokinetic study of XOMA 052 in rheumatoid arthritis in March of 2009. Depending on our available resources and timing, we may initiate additional small XOMA 052 proof-of-concept trials in other indications in 2009.

In the near-term, our ability to fund ongoing operations is also dependent on our royalty streams, which include worldwide sales of LUCENTIS<sup>®</sup>, for which Genentech, Inc. (a wholly-owned member of the Roche Group (Roche), referred to herein as Genentech) licensed our bacterial cell expression technology, and sales of CIMZIA<sup>®</sup> in the U.S. and Switzerland, for which UCB Celltech, a branch of UCB S.A. (UCB), licensed our bacterial cell expression technology. Genentech, UCB and their partners are responsible for the manufacturing, marketing and sales efforts in support of these products.

Previously, we also relied on a royalty stream from RAPTIVA<sup>®</sup>, a drug we developed under a collaboration agreement with Genentech, from which we earn mid-single digit royalties from worldwide sales. In February of 2009, the European Medicines Agency (EMA) announced that it had recommended suspension of the marketing authorization of RAPTIVA<sup>®</sup> in the European Union and that its Committee for Medicinal Products for Human Use (CHMP) had concluded that the benefits of RAPTIVA<sup>®</sup> no longer outweigh its risks and EMD Serono Inc., the company that markets RAPTIVA<sup>®</sup> in Canada (EMD Serono), announced that, in consultation with Health Canada, the Canadian health authority (Health Canada), it has suspended marketing of RAPTIVA<sup>®</sup> in Canada. Also in February of 2009, the U.S. Food and Drug Administration (FDA) issued a public health advisory concerning three





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confirmed reports, and one possible report, of progressive multifocal leukoencephalopathy ( PML ) in patients using RAPTIVA®. In March of 2009, Merck Serono Australia Pty Ltd, the company that markets RAPTIVA® in Australia ( Merck Serono Australia ), announced that, following a recommendation by the Therapeutic Goods Administration, the Australian health authority ( TGA ), it is withdrawing RAPTIVA® from the Australian market. In April of 2009, Genentech announced 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 voluntary action not mandated by the FDA, the U.S. market withdrawal was particularly unexpected. As a result of these announcements, we expect sales of RAPTIVA® to cease in the second quarter of 2009. These events have significant adverse consequences under our term loan with Goldman Sachs Specialty Lending Holdings, Inc. ( Goldman Sachs ), as discussed in the *Liquidity and Capital Resources* section.

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

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

In January of 2009, we announced a workforce reduction of approximately 42%, or 144 employees, a majority of which were employed in manufacturing and related support functions. This decision was made based on the challenging economic conditions and a decline in forecasted manufacturing demand in 2009. We expect an annualized reduction of approximately \$27 million in cash expenditures when changes are completed. We remain staffed with approximately 195 employees to develop XOMA 052, develop and license proprietary products and technology, and continue fully funded antibody discovery and development activities with our pharmaceutical partners in collaborations and the U.S. government in biodefense. We recorded a charge in the first quarter of 2009 of \$3.3 million for severance, other termination benefits and outplacement services in connection with the workforce reduction.

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

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

Total revenues were \$39.7 million and \$12.1 million for the three months ended March 31, 2009 and 2008, respectively, as shown in the table below (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
License and collaborative fees	\$ 27,700	\$ 25
Contract and other revenue	7,398	7,111
Royalties	4,606	4,921
 Total revenues	 \$ 39,704	 \$ 12,057

License and collaborative fees were \$27.7 million and \$25,000 for the three months ended March 31, 2009 and 2008, respectively. These revenues include fees and milestone payments related to the out-licensing of our products and technologies. The \$27.7 million increase in license

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and collaborative fees for the three months ended March 31, 2009, compared to the same period of 2008, is primarily due to \$27.5 million in revenue recognized during the first quarter of 2009 related to the expansion of our collaboration agreement with Takeda to provide Takeda with access to multiple antibody technologies. In addition, we received a milestone payment of \$0.2 million from Pfizer Inc. ( Pfizer ) in the first quarter of 2009. The generation of future revenues related to license fees and other collaborative arrangements is dependent on our ability to attract new licensees to our bacterial cell expression and other antibody technologies and new collaboration partners.

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Contract and other revenue was \$7.4 million and \$7.1 million for the three months ended March 31, 2009 and 2008, respectively. These revenues include agreements where we provide contracted research and development and manufacturing services to our collaboration partners, including Takeda, SPRI, Novartis and NIAID. The increase in contract and other revenue of \$0.3 million is primarily due to increased activities under our contracts with NIAID Contract No. HHSN272200800028C ( NIAID 3 ), Novartis, SPRI and Takeda. These increases in contract and other revenue were partially offset by decreases in revenue recognized on our NIAID Contract No. HHSN266200600008C/N01-A1-60008 ( NIAID 2 ) and on our AVEO Pharmaceuticals, Inc. (now with SPRI and referred to herein together as SPRI/AVEO ) contract. These decreases are due to the Company nearing the end of contracted service arrangements with NIAID 2 and SPRI/AVEO. We expect to continue to generate revenue in 2009 related to our NIAID 3 contract, which is a \$65 million multiple-year contract, and related to our existing agreements with Novartis, SPRI and Takeda, under the latter of which we initiated new therapeutic antibody programs in the third quarter of 2008. Depending on whether and when we obtain new government and other contracts, we may experience a decline in contract revenues from 2008 levels.

Revenue from royalties was \$4.6 million and \$4.9 million for the three months ended March 31, 2009 and 2008, respectively. The decrease in revenue from royalties of \$0.3 million for the three months ended March 31, 2009, compared to the same period of 2008, is due to a decrease in royalties earned from sales of RAPTIVA® worldwide of \$0.7 million, partially offset by an increase in royalties earned from worldwide sales of LUCENTIS® of \$0.4 million. During the three months ended March 31, 2009 and March 31, 2008, royalties received from sales of CIMZIA® were immaterial.

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

According to Roche, U.S. sales of RAPTIVA® were 26 million Swiss francs, approximately \$23 million, for the three months ended March 31, 2009 compared with \$26 million for the same period of 2008. According to Merck Serono, sales of RAPTIVA® outside of the U.S. were 14 million, approximately \$18 million, for the three months ended March 31, 2009 compared with 22 million, approximately \$32 million, for the same period of 2008.

According to Roche, U.S. sales of LUCENTIS® were 279 million Swiss francs, approximately \$244 million, for the three months ended March 31, 2009 compared with \$198 million for the same period of 2008. According to Novartis, sales of LUCENTIS® outside the United States were \$229 million for the three months ended March 31, 2009 compared with \$195 million for the same period of 2008. We expect royalty revenues from sales of LUCENTIS® worldwide to continue to increase in 2009. In addition, in January of 2009, Novartis announced that LUCENTIS® was approved in Japan for the treatment of (wet) age-related macular degeneration.

In January of 2009, UCB announced that the FDA had issued a Complete Response Letter relating to the Biologics License Application ( BLA ) of CIMZIA® for the treatment of rheumatoid arthritis. As a prerequisite for approval of CIMZIA® for this indication, UCB announced in February of 2009 that the FDA required further analysis of existing data and a new safety update and that no additional studies were needed to fulfill the FDA's request. In April of 2009, UCB announced that a response was submitted to the FDA. We expect royalty revenues from sales of CIMZIA® to increase in 2009.

### ***Research and Development Expenses***

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

Research and development expenses were \$16.5 million for the three months ended March 31, 2009, compared with \$19.2 million for the three months ended March 31, 2008. The decrease of \$2.7 million is primarily a result of our continuing focus on cost control, as well as decreased spending on NIAID 2 and SPRI/AVEO-related contract activities due to the Company nearing the end of contracted service arrangements. These decreases were partially offset by increased spending on the development of XOMA 052, including Phase 1 clinical trials, the preclinical development of five antibodies, and on our contracts with Novartis, SPRI, NIAID 3 and Takeda.



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We recorded \$7.6 million in research and development salaries and employee-related expenses for the three months ended March 31, 2009, compared with \$8.7 million for the same period of 2008. Included in these expenses for the first quarter of 2009 were \$6.4 million for salaries and benefits, \$0.6 million for accrued bonus expense and \$0.6 million for share-based compensation, which is a non-cash expense, compared with \$7.7 million, \$0.7 million and \$0.3 million, respectively, for the first quarter of 2008. The \$1.1 million decrease in salaries and employee-related expenses in the first quarter of 2009 as compared to the same period of 2008 is primarily due to decreased salaries and benefits as a result of the workforce reduction announced in January of 2009, partially offset by an increase in share-based compensation expense in the period. See *Results of Operations: Share-Based Compensation* for further discussion of our share-based compensation expense.

Our research and development activities can be divided into earlier stage programs and later stage programs. Earlier stage programs include molecular biology, process development, pilot-scale production and preclinical testing. Also included in earlier stage programs are costs related to excess manufacturing capacity, which we expect will continue to decrease in 2009 as a result of the workforce reduction. 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>2009</b>	<b>2008</b>
Earlier stage programs	\$ 12,603	\$ 13,035
Later stage programs	3,918	6,176
<b>Total</b>	<b>\$ 16,521</b>	<b>\$ 19,211</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>2009</b>	<b>2008</b>
Internal projects	\$ 9,084	\$ 13,202
Collaborative and contract arrangements	7,437	6,009
<b>Total</b>	<b>\$ 16,521</b>	<b>\$ 19,211</b>

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 (Novartis and NIAID 3) accounted for more than 10% but less than 20%, of our total research and development expenses. For the three months ended March 31, 2008, our largest development program (XOMA 052) accounted for more than 20% and less than 30%, and one development program (SPRI/AVEO) accounted for more than 10% but less than 20%, of our total research and development expenses.

We currently expect to continue to reduce our research and development spending in 2009, as compared to 2008. In April of 2009, we completed enrollment of our Phase 1 clinical trials of XOMA 052. We plan to complete our Phase 1 clinical testing of XOMA 052 in Type 2 diabetes and initiate a major Phase 2 Type 2 diabetes study in the third quarter of 2009. We have been approached by a number of companies offering to collaborate on our testing and development of XOMA 052 for Type 2 diabetes, and we will seek to enter into a collaboration arrangement by the end of 2009.

In addition, we initiated a Phase 2a pharmacokinetic study of XOMA 052 in rheumatoid arthritis in March of 2009. Depending on our available resources and timing, we may initiate additional small XOMA 052 proof-of-concept trials in other indications in 2009.

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



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**Table of Contents*****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 \$6.1 million and \$5.9 million for the three months ended March 31, 2009 and 2008, respectively. The \$0.2 million increase for the three months ended March 31, 2009, as compared to the same period of 2008, is primarily related to \$0.2 million in fees incurred to date related to the potential restructuring of the Goldman Sachs term loan, as discussed in further detail below in the *Liquidity and Capital Resources* section.

We recorded \$3.2 million in selling, general and administrative salaries and employee-related expenses for the three months ended March 31, 2009, compared with \$3.3 million for the same period of 2008. Included in these expenses for the first quarter of 2009 were \$2.4 million for salaries and benefits, \$0.3 million for accrued bonus expense and \$0.5 million for share-based compensation, which is a non-cash expense, compared with \$2.8 million, \$0.3 million and \$0.2 million, respectively, for the first quarter of 2008. The \$0.1 million decrease in salaries and employee-related expenses in the first quarter of 2009 as compared to the same period of 2008 is primarily due to decreased salaries and benefits as a result of the workforce reduction announced in January of 2009, partially offset by an increase in share-based compensation expense in the period. See *Results of Operations: Share-Based Compensation* for further discussion of our share-based compensation expense.

***Restructuring Charges***

As discussed in the *Overview* section, we announced a workforce reduction of approximately 42% in January of 2009. As part of the January of 2009 workforce reduction, we recorded a charge of \$3.3 million related to severance, other termination benefits and outplacement services, shown as *Restructuring* in the statement of operations for the three months ended March 31, 2009. We do not expect to incur any additional restructuring charges for employee severance and other termination benefits related to the January of 2009 workforce reduction.

As a result of the workforce reduction in January of 2009, we have significantly reduced operations in four of our leased buildings. We have plans to consolidate these operations in phases during the remainder of 2009. Our leases on these four buildings expire at times varying from 2011 to 2014, and total minimum lease payments due from April 1, 2009 until expiration of the leases are \$6.8 million. In addition, the net book value of fixed assets in these four buildings potentially subject to write-down is approximately \$11.7 million as of March 31, 2009. We are currently evaluating our options as to the future use of these leased spaces. We anticipate that we will incur some level of restructuring charges throughout the remainder of 2009 as we consolidate facilities.

As of March 31, 2009, we performed an analysis of the long-lived assets related to the four leased buildings in accordance with Statement of Financial Accounting Standards No. 144 *Accounting for Impairment or Disposal of Long-Lived Assets* ( SFAS 144 ). Based on estimated undiscounted future cash inflows, we have determined that there is no current impairment relating to these assets, and will continue to assess for impairment at each future reporting period.

***Other Income (Expense)***

Investment and interest income was \$30,000 and \$0.4 million for the three months ended March 31, 2009 and 2008, respectively. Investment and interest income consists primarily of interest earned on our cash and investment balances. The differences between 2009 and 2008 balances resulted from varying average cash balances and interest rates.

Interest expense was \$1.8 million and \$1.5 million for the three months ended March 31, 2009 and 2008, respectively. The increase in 2009 compared to 2008 is due to an increase in the principal balance of our long-term debt, partially offset by a decrease in the interest rates.

***Income Taxes***

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 \$29.0 million expansion fee, of which \$5.8 million was withheld for payment to the Japanese taxing authority. No income tax expense was recognized for the three months ended March 31, 2008.

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



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We did not have unrecognized tax benefits as of March 31, 2009 and do not expect this to change significantly over the next twelve months. In connection with the adoption of FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes ( FIN 48 ), we will recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of March 31, 2009, we have not accrued interest or penalties related to uncertain tax positions.

**Table of Contents*****Share-Based Compensation***

In February of 2009, our Board of Directors approved a company-wide grant of 4,730,000 share options, of which 4,568,000 were issued as part of our annual incentive compensation package. These options vest monthly over four years and include an acceleration clause based on meeting certain performance measures. As of March 31, 2009, we have assessed the probability of achieving the performance measures and have determined that accelerated expense recognition is not appropriate at this time. We will reassess the probability at each future reporting period and accelerate expense recognition accordingly.

During the three months ended March 31, 2009 and 2008, we recognized \$1.0 million and \$0.5 million, respectively, in share-based compensation expense. The increase in share-based compensation expense for the first quarter of 2009 as compared to the same period of 2008 is due to the additional expense for the share option grant in February of 2009, combined with lower recognition of expense in 2008 related to the share options granted in February of 2008 and October of 2007, which were not deemed granted for accounting purposes until shareholder approval, which was obtained in the second quarter of 2008.

As of March 31, 2009, there was \$11.3 million of unrecognized share-based compensation expense related to unvested shares with a weighted-average remaining recognition period of 2.9 years.

***Liquidity and Capital Resources***

Cash, cash equivalents and short-term investments at March 31, 2009 were \$21.6 million compared with \$10.8 million at December 31, 2008. Net cash provided by operating activities was \$15.3 for the three months ended March 31, 2009, compared with net cash used in operating activities of \$14.4 million for the same period in 2008. The \$29.7 million increase in cash provided by operations in the first quarter of 2009 as compared to same period of 2008 is primarily due to the receipt of \$23.2 million in the first quarter of 2009 related to the expansion of our existing collaboration with Takeda.

In addition, accrued liabilities increased in the first quarter of 2009 by \$2.8 million related to restructuring charges, an increase in clinical trial costs and costs accrued relating to the expansion of our existing collaboration with Takeda. Accrued interest on interest bearing obligations increased in the first quarter of 2009 by \$1.7 million related to the interest payment due on the Goldman Sachs loan facility on April 1, 2009. Finally, receivables decreased by \$7.4 million in the first quarter of 2009 due to a decline in contract and royalty revenues. These increases in cash were partially offset by a decrease in the accounts payable balance of \$4.9 million in the first quarter of 2009 related to the pay down of the balance in the period.

Comparatively, in the first quarter of 2008, accrued liabilities decreased by \$2.7 million primarily related to the payment of 2007 bonuses in the first quarter of 2008. Accrued interest on interest bearing obligations decreased by \$0.5 million in the first quarter of 2008, due to an interest payment made on March 31, 2008 related to the Goldman Sachs loan facility. In May of 2008, the Goldman Sachs loan facility was refinanced and the interest payment dates were changed from March 31 and September 30 to April 1 and October 1 of each year. Finally, receivables decreased by \$4.4 million in the first quarter of 2008 due to a decline in contract revenues.

Net cash used in investing activities was \$3.3 million in the first quarter of 2009, compared with net cash provided by investing activities of \$8.8 million in the first quarter of 2008. Cash used in investing activities in the first quarter of 2009 primarily consisted of an increase in restricted cash of \$4.5 million relating to our loan facility with Goldman Sachs. Cash received from our royalty streams is held in a restricted cash account for payment of interest due on our Goldman Sachs loan facility on April 1 and October 1 of each year. This cash outflow was partially offset by proceeds from maturities of investments in the period of \$1.3 million.

Net cash provided by investing activities in the first quarter of 2008 of \$8.8 million related to net sales and maturities of investments of \$5.9 million and a decrease in restricted cash of \$5.1 million related to the Goldman Sachs loan facility. Restricted cash decreased in the first quarter of 2008 due to the payment of interest on March 31, 2008. As discussed above, the refinancing of this loan facility in May of 2008 resulted in a change in interest payment dates to April 1 and October 1 of each year. These cash inflows were partially offset by purchases of property and equipment of \$2.2 million in the first quarter of 2008.

Net cash provided by financing activities was \$41,000 in the first quarter of 2009, compared with net cash used by financing activities of \$8.1 million in the same period of 2008. Cash provided by financing activities in the first quarter of 2009 related to the issuance of common shares. Cash used by financing activities in the first quarter of 2008 primarily related to the principal repayment of \$8.2 million of our original loan facility with Goldman Sachs, partially offset by the issuance of common shares of \$0.1 million.

***Goldman Sachs Term Loan***

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In May of 2008, we entered into a five-year, \$55.0 million amended and restated term loan facility with Goldman Sachs, refinancing our original facility entered into in November of 2006, and borrowed the full amount thereunder. As of March 31, 2009, the interest rate on the new facility was 12.3%. The debt is secured by all rights to receive payments due to the Company relating to

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RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup>, and CIMZIA<sup>®</sup>. Payments received by XOMA in respect of these payment rights, in addition to a standing reserve equal to the next semi-annual interest payment, are held in a custodial account which is classified as restricted cash. This cash account and the interest earned thereon can be used solely for the payment of the semi-annual interest amounts due on April 1 and October 1 of each year and, at that time, amounts in excess of the interest reserve requirement may be used to pay down principal or be distributed back to us, at the discretion of Goldman Sachs. We may prepay indebtedness under the facility at any time, subject to certain prepayment premiums if prepaid during the first four years.

The on-going requirements of this loan facility include a financial test that requires us to maintain a specified ratio of royalties collected to interest payable and a requirement that quarterly U.S. sales of RAPTIVA<sup>®</sup> and LUCENTIS<sup>®</sup> and outside-the-U.S. sales of RAPTIVA<sup>®</sup> exceed certain specified minimum levels. Our ability to comply with these requirements is dependent on continued sales by Genentech, UCB and their partners of RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup> at adequate levels, and any significant reduction in such sales could cause us to violate or be in default under these provisions, which could result in acceleration of our obligation to repay this debt.

As discussed in the *Overview* section, in the first quarter of 2009, RAPTIVA<sup>®</sup> was recommended for withdrawal from the European Union, Canadian and Australian markets, and in April of 2009, Genentech announced a phased voluntary withdrawal of RAPTIVA<sup>®</sup> from the U.S. market. As a voluntary action not mandated by the FDA, the U.S. market withdrawal was particularly unexpected. As a result of RAPTIVA<sup>®</sup> sales levels in the first quarter, we are no longer in compliance with the requirements of the relevant provisions of this loan facility, and as a consequence the lenders currently have the right to accelerate payment of the full amount of the loan. We have received a notice from our lenders to this effect and are currently in discussions with the lenders regarding a restructuring of the terms of this facility to address the effects of these developments, but we cannot be certain that we will reach agreement with the lenders on acceptable terms, or at all, as a result of these discussions or that the lenders will not accelerate payment of the loan at any time. If the lenders accelerate payment, we currently would not have the resources to pay the full amount due.

Accordingly, the outstanding principal balance under our Goldman Sachs loan facility of \$50.4 million has been reclassified as a current obligation at March 31, 2009. The balance in restricted cash at March 31, 2009 was \$14.0 million relating to this facility. On April 1, 2009, our balance in restricted cash was used to make an interest payment of \$3.1 million and a principal repayment of \$8.4 million, reducing the outstanding principal balance of this loan to \$42.0 million. In addition, our interest rate decreased to 11.5%, as a result of the decline in six-month LIBOR.

For the three months ended March 31, 2009 and 2008, we incurred interest expense of \$1.6 million and \$0.8 million, respectively, and amortization expense related to the debt issuance costs of \$0.1 million and \$0.3 million, respectively, in connection with this loan.

### ***Novartis Note***

In May of 2005, we executed a secured note agreement with Chiron Corporation (now Novartis), which is due and payable in full in June of 2015. Under the note agreement, we borrowed semi-annually to fund up to 75% of our research and development and commercialization costs under our collaboration arrangement with Novartis, not to exceed \$50.0 million in aggregate principal amount. As of March 31, 2009, the interest rate was 3.85%. At our election, the semi-annual interest payments can be added to the outstanding principal amount, in lieu of a cash payment, as long as the aggregate principal amount does not exceed \$50.0 million and we have made this election for all interest payments thus far. Loans under the note agreement are secured by our interest in the collaboration with Novartis, including any payments owed to us thereunder.

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

At March 31, 2009, the outstanding principal balance under this note agreement totaled \$12.9 million and for the quarters ended March 31, 2009 and 2008, we incurred, and added to the principal balance of the note, interest expense of \$0.1 million and \$0.4 million, respectively.

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

On October 21, 2008, we entered into a common share purchase agreement (the *Purchase Agreement*) with Azimuth Opportunity Ltd. ( *Azimuth* ), pursuant to which we obtained a committed equity line of credit facility (the *Facility*) under which we may sell up to \$60 million of our registered common shares to Azimuth over a 24-month period, subject to certain conditions and limitations. The *Purchase Agreement* currently requires a minimum share price of \$1.00 per share to allow us to issue shares to Azimuth under the *Facility*. However, at its election, Azimuth may buy shares below the threshold price at a negotiated discount. We are not obligated to utilize any of the \$60 million *Facility* and remain free to enter other financing transactions. Shares under the *Facility* are sold pursuant to a prospectus which forms a part of a registration

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statement declared effective by the Securities and Exchange Commission on May 29, 2008.

We did not sell any common shares under, or make any modifications to, this facility for the three months ended March 31, 2009, and \$52.5 million remains available under the Facility.

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We have incurred significant operating losses and negative cash flows from operations since our inception. At March 31, 2009, we had cash and cash equivalents of \$21.6 million and restricted cash of \$14.0 million. During 2009, we expect to continue using our cash and cash equivalents to fund ongoing operations. Additional licensing, antibody discovery collaboration agreements, government funding and financing arrangements may positively impact our cash balances. Based on anticipated spending levels, revenues, collaborator funding and other sources of funding we believe to be available, we estimate that we have sufficient cash resources to meet our anticipated net cash needs through the next twelve months, excluding a potential acceleration of our loan from Goldman Sachs, as discussed in the *Liquidity and Capital Resources: Goldman Sachs Term Loan* section. Any significant revenue shortfalls, increases in planned spending on development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. In addition, as a result of RAPTIVA® sales levels in the first quarter, the lenders under our loan from Goldman Sachs currently have the right to accelerate payment of the full amount of the loan. In the event the lenders accelerate full payment of this loan or we are not able to restructure the terms of the loan and otherwise maintain at least twelve months of cash resources, there will be substantial doubt as to our ability to continue as a going concern. Progress or setbacks by potentially competing products may also affect our ability to raise new funding on acceptable terms. If adequate funds are not available, we have developed contingency plans that may require us to delay, reduce the scope of, or eliminate one or more of our product development programs and further reduce personnel-related costs.

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

For a further discussion of the risks related to our business and their effects on our cash flow and ability to raise new funding on acceptable terms, see *Item 1A: Risk Factors*.

### **Critical Accounting Policies**

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition, research and development expense, long-lived assets and share-based compensation to be critical policies. There have been no significant changes in our critical accounting policies during the three months ended March 31, 2009, except as noted below, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 11, 2009 ( 2008 Form 10-K ).

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

In accordance with SFAS 144, we record impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. At March 31, 2009, we have determined that there is no current impairment relating to our long-lived assets, and will continue to assess for impairment at each future reporting period.

### **Subsequent Events**

#### ***Withdrawal of RAPTIVA® from U.S. Market***

In April of 2009, Genentech announced 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 voluntary action not mandated by the FDA, the U.S. market withdrawal was particularly unexpected. We earn mid-single digit royalties from sales of RAPTIVA®, which was approved by the FDA for the treatment of chronic moderate-to-severe plaque psoriasis. As a result of this announcement and other related events, we expect sales of RAPTIVA® to cease in the second quarter of 2009. This and other related events have significant adverse consequences under our term loan with Goldman Sachs, as discussed in the *Liquidity and Capital Resources: Goldman Sachs Term Loan* section.

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***Lawsuit Alleging RAPTIVA® Injuries***

In April of 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, asserting claims against Genentech, us and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraud, wrongful death and other claims based on injuries alleged to have occurred as a result of three individuals' treatment with RAPTIVA®. The complaint seeks unspecified compensatory and punitive damages. Our agreement with Genentech provides for an indemnity of us by Genentech, which we believe is applicable to this matter. We believe the claims against us to be without merit and intend to defend against them vigorously.

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

Certain statements contained herein related to discussions with our lenders regarding our Goldman Sachs loan, the sufficiency of our cash resources, and our efforts to enter into a collaborative arrangement with respect to XOMA 052, as well as other statements related to current plans for product development and existing and potential collaborative and licensing relationships, or that otherwise relate to future periods, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on assumptions that may not prove accurate. Actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market. Among other things, discussions with our lenders may not result in an agreement to restructure our loan facility on acceptable terms, or at all, and our lenders could accelerate payment of the loan at any time; the period for which our cash resources are sufficient could be shortened if our lenders accelerate payment of our loan from Goldman Sachs, if expenditures are made earlier or in larger amounts than anticipated or are unanticipated, if anticipated revenues or cost sharing arrangements do not materialize, or if funds are not otherwise available on acceptable terms; and, we may not be able to enter into a collaborative arrangement with respect to XOMA 052 on acceptable terms by the end of 2009, or at all. These and other risks, including those related to the results of preclinical testing; the timing or results of pending and future clinical trials (including the design and progress of clinical trials; safety and efficacy of the products being tested; action, inaction or delay by the United States Food and Drug Administration ( FDA ), European or other regulators or their advisory bodies; and analysis or interpretation by, or submission to, these entities or others of scientific data); changes in the status of existing collaborative relationships; the ability of collaborators and other partners to meet their obligations; our ability to meet the demand of the United States government agency with which we have entered our government contracts; competition; market demands for products; scale-up and marketing capabilities; availability of additional licensing or collaboration opportunities; international operations; share price volatility; our financing needs and opportunities; uncertainties regarding the status of biotechnology patents; uncertainties as to the costs of protecting intellectual property; and risks associated with our status as a Bermuda company, are described in more detail in *Item 1A: Risk Factors*.

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

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

We hold interest-bearing instruments that are classified as cash, cash equivalents and short-term investments. Fluctuations in interest rates can affect the principal values and yields of fixed income investments. If interest rates in the general economy were to rise rapidly in a short period of time, our fixed income investments could lose value.

The following table presents the amounts and related weighted-average interest rates of our cash and investments at March 31, 2009 and December 31, 2008 (in thousands, except interest rates):

	Maturity	Carrying Amount (in thousands)	Fair Value (in thousands)	Average Interest Rate
March 31, 2009				
Cash and cash equivalents	Daily to 90 days	\$ 21,561	\$ 21,561	0.44%
December 31, 2008				
Cash and cash equivalents	Daily to 90 days	\$ 9,513	\$ 9,513	2.67%
Short-term investments	91 days to less than 12 months	1,301	1,299	4.64%

In May of 2008, we entered into a five-year, \$55.0 million amended and restated term loan facility with Goldman Sachs, refinancing our original facility entered into in November of 2006, and borrowed the full amount thereunder. As of March 31, 2009, \$50.4 million remains outstanding under the new facility, which has been reclassified as a current obligation. Interest on the new facility is charged at a rate of the greater of (x) six-month LIBOR or (y) 3.0%, plus 8.5%, which was 12.3% at March 31, 2009.





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As of March 31, 2009, we have an outstanding principal balance on our note with Novartis of \$12.9 million, which is due in 2015. The interest rate on this note is charged at a rate of six-month LIBOR plus 2%, which was 3.85% at March 31, 2009. No further borrowing is available under this facility.

The variable interest rates related to our long-term debt instruments are based on LIBOR. We estimate that a hypothetical 100 basis point change in interest rates could increase or decrease our interest expense by approximately \$642,000 on an annualized basis.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### ***Evaluation of Controls and Procedures***

Under the supervision and with the participation of our management, including our Chairman, Chief Executive Officer and President and our Vice President, Finance and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based on this evaluation, our Chairman, Chief Executive Officer and President and our Vice President, Finance and Chief Financial Officer concluded that our disclosure controls and procedures were 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**

In April of 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, asserting claims against Genentech, XOMA Ltd. ( the Company ) and others for alleged strict liability for failure to warn, strict product liability, negligence, breach of warranty, fraud, wrongful death and other claims based on injuries alleged to have occurred as a result of three individuals' treatment with RAPTIV<sup>®</sup>. The complaint seeks unspecified compensatory and punitive damages. The Company's agreement with Genentech provides for an indemnity of XOMA by Genentech which the Company believes is applicable to this matter. The Company believes the claims against it to be without merit and intends to defend against them vigorously.

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

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

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

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

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

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

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

While our refocused business strategy will reduce capital expenditures and other operating expenses, we will need to commit substantial funds to continue development of our product candidates and we may not be able to obtain sufficient funds on acceptable terms, or at all. If adequate funds are not available, we may have to raise additional funds in a manner that may dilute or otherwise adversely affect the rights of existing shareholders, curtail or cease operations, or file for bankruptcy protection in extreme circumstances. We have spent, and we expect to continue to spend, substantial funds in connection with:

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

various human clinical trials, and

protection of our intellectual property.

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

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

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development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. In addition, as a result of the recent decline in sales of RAPTIVA<sup>®</sup>, we are no longer in compliance with the requirements of the relevant provisions of our loan from Goldman Sachs, and as a consequence the lenders under this loan currently have the right to accelerate payment of the full amount of the loan. In the event the lenders accelerate full payment of this loan or we are not able to restructure the terms of the loan and otherwise maintain at least twelve months of cash resources, there will be substantial doubt as to our ability to continue as a going concern. If adequate funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our product development programs and further reduce personnel-related costs. Progress or setbacks by potentially competing products may also affect our ability to raise new funding on acceptable terms. As a result, we do not know when or whether:

operations will generate meaningful funds,

royalties will be sufficient to meet debt covenants,

additional agreements for product development funding can be reached,

strategic alliances can be negotiated, or

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

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

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

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

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

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

Recent volatility in the financial markets has also created liquidity problems in investments previously thought to bear a minimal risk. For example, money market fund investors, including us, have in the past been unable to retrieve the full amount of funds, even in highly-rated liquid money market accounts, upon maturity. 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. As of March 31, 2009, we have received the full amount of proceeds from matured money market fund investments.

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments since March 31, 2009, no assurance can be given that further deterioration in conditions

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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.

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

As of March 31, 2009, we had approximately \$63.3 million of indebtedness outstanding, including \$12.9 million with Novartis AG ( Novartis ) classified as long-term debt, and \$50.4 million with Goldman Sachs reclassified in the period as a current obligation. On April 1, 2009, a principal repayment of \$8.4 million was made on our Goldman Sachs loan facility, reducing the outstanding principal balance of this loan to \$42.0 million. We may not be able to generate cash sufficient to pay the principal of, interest on and other amounts due in respect of our indebtedness when due. We may also incur additional debt that may be secured.

In connection with our original collaboration with Novartis, Novartis extended a loan to us (through our U.S. subsidiary) to fund up to 75% of our expenses thereunder. The loan bears interest at an annual rate of six-month LIBOR plus 2%, which was equal to 3.85% at March 31, 2009, and any unpaid principal amount together with accrued and unpaid interest is due and payable in full in June of 2015. This loan is secured on a first priority basis by a pledge of our interest in the collaboration. Although the collaboration was restructured in November of 2008 and we may not draw any additional funds under the loan facility, we remain liable for amounts previously borrowed under this facility.

In November of 2006, XOMA (US) LLC entered into a five-year, \$35.0 million term royalty-based loan facility with Goldman Sachs and borrowed the full amount thereunder. In May of 2008, this term loan facility was replaced with a new five-year term royalty-based loan facility. The loan bears interest at an annual rate equal to the greater of six-month LIBOR or 3%, plus a margin of 8.5%. As of March 31, 2009, the interest rate on this loan was 12.3%.

The new Goldman Sachs loan is guaranteed by XOMA and secured on a first priority basis by the payment rights relating to RAPTIVA<sup>®</sup>, LUCENTIS<sup>®</sup> and CIMZIA<sup>®</sup>. So long as this loan is outstanding, these assets will not be available to XOMA or any other lender to secure future indebtedness without the consent of the lenders.

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

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

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

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

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

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

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

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

not have sufficient funds to pay or which may be prohibitively high under the circumstances at the time we would otherwise choose to repay such debt.

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

NASDAQ-listed companies are subject to delisting for, among other things, failure to maintain a minimum closing bid price per share of \$1.00 for 30 consecutive business days. The closing price per share of our common shares has been below \$1.00 since December 9, 2008. NASDAQ has temporarily suspended the minimum bid price requirement in response to current market conditions. This suspension is currently set to expire on July 20, 2009. There can be no assurance that this extension will be extended further.



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

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

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

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

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

We have experienced significant losses and, as of March 31, 2009, we had an accumulated deficit of \$778.9 million.

For the quarter ended March 31, 2009, we had a net income of approximately \$6.2 million or \$0.04 per common share (basic and diluted). For the quarter ended March 31, 2008, we had a net loss of approximately \$14.2 million or \$0.11 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, 2009, which may give other shareholders dividend, conversion, voting, and liquidation rights, among other rights, which may be superior to the rights of holders of our common shares. In addition, we are authorized to issue, generally without shareholder approval, up to 210,000,000 common shares, of which 142,326,493 were issued and outstanding as of May 4, 2009. If we issue additional equity securities, the price of our common shares may be materially and adversely affected. On October 21, 2008, we entered into a common share purchase agreement with Azimuth Opportunity, Ltd. ( "Azimuth" ), pursuant to which we obtained a committed equity line of credit facility under which we may sell up to \$60.0 million of our registered common shares to Azimuth over a 24-month period, subject to certain conditions and limitations. Through May 4, 2009, we have sold 7,932,432 common shares under this facility for aggregate gross proceeds of \$7.5 million.

### **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.



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

There can be no assurance that the market price of our common shares will not decline below its present market price or that there will be an active trading market for our common shares. The market prices of biotechnology companies have been and are likely to continue to be highly volatile. Fluctuations in our operating results and general market conditions for biotechnology stocks could have a significant impact on the volatility of our common share price. We have experienced significant volatility in the price of our common shares. From January 1, 2009 through May 4, 2009, our share price has ranged from a high of \$0.94 to a low of \$0.37. Factors contributing to such volatility include, but are not limited to:

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

results of preclinical studies and clinical trials,

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

developments regarding regulatory filings,

announcements of new collaborations,

failure to enter into collaborations,

developments in existing collaborations,

our funding requirements and the terms of our financing arrangements,

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

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

government regulations,

developments in patent or other proprietary rights,

the number of shares issued and outstanding,

the number of shares trading on an average trading day,

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

market speculation regarding any of the foregoing.

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

Our product candidates, including XOMA 052 and XOMA 3AB, cannot be manufactured and marketed in the United States and other countries without required regulatory approvals. The United States government and governments of other countries extensively regulate many aspects of our product candidates, including:

testing,

manufacturing,

promotion and marketing, and

exporting.

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

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

Changes in the regulatory approval policy during the development period, changes in, or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. State regulations may also affect our proposed products. The FDA has substantial discretion in both the product approval process and manufacturing facility approval process and, as a result of this discretion and uncertainties about outcomes of testing, we cannot predict at what point, or whether, the FDA will be satisfied with our or our collaborators' submissions or whether the FDA will raise questions which may be material and delay or preclude product approval or manufacturing facility approval. As we accumulate additional clinical data, we will submit it to the FDA, and such data may have a material impact on the FDA product approval process.

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

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

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

Furthermore, a marketing approval of a product may be withdrawn by the FDA, the European Commission or another regulatory agency or such a product may be voluntarily withdrawn by the company marketing it based, for example, on subsequently-arising safety concerns. In February of 2009, the EMEA announced that it had recommended suspension of the marketing authorization of RAPTIVA® in the European Union and that its Committee for Medicinal Products for Human Use ( CHMP ) had concluded that the benefits of RAPTIVA® no longer outweigh its risks because of safety concerns, including the occurrence of PML in patients taking the medicine. In April of 2009, Genentech announced 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 voluntary action not mandated by the FDA, the U.S. market withdrawal was particularly unexpected.

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.

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

Our potential products, including XOMA 052 and XOMA 3AB, will require significant additional research and development, extensive preclinical studies and clinical trials and regulatory approval prior to any commercial sales. This process is lengthy and expensive, often taking a number of years. As clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly. As a result, it is uncertain whether:

our future filings will be delayed,

our preclinical and clinical studies will be successful,

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

we will be able to provide necessary additional data,

results of future clinical trials will justify further development, or

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

For example, in 2003, we completed two Phase 1 trials of XOMA 629, a BPI-derived topical peptide compound targeting acne, evaluating the safety, skin irritation and pharmacokinetics. In January of 2004, we announced the initiation of Phase 2 clinical testing in patients with mild-to-moderate acne. In August of 2004, we announced the results of a Phase 2 trial with XOMA 629 gel. The results were inconclusive in terms of clinical benefit of XOMA 629 compared with vehicle gel. In 2007, after completing an internal evaluation of this program, we chose to reformulate and focus development efforts on the use of this reformulated product candidate in superficial skin infections, including impetigo and the eradication of staphylococcus aureus, including MRSA. In the fourth quarter of 2008, we decided to curtail all spending on XOMA 629 in response to current economic conditions and to focus our financial resources on XOMA 052.

The timing of the commencement, continuation and completion of clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In addition, we will conduct clinical trials in foreign countries in the future which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign clinical research organizations, as well as expose us to risks associated with foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in the foreign currency where the trial is being conducted.

All of our product candidates are prone to the risks of failure inherent in drug development. Preclinical studies may not yield results that would satisfactorily support the filing of an IND (or a foreign equivalent) with respect to our product candidates. Even if these applications would be or have been filed with respect to our product candidates, the results of preclinical studies do not necessarily predict the results of clinical trials. Similarly, early-stage clinical trials in healthy volunteers do not predict the results of later-stage clinical trials, including the safety and efficacy profiles of any particular product candidates. In addition, t