

XOMA LTD /DE/  
Form 10-Q  
November 09, 2006  
Table of Contents

---

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

**Washington, D.C. 20549**

**FORM 10-Q**

**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2006

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 ☐

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

Large Accelerated Filer ☐

Accelerated Filer ☒

Non-Accelerated filer ☐

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

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

**Class**

**Outstanding at November 6, 2006**

Common shares US \$.0005 par value

101,499,582

---

**Table of Contents**

**XOMA Ltd.**

**FORM 10-Q**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I FINANCIAL INFORMATION</b>	
Item 1. Condensed Consolidated Financial Statements	
<u>Condensed Consolidated Balance Sheets as of September 30, 2006 (unaudited) and December 31, 2005</u>	1
<u>Condensed Consolidated Statements of Operations (unaudited) for the Three and Nine Months Ended September 30, 2006 and 2005</u>	2
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the Nine Months Ended September 30, 2006 and 2005</u>	3
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	4
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	18
Item 4. <u>Controls and Procedures</u>	18
<b>PART II OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	19
Item 1a. <u>Risk Factors</u>	19
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
Item 3. <u>Defaults upon Senior Securities</u>	32
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	32
Item 5. <u>Other Information</u>	33
Item 6. <u>Exhibits</u>	33
<u>Signatures</u>	34

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

(in thousands, except share and per share amounts)

	September 30,	December 31,
	2006	2005
	(unaudited)	(note 1)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,517	\$ 20,804
Short-term investments	12,942	22,732
Receivables, net	6,489	5,186
Related party receivables	55	98
Prepaid expenses	1,370	975
Debt issuance costs	477	493
Total current assets	31,850	50,288
Property and equipment, net	22,144	19,056
Related party receivables long-term	75	93
Debt issuance costs long-term	2,067	2,683
Deposits	457	457
Total assets	\$ 56,593	\$ 72,577
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>(NET CAPITAL DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$ 3,702	\$ 5,648
Accrued liabilities	5,623	5,717
Accrued interest	949	1,652
Deferred revenue	5,738	3,527
Total current liabilities	16,012	16,544
Deferred revenue long-term	4,285	4,333
Convertible debt long-term	58,400	60,000
Interest bearing obligation long-term	15,793	12,373
Total liabilities	94,490	93,250
Commitments and contingencies		
Shareholders' equity (net capital deficiency):		
Preference shares, \$.05 par value, 1,000,000 shares authorized		
Series A, 135,000 designated, no shares issued and outstanding		
Series B, 8,000 designated, 2,959 shares issued and outstanding; aggregate liquidation preference of \$29.6 million	1	1

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

Common shares, \$.0005 par value, 210,000,000 shares authorized, 97,569,353 and 86,312,712 shares outstanding at September 30, 2006 and December 31, 2005, respectively	49	43
Additional paid-in capital	675,143	655,041
Accumulated comprehensive income (loss)	(44)	(66)
Accumulated deficit	(713,046)	(675,692)
Total shareholders' equity (net capital deficiency)	(37,897)	(20,673)
Total liabilities and shareholders' equity (net capital deficiency)	\$ 56,593	\$ 72,577

*See accompanying notes to condensed consolidated financial statements.*

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2006</b>	<b>September 30, 2005</b>	<b>September 30, 2006</b>	<b>September 30, 2005</b>
<b>Revenues:</b>				
License and collaborative fees	\$ 636	\$ 856	\$ 2,021	\$ 4,036
Contract and other revenue	3,813	1,858	11,588	4,050
Royalties	2,906	1,712	6,862	4,492
<b>Total revenues</b>	<b>7,355</b>	<b>4,426</b>	<b>20,471</b>	<b>12,578</b>
<b>Operating costs and expenses:</b>				
Research and development (including contract related of \$3,331 and \$7,942, respectively, for the three and nine months ended September 30, 2006, and \$956 and \$2,741 for the three and nine months ended September 30, 2005)	12,671	9,383	36,956	28,932
General and administrative	4,189	3,243	13,628	10,703
<b>Total operating costs and expenses</b>	<b>16,860</b>	<b>12,626</b>	<b>50,584</b>	<b>39,635</b>
Loss from operations	(9,505)	(8,200)	(30,113)	(27,057)
<b>Other income (expense):</b>				
Investment and interest income	329	454	1,171	1,441
Interest expense	(1,655)	(1,236)	(8,400)	(3,014)
Other income (expense)	(5)	(10)	(12)	41,174
<b>Net income (loss) from operations before taxes</b>	<b>(10,836)</b>	<b>(8,992)</b>	<b>(37,354)</b>	<b>12,544</b>
Provision for income taxes		2		40
<b>Net income (loss)</b>	<b>\$ (10,836)</b>	<b>\$ (8,994)</b>	<b>\$ (37,354)</b>	<b>\$ 12,504</b>
<b>Basic net income (loss) per common share</b>	<b>\$ (0.11)</b>	<b>\$ (0.10)</b>	<b>\$ (0.40)</b>	<b>\$ 0.15</b>
<b>Diluted net income (loss) per common share</b>	<b>\$ (0.11)</b>	<b>\$ (0.10)</b>	<b>\$ (0.40)</b>	<b>\$ 0.13</b>
<b>Shares used in computing basic net income (loss) per common share</b>	<b>97,414</b>	<b>86,277</b>	<b>94,041</b>	<b>86,091</b>
<b>Shares used in computing diluted net income (loss) per common share</b>	<b>97,414</b>	<b>86,277</b>	<b>94,041</b>	<b>117,666</b>

*See accompanying notes to condensed consolidated financial statements.*

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	<b>2005</b>
	<b>2006</b>	<b>2005</b>
Cash flows from operating activities:		
Net income (loss)	\$ (37,354)	\$ 12,504
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	3,731	3,359
Common shares contributed to 401(k) and management incentive plans	1,088	1,304
Share-based compensation expense	831	
Accrued interest on convertible notes and other interest bearing obligations	(287)	789
Revaluation of embedded derivative	4,144	
Amortization of discount, premium and issuance costs of convertible debt	750	328
Amortization of premium on short-term investments	29	22
Gain on extinguishment of debt		(40,935)
Loss on disposal/retirement of property and equipment	10	10
Gain on sale of investments		(286)
Other non-cash adjustments	(4)	
Changes in assets and liabilities:		
Receivables and related party receivables	(1,242)	(3,530)
Prepaid expenses	(395)	(114)
Deposits		(298)
Accounts payable	(1,946)	535
Accrued liabilities	(94)	(14,331)
Deferred revenue	2,163	(452)
Net cash used in operating activities	(28,576)	(41,095)
Cash flows from investing activities:		
Proceeds from sales/maturities of investments	29,679	7,049
Purchase of investments	(19,891)	(37,780)
Purchase of property and equipment	(6,829)	(2,612)
Net cash provided by (used in) investing activities	2,959	(33,343)
Cash flows from financing activities:		
Principal payments of short-term loan		(115)
Payments under capital lease obligations		(188)
Proceeds from issuance of long-term debt	3,003	8,844
Proceeds from issuance of convertible notes	11,969	56,549
Proceeds from issuance of common shares	358	124
Net cash provided by financing activities	15,330	65,214
Net decrease in cash and cash equivalents	(10,287)	(9,224)
Cash and cash equivalents at the beginning of the period	20,804	23,808
Cash and cash equivalents at the end of the period	\$ 10,517	\$ 14,584

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

*See accompanying notes to condensed consolidated financial statements.*



## **Table of Contents**

### **1. OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### **Business**

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

#### **Basis of Presentation**

The condensed consolidated financial statements include the accounts of XOMA and its subsidiaries. All significant intercompany accounts and transactions were eliminated during consolidation. The unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q. These financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these statements should be read in conjunction with the audited Consolidated Financial Statements and related Notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 8, 2006.

In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which are necessary to present fairly the Company's consolidated financial position as of September 30, 2006, the consolidated results of the Company's operations for the three and nine months ended September 30, 2006 and 2005, and the Company's cash flows for the nine months then ended. The condensed consolidated balance sheet amounts at December 31, 2005, 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.

#### **Critical Accounting Policies**

There have been no significant changes in critical accounting policies, except as noted below, during the nine months ended September 30, 2006, as compared with those previously disclosed in its Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 8, 2006.

#### *Contract Revenue*

Contract revenue for research and development involves the Company providing research and development for manufacturing processes to collaborative partners or others. The Company recognizes revenue under these arrangements as the related research and development costs are incurred and collectibility is reasonably assured. Revenues for certain contracts are accounted for by a proportional performance, or output based, method where performance is based on agreed progress toward elements defined in the contract.

#### *Share Based Compensation*

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), Stock-Based Payment ( SFAS 123R ), which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors, including employee share options and employee share purchases related to the Employee Share Purchase Plan, on estimated fair values. The Company is using the modified prospective method. Under this method, the Company is required to record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. 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. Further, 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



## **Table of Contents**

issues. The Company reviews its valuation assumptions quarterly and, as a result, it is likely to change its valuation assumptions used to value share based awards granted in future periods.

### **Estimates**

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

### **Concentration of Risk**

Cash, cash equivalents, short-term investments and accounts receivable are financial instruments, which potentially subject the Company to concentrations of credit risk. The Company maintains money market funds and short-term investments that bear minimal risk. The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the nine months ended September 30, 2006, two customers represented 44% and 33% of total revenues and, as of September 30, 2006, there were billed and unbilled receivables of \$5.4 million outstanding from these customers representing 38% and 44% of the balance. For the nine months ended September 30, 2005, four customers represented 44%, 22%, 16% and 12% of total revenues and, as of September 30, 2005, there were billed and unbilled receivables of \$3.9 million from two of these customers representing 46%, and 43% of the balance.

### **Share-Based Compensation**

The Company grants qualified and non-qualified share options, shares and other share related awards under various plans to directors, officers, employees and other individuals. To date, share-based compensation issued under these plans consists of qualified and non-qualified incentive share options and shares. Share options are granted at exercise prices of not less than the fair market value of the Company's common shares on the date of grant. Generally, share options granted to employees fully vest four years from the grant date and expire ten years from the date of the grant or three months from the date of termination of employment (longer in case of death or certain retirements). Certain options granted to directors fully vest on the date of grant and certain options may fully vest upon a change of control of the Company. Additionally, the Company has an Employee Share Purchase Plan ( ESPP ) that allows employees to purchase Company shares at a purchase price equal to 95% of the closing price on the exercise date. For ESPP periods beginning prior to December 31, 2004, the purchase price per common share is 85% of fair market value at the lower of either the first day of the 24 month offering period or the last day of the period. As of September 30, 2006, the Company had approximately 6.2 million common shares reserved for future issuance under its share option plans and ESPP.

Prior to the adoption of SFAS 123R on January 1, 2006, the Company accounted for its share-based compensation plans under the intrinsic value method described in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, ( APB 25 ) and related Interpretations as permitted by Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ( SFAS 123 ), as amended by Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure ( SFAS 148 ). In general, as the exercise price of the options granted under the Company's plans was equal to the market price of the underlying common shares on the grant date, no share-based employee compensation cost was recognized. As required by SFAS 148 prior to the adoption of SFAS 123R, the Company provided pro forma net income (loss) and pro forma net income (loss) per common share disclosures for share-based awards, as if SFAS 123 had been applied.

SFAS 123R requires all share based payments to be recognized in the financial statements based on their fair values. The Company is using the modified prospective method. Under this method, compensation cost recognized during the three and nine month periods ended September 30, 2006, includes compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123 amortized on a graded vesting basis over the options' vesting period, and compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R amortized on a straight-line basis over the options' vesting period. The Company elected to use the modified prospective transition method as permitted by SFAS 123R and, therefore, has not restated its financial results for prior periods to reflect expensing of share-based compensation. As a result, the results for the three and nine months ended September 30, 2006, are not comparable to the same periods of the prior year.

**Table of Contents**

The following table illustrates the effect on net income (loss) and net income (loss) per share had the Company applied the fair value recognition provisions of SFAS 123 to account for its share plans and ESPP for the three and nine month periods ended September 30, 2005 (in thousands, except per share amounts):

	Three Months Ended	Nine Months Ended
	September 30, 2005	September 30, 2005
Net income (loss) as reported	\$ (8,994)	\$ 12,504
Deduct: Total share-based employee compensation expense under SFAS 123	(142)	(3,305)
Pro forma net income (loss)	\$ (9,136)	\$ 9,199
Net income (loss) per common share:		
Basic as reported	\$ (0.10)	\$ 0.15
Basic pro forma	\$ (0.11)	\$ 0.11
Diluted as reported	\$ (0.10)	\$ 0.13
Diluted pro forma	\$ (0.11)	\$ 0.10

The historical pro forma impact of applying the fair value method prescribed by SFAS 123 is not representative of the impact that may be expected in the future due to changes resulting from additional grants in future years and changes in assumptions such as expected life, volatility and interest rates used to estimate fair value of the grants in future years.

The following table shows total share-based compensation expense included in the condensed consolidated statements of operations for the three and nine month periods ended September 30, 2006 (in thousands).

	Three Months Ended	Nine Months Ended
	September 30, 2006	September 30, 2006
Research and development	\$ 110	\$ 380
General and administrative	74	451
Total share-based compensation expense	\$ 184	\$ 831

Basic and diluted net income (loss) per common share is (.01) lower for the nine months ended September 30, 2006, as a result of implementing SFAS 123R. There was no capitalized share-based compensation cost as of September 30, 2006. There were no recognized tax benefits during the three and nine months ended September 30, 2006. The adoption of SFAS 123R had no impact on cash flows from operations or financing.

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 a Black-Scholes model with the following weighted-average assumptions for the three and nine months ended September 30, 2006 and 2005.

Three Months Ended

Nine Months Ended

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

	September 30,		September 30,	
	2006	2005	2006	2005
Dividend yield	0%	0%	0%	0%
Expected volatility	75%	81%	80%	83%
Risk-free interest rate	4.56%	4.01%	4.65%	4.09%
Expected life	5.3 years	4.0 years	5.3 years	4.3 years

Prior to the adoption of SFAS 123R, the Company's Board of Directors approved the acceleration of vesting of all outstanding employee share options with an exercise price greater than \$3.00 per share. Because the exercise price of all the accelerated options exceeded the market price per share of the common shares as of the new measurement date, the acceleration had no impact on the Company's earnings in 2005. Since the accelerated options had exercise prices in excess of the current market value of the Company's common shares, the options had limited economic value and were not fully achieving their original objective of incentive compensation and employee retention. The modification allows expense recognized after the adoption of SFAS 123R to better reflect the Company's compensation strategies.

**Table of Contents**

Share option activity for the nine months ended September 30, 2006, is as follows:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2005	5,422,096	\$ 4.96		
Granted	1,424,800	1.69		
Exercises	(2,552)	1.41		
Forfeited, expired or canceled	(628,823)	4.84		
Options outstanding at September 30, 2006	6,215,521	\$ 4.22	6.63	\$ 751,105
Options exercisable at September 30, 2006	4,160,393	\$ 5.49	5.40	\$ 226,750

Unvested share activity for the nine months ended September 30, 2006 and 2005, is summarized below:

	Nine Months Ended September 30,			
	2006		2005	
Unvested	Weighted-Average	Unvested	Weighted-Average	
Number of	Grant-Date Fair Value	Number of	Grant-Date Fair Value	
Shares		Shares		
Unvested balance at December 31	1,234,838 \$ 1.56	1,890,034 \$ 5.50		
Granted	1,424,800 1.69	1,266,750 1.48		
Vested	(490,370) 1.54	(1,694,130) 5.58		
Forfeited	(114,140) 1.62	(276,804) 3.50		
Unvested balance at September 30	2,055,128 \$ 1.65	1,185,850 \$ 1.56		

At September 30, 2006, there was \$1.3 million of unrecognized share-based compensation expense related to unvested share options with a weighted average remaining recognition period of 2.8 years.

**Comprehensive Income (Loss)**

Unrealized gains or losses on the Company's available-for-sale securities are included in accumulated comprehensive income (loss). Comprehensive income (loss) and its components for the three and nine months ended September 30, 2006 and 2005, are as follows (in thousands):

Three Months Ended		Nine Months Ended	
September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005

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

Net income (loss)	\$ (10,836)	\$ (8,994)	\$ (37,354)	\$ 12,504
Unrealized gain (loss) on securities available-for-sale	27	(32)	22	(312)
Comprehensive income (loss)	\$ (10,809)	\$ (9,026)	\$ (37,332)	\$ 12,192

### 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 (decrease) the net income (loss) per share.

**Table of Contents**

The following outstanding securities were considered in the computation of diluted net income (loss) per share. Those that are antidilutive were not included in the computation of diluted net income (loss) per share (in thousands):

	September 30,	
	2006	2005
Options for common shares	6,216	5,392
Warrants for common shares	125	125
Convertible preference shares, notes and related interest, as if converted	37,322	38,827

The following is a reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2006	2005	2006	2005
<b>Numerator</b>				
Net income (loss)	\$ (10,836)	\$ (8,994)	\$ (37,354)	\$ 12,504
Interest on convertible long-term debt				2,863
Net income (loss) used for diluted net income (loss) per share	\$ (10,836)	\$ (8,994)	\$ (37,354)	\$ 15,367
<b>Denominator</b>				
Weighted average shares outstanding used for basic net income (loss) per share	94,414	86,277	97,041	86,091
Effect of dilutive share options				86
Effect of convertible preference shares				3,818
Effect of convertible long-term debt				27,671
Weighted-average shares outstanding and dilutive securities used for diluted net income (loss) per share	94,414	86,277	97,041	117,666

**Receivables**

Receivables consist of the following (in thousands):

	September 30,	December 31,
	2006	2005
Trade receivables	\$ 3,348	\$ 2,880
Collaborations	2,929	1,916
Other receivables	212	390
Total	\$ 6,489	\$ 5,186



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

Accrued liabilities consist of the following (in thousands):

	September 30,	December 31,
	2006	2005
Accrued payroll costs	\$ 1,931	\$ 2,084
Accrued management incentive compensation	1,683	1,758
Accrued legal fees	757	813
Accrued insurance	500	
Accrued collaborations	184	
Customer advances	133	750
Other	435	312
Total	\$ 5,623	\$ 5,717

**Recent Accounting Pronouncements**

In July of 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes ( FIN 48 ), an interpretation of FASB Statement No. 109, Accounting for Income Taxes ( FAS 109 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 will be effective beginning with the first annual period after December 15, 2006. The Company is still evaluating what impact, if any, the adoption of this standard will have on its financial position or results of operations.

**2. CONVERTIBLE DEBT**

In February of 2006, the Company completed an exchange offer with holders of its 6.5% convertible senior notes due 2012 in which the Company exchanged \$60.0 million aggregate principal amount of its new 6.5% Convertible SNAPS<sub>SM</sub> due 2012 (the New Notes ) for all \$60.0 million aggregate principal amount of its then outstanding convertible senior notes due 2012. The Company also issued an additional \$12.0 million of New Notes to the public for cash at a public offering price of 104% of principal, or \$12.5 million. The New Notes are initially convertible into approximately 38.4 million common shares at a conversion rate of 533.4756 of common shares per \$1,000 principal amount of New Notes, which is equivalent to a conversion price of approximately \$1.87 per common share. Before February 10, 2010, the Company may not redeem the New Notes. On or after February 10, 2010, the Company may redeem any or all of the New Notes at 100% of the principal amount, plus accrued and unpaid interest. In addition, the Company may automatically convert some or all of the New Notes on or prior to the maturity date if the closing price of its common shares has exceeded 150% of the conversion price then in effect for at least 20 trading days during any consecutive 30 trading day period ending within five trading days prior to the notice of auto-conversion. If the Company elects to automatically convert, or if holders elect to voluntarily convert, some or all of the New Notes on or prior to February 10, 2010, it must pay or provide for additional interest equal to four years' worth of interest less any interest paid or provided for, on the principal amount so converted, prior to the date of conversion. Additional interest, if any, shall be paid in cash or, solely at the Company's option and subject to certain limitations, in its common shares valued at the conversion price then in effect.

In accounting for the New Notes, the Company applied guidance as set forth in EITF 96-19, Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities, as amended ( SFAS 133 ), EITF 05-7, EITF 00-19, and EITF 01-6 as follows. The exchange offer is a modification of existing debt, rather than an extinguishment. The additional interest payment upon conversion is an embedded derivative requiring separate accounting. The Company considered the provisions of EITF 05-2 and concluded that this is not conventional convertible debt.

In accordance with SFAS 133, the Company has separately accounted for the additional interest payment feature of the New Notes as an embedded derivative instrument, which is measured at fair value and classified on the balance sheet with the convertible debt. Changes in the fair value of the embedded derivative are recognized in earnings as a component of other income (expense). At the time of issuance, the

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

Company estimated the fair value of the additional interest payment feature to be \$5.8 million, including approximately \$1.0 million related to the New Notes issued for cash, based on current information including share price. For the New Notes issued in the exchange offer and in the new money offering, this amount was subtracted from the carrying value of the debt, reflected as a debt discount, which is amortized as interest expense using the effective interest method through the date the notes are scheduled to mature, and separately reported as a derivative liability.

**Table of Contents**

Convertible debt consisted of the following (in thousands):

	September 30,	December 31,
	2006	2005
Convertible debt	\$ 52,364	\$ 60,000
Embedded derivative	5,700	
Premium	336	
Total	\$ 58,400	\$ 60,000

The additional New Notes were issued, to the initial purchasers, for net proceeds of \$11.8 million. Debt issuance costs related to the New Notes of approximately \$0.7 million are being amortized on a straight-line basis over the 72 month life of the notes. Additional debt issuance costs of \$2.0 million, related to the modification of the existing debt, were expensed as incurred with \$1.1 million and \$0.9 million expensed during the quarters ended March 31, 2006 and December 31, 2005, respectively.

For the three months ended September 30, 2006, \$20,000 of New Notes were converted into 13,097 common shares including 2,427 shares related to the additional interest payment feature of the notes. The Company recorded a \$176,000 charge to interest expense during the quarter ended September 30, 2006, as a result of an increase in the fair value of the embedded derivative on its convertible debt including \$2,000 related to the converted notes.

For the nine months ended September 30, 2006, \$15.5 million of New Notes were converted into 10,398,267 common shares including 2,145,398 shares related to the additional interest payment feature of the notes. The Company recorded a \$4.1 million charge to interest expense during the nine months ended September 30, 2006, as a result of an increase in the fair value of the embedded derivative on its convertible debt including \$2.7 million related to the converted notes.

For the three months ended September 30, 2006 and 2005, the Company incurred \$0.9 million and \$1.0 million, respectively, in interest expense payable on its convertible debt. For the nine months ended September 30, 2006 and 2005, the Company incurred \$2.8 million and \$2.5 million, respectively, in interest expense payable on its convertible debt. Interest expense is payable on a semi-annual basis. Additionally, the Company amortized a net of \$0.3 million and \$0.7 million, respectively, in debt issuance costs, premium and discount for the three and nine months ended September 30, 2006, and amortized \$0.1 million and \$0.3 million, respectively, in debt issuance costs for the three and nine months ended September 30, 2005.

### 3. COLLABORATIVE AND OTHER ARRANGEMENTS

In April of 2006, Chiron Corporation ( Chiron ) announced that its shareholders had approved the amended merger agreement under which Novartis AG would acquire all Chiron shares it did not already own and the acquisition was consummated. Although the Company is continuing to evaluate the impact of this acquisition, it does not yet know what effect this transaction will have on its collaboration.

In May of 2006, the Company entered into a collaboration agreement with the Schering-Plough Research Institute division of Schering Corporation ( SPRI ) for therapeutic monoclonal antibody discovery and development. Under the agreement, SPRI will make upfront and milestone payments to the Company, fund the Company's R&D and manufacturing activities related to the agreement and pay the Company royalties on sales of products resulting from the collaboration. During the collaboration, the Company will discover therapeutic antibodies against one or more targets selected by SPRI. The Company will recognize revenue on the upfront payment on a straight-line basis over the term of the contract, on the services as they are performed and on the milestones and royalties as they are received.

Beginning in the quarter ended June 30, 2006, the Company became eligible for a royalty from Genentech on worldwide sales of LUCENTIS (ranibizumab injection), a new drug for the treatment of neovascular (wet) AMD. This royalty obligation results from an existing agreement with Genentech related to the licensing of the Company's bacterial cell expression technology.

In July of 2006, the Company announced that it had been awarded a \$16.3 million dollar contract (Contract No. HHSN266200600008C/N01-A1-60008) funded with Federal funds from the National Institute of Allergy and Infectious Diseases ( NIAID ), a

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

part of the National Institutes of Health, Department of Health and Human Services, to produce botulinum neurotoxin monoclonal antibodies for the treatment of botulism to protect U.S. citizens against the harmful effects of botulinum neurotoxins used in bioterrorism.

## **Table of Contents**

### **4. LEGAL PROCEEDINGS**

In September of 2004, XOMA (US) LLC entered into a collaboration with Aphton Corporation ( Aphton ) for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In May of 2006, Aphton filed for bankruptcy protection under Chapter 11, Title 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, No. 06-10510 (CSS). XOMA (US) LLC filed a proof of claim in the proceeding, as a unsecured creditor of Aphton, for approximately \$594,000. It is not presently known what, if any, distributions will be made to holders of unsecured claims.

### **5. SUBSEQUENT EVENTS**

On November 2, 2006, the Company announced that it had entered into a collaboration agreement with Takeda Pharmaceutical Company Limited ( Takeda ) for therapeutic monoclonal antibody discovery and development. Under the agreement, Takeda will make upfront and milestone payments to the Company, fund the Company's R&D and manufacturing activities for preclinical and early clinical supplies and pay the Company royalties on sales of products resulting from the collaboration. During the collaboration, the Company will discover therapeutic antibodies against multiple targets selected by Takeda. The Company will recognize revenue on the upfront payment on a straight-line basis over the term of the contract, on the services as they are performed and on the milestones and royalties as they are received.

On November 9, 2006, XOMA (US) LLC entered into a five-year, \$35.0 million term loan facility ( the facility ) with Goldman Sachs Specialty Lending Holdings, Inc. and borrowed the full amount thereunder. The loan is guaranteed by the Company. Indebtedness under the facility will bear interest at an annual rate equal to six-month LIBOR plus 5.25% and is secured by all rights to receive payments due XOMA (US) LLC relating to RAPTIVA®, LUCENTIS and CIMZIA. Payments received by XOMA (US) LLC in respect of these payment rights will be used to make semi-annual interest payments under the facility, and amounts in excess of interest requirements may be used to pay down principal at the discretion of the lender. XOMA (US) LLC may prepay indebtedness under the facility at any time, subject to certain prepayment premiums. Proceeds from the loan will be used for general corporate purposes.

**Table of Contents****ITEM 2 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

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

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

Total revenues for the three and nine months ended September 30, 2006, were \$7.4 million and \$20.5 million, respectively, compared with \$4.4 million and \$12.6 million, respectively, for the same periods of 2005.

License and collaborative fee revenues were \$0.6 million and \$2.0 million, respectively, for the three and nine months ended September 30, 2006, compared with \$0.9 million and \$4.0 million, respectively, for the same periods of 2005. These revenues include amortization of upfront payments, milestone revenues and licensing revenues related to the outlicensing of our products and technologies and other collaborative arrangements. The decrease of \$2.0 million for the nine months ended September 30, 2006, resulted primarily from an outlicensing agreement with Merck & Co. Inc. in the quarter ended June 30, 2005.

Contract revenues were \$3.8 million and \$11.6 million, respectively, for the three and nine months ended September 30, 2006, compared with \$1.9 million and \$4.1 million, respectively, for the same periods of 2005. The increase of \$1.9 million for the three months ended September 30, 2006, resulted primarily from contracts entered into in 2006 with Schering Plough Research Institute (SPRI), Cubist Pharmaceuticals, Inc. (Cubist), Taligen Therapeutics Inc. (Taligen) and AVEO Pharmaceuticals, Inc. (AVEO). The increase of \$7.5 million for the nine months ended September 30, 2006, partially resulted from the above 2006 contracts but was primarily caused by contract manufacturing process services performed under our contracts with the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health, Department of Health and Human Services, entered into in March of 2005 to develop three anti-botulinum neurotoxin monoclonal antibody therapeutics and, in July of 2006, to produce monoclonal antibodies for the treatment of botulism to protect U.S. citizens against the harmful effects of botulinum neurotoxins used in bioterrorism. The increase from these contracts was partially offset by a reduction in clinical trial services performed on behalf of Genentech, Inc. (Genentech).

The March 2005 NIAID contract work is being performed over an eighteen month period and is 100% funded with federal funds from NIAID under Contract No. HHSN266200500004C. We are recognizing revenue over the life of the contract as the services are performed on a proportional performance basis and, as per the terms of the contract, a 10% retention on all revenue is being deferred and classified as a receivable until final acceptance of the contract which was achieved in October of 2006. Therefore, the 10% retention will be recognized in the fourth quarter of 2006. The July 2006 NIAID contract work is being performed on a cost plus fixed fee basis, per the terms of the contract, over a three year period and is 100% funded with federal funds from NIAID under Contract No. HHSN266200600008C/N01-A1-60008. We are recognizing revenue as the services are performed on a proportional performance basis.

Royalties were \$2.9 million and \$6.9 million, respectively, for the three and nine months ended September 30, 2006, compared with \$1.7 million and \$4.5 million, respectively, for the same periods of 2005. The increases of \$1.2 million and \$2.4 million, respectively, for the three and nine months ended September 30, 2006, resulted primarily from an increase in RAPTIVA® royalties and the inception of LUCENTIS royalties earned under our royalty arrangements with Genentech.

***Operating Costs and Expenses***

Research and development expenses consist of direct and research-related allocated overhead costs such as salaries and related personnel costs, patents, materials and supplies in addition to costs related to clinical trials to validate our testing processes and procedures and related overhead expenses. Research and development expenses include independent research and development and costs associated with collaborative research and development as well as contract research and development arrangements. Research



**Table of Contents**

and development expenses were \$12.7 million and \$37.0 million, respectively, for the three and nine months ended September 30, 2006, compared with \$9.4 million and \$28.9 million, respectively, for the same periods of 2005, an increase of 35% and 28%, respectively. These increases primarily reflect increases in spending on our contracts with NIAID, Taligen and AVEO, our development of XOMA 052 and NEUPREX®, and our collaborations with Lexicon Genetics Incorporated ( Lexicon ) and SPRI, partially offset by decreased spending on our collaboration agreements with Novartis Vaccines and Diagnostics, Inc. ( Novartis formerly known as Chiron Corporation), Genentech, Aphton Corporation ( Aphton ) and Millennium Pharmaceuticals, Inc., and our development of XMP.629. In addition, for the three and nine months ended September 30, 2006, we recorded \$0.1 million and \$0.4 million, respectively, of share-based compensation expense. No share based compensation expense was recorded in 2005.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2006	2005	September 30, 2006	2005
Earlier stage programs	\$ 11,211	\$ 7,647	\$ 30,255	\$ 21,680
Later stage programs	1,460	1,736	6,701	7,252
<b>Total</b>	<b>\$ 12,671</b>	<b>\$ 9,383</b>	<b>\$ 36,956</b>	<b>\$ 28,932</b>

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

	Three Months Ended		Nine Months Ended	
	September 30, 2006	2005	September 30, 2006	2005
Internal projects	\$ 7,977	\$ 5,496	\$ 23,161	\$ 17,625
Collaborative arrangements	4,694	3,887	13,795	11,307
<b>Total</b>	<b>\$ 12,671</b>	<b>\$ 9,383</b>	<b>\$ 36,956</b>	<b>\$ 28,932</b>

For the three months ended September 30, 2006, two development programs (our Novartis collaboration and NIAID) accounted for more than 10% but less than 20%, one development program (XOMA 052) accounted for more than 20% but less than 30% and no development program accounted for more than 30% of our total research and development expenses. For the nine months ended September 30, 2006, three development programs (our Novartis collaboration, NIAID and XOMA 052) accounted for more than 10% but less than 20%, and no development program accounted for more than 20% of our total research and development expenses. For the three months ended September 30, 2005, one development program (our Novartis collaboration) accounted for more than 40% but less than 50% and no development program accounted for more than 50% of our total research and development expenses. For the nine months ended September 30, 2005, one development program (our Novartis collaboration) accounted for more than 30% but less than 40% and no development program accounted for more than 40% of our total research and development expenses.

We currently anticipate that research and development expenses will continue to increase in 2006 as compared with 2005. We expect our spending on our oncology collaboration with Novartis, including HCD122, to continue as well as increases in spending on our collaborations with Lexicon and SPRI, our contracts with NIAID, our development of XOMA 052 and NEUPREX®, and other new projects. Future research and development spending may also be impacted by potential new licensing or collaboration arrangements, as well as the termination of existing agreements. Beyond this, the scope and magnitude of future research and development expenses are difficult to predict at this time.

General and administrative expenses include salaries and related personnel costs, facilities costs and professional fees. General and administrative expenses for the three and nine months ended September 30, 2006, were \$4.2 million and \$13.6 million, respectively, compared



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

with \$3.2 million and \$10.7 million, respectively, for the same periods of 2005. The increase of \$1.0 million for the three months ended September 30, 2006, compared with the three months ended September 30, 2005, resulted primarily from increased employee and related expenses and professional fees. The increase of \$2.9 million for the nine months ended September 30, 2006, compared with the nine months ended September 30, 2005, resulted primarily from increased professional fees of which \$1.1 million related to our February debt exchange. In addition, for the three and nine months ended September 30, 2006, we recorded

## **Table of Contents**

\$0.1 million and \$0.4 million, respectively, of share-based compensation expense. No share-based compensation expense was recorded in 2005.

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

Investment and interest income for the three and nine months ended September 30, 2006, was \$0.3 million and \$1.2 million, respectively, compared with \$0.5 million and \$1.4 million, respectively, for the same periods of 2005. Investment and interest income consists primarily of interest earned on our cash and investment balances. The nine month period ended September 30, 2005, includes a \$0.3 million one-time gain on the sale of short-term investments.

Interest expense for the three and nine months ended September 30, 2006, was \$1.7 million and \$8.4 million, respectively, compared with \$1.2 million and \$3.0 million, respectively, for the same periods of 2005. Interest expense for the three months ended September 30, 2006, consists of \$0.2 million from the revaluation of the embedded derivative from our convertible debt, \$0.9 million of interest payable on our convertible debt, \$0.3 million in net amortization of debt issuance costs, discount and premium on our convertible debt and \$0.3 million of interest payable on our note with Novartis. Interest expense for the nine months ended September 30, 2006, consists of \$4.1 million from the revaluation of the embedded derivative from our convertible debt, \$2.8 million of interest payable on our convertible debt, \$0.8 million in net amortization of debt issuance costs, discount and premium on our convertible debt and \$0.7 million of interest payable on our note with Novartis. Our 2005 interest expense consisted primarily of interest payable on our convertible notes.

Other income (expense) for the three and nine months ended September 30, 2006, was zero compared with zero and \$41.2 million, respectively for the three and nine months ended September 30, 2005. The amount for the nine months ended September 30, 2005, consists primarily of a one-time gain related to the extinguishment of the Genentech development loan as a result of the restructuring of the Genentech agreement, which occurred in January of 2005.

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

Prior to the adoption of Financial Accounting Standards No. 123 (revised 2004), Stock-Based Payment ( SFAS 123R ) on January, 1, 2006, we accounted for our share-based compensation plans under the intrinsic value method described in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, ( APB 25 ) and related Interpretations as permitted by Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation ( SFAS 123 ), as amended by Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure ( SFAS 148 ). In general, as the exercise price of the options granted under our plans was equal to the market price of the underlying common shares on the grant date, no share-based employee compensation cost was recognized. As required by SFAS 148 prior to the adoption of SFAS 123R, we provided pro forma net income (loss) and pro forma net income (loss) per common share disclosures for share-based awards, as if SFAS 123 had been applied.

SFAS 123R requires all share based payments to be recognized in the financial statements based on their fair values. We are using the modified prospective method. Under this method, compensation cost recognized during the three and nine month periods ended September 30, 2006, includes compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123 amortized on a graded vesting basis over the options' vesting period, and compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R amortized on a straight-line basis over the options' vesting period. We elected to use the modified prospective transition method as permitted by SFAS 123R and, therefore, have not restated our financial results for prior periods to reflect expensing of share-based compensation. As a result, the results for the three and nine months ended September 30, 2006, are not comparable to the same periods of the prior year.

Prior to the adoption of SFAS 123R, our Board of Directors approved the acceleration of vesting of all outstanding employee share options with an exercise price greater than \$3.00 per share. Because the exercise price of all the accelerated options exceeded the market price per share of the common shares as of the new measurement date, the acceleration had no impact on our earnings in 2005. Since the accelerated options had exercise prices in excess of the current market value of our common shares, the options had limited economic value and were not fully achieving their original objective of incentive compensation and employee retention. The modification allows expense recognized after the adoption of SFAS 123R to better reflect our compensation strategies.

During the three and nine months ended September 30, 2006, we recognized \$0.2 million and \$0.8 million, respectively, in share-based compensation expense. At September 30, 2006, there was \$1.3 million of unrecognized share-based compensation expense related to unvested shares with a weighted average remaining recognition period of 2.8 years.



## **Table of Contents**

### **Liquidity and Capital Resources**

Cash, cash equivalents and short-term investments at September 30, 2006, was \$23.5 million compared with \$43.5 million at December 31, 2005. This \$20.0 million decrease reflects cash used in operations of \$28.6 million and cash used in the purchase of fixed assets of \$6.8 million partially offset by cash provided by financing activities \$15.3 million, primarily from the \$12.5 million in New Notes issued for cash in our convertible debt exchange.

Net cash used in operating activities was \$28.6 million for the nine months ended September 30, 2006, compared with \$41.1 million for the same period in 2005.

Cash used in operations for the nine months ended September 30, 2006, consisted of a net loss of \$37.4 million with non-cash addbacks for the revaluation of our embedded derivative of \$4.1 million, depreciation and amortization of \$4.5 million and equity related compensation of \$1.9 million partially offset by a decrease in accrued interest of \$0.3 million and an increase in assets of \$1.6 million. During the nine months ended September 30, 2006, we made payments of \$2.7 million for debt issuance costs on our convertible debt of which \$2.0 million affected cash from operations, \$3.7 million for interest on our convertible debt and \$1.1 million for our Management Incentive Compensation Program ( MICP ), which is paid in March of each year.

Cash used in operations for the nine months ended September 30, 2005, consisted of a net income of \$12.5 million with non-cash deductions of \$40.9 million for a gain on the extinguishment of our debt with Genentech and a \$0.3 million gain on a sale of investments along with an increase in assets of \$3.9 million and a net decrease in liabilities of \$14.2 million partially offset by non-cash addbacks for depreciation and amortization of \$3.7 million, equity related compensation of \$1.3 million and accrued interest of \$0.8 million. During the nine months ended September 30, 2005, we made payments of \$4.0 million on our Genentech collaboration liability, \$2.9 million on our Novartis collaboration liability, \$1.9 million for interest on our convertible debt and \$1.3 million for our MICP.

Net cash provided by investing activities for the nine months ended September 30, 2006, was \$3.0 million compared with \$33.3 million used in investing activities for the nine months ended September 30, 2005. The \$36.3 million increase in cash 2006 compared with 2005 reflected a \$40.5 million decrease in purchases, net of sales, of investments and a \$4.2 million increase in purchases of property and equipment.

Net cash provided by financing activities for the nine months ended September 30, 2006 and 2005, was \$15.3 million and \$65.2 million, respectively. Financing activities for the nine months ended September 30, 2006, consisted of \$12.5 million in proceeds from the issuance of convertible notes, offset by \$0.5 million in debt issuance costs, a \$3.0 million advance on our line of credit with Novartis and \$0.4 million in proceeds from the issuance of common shares. Financing activities for the nine months ended September 30, 2005, consisted of an issuance of \$60.0 million of convertible senior notes for net proceeds of \$56.6 million, an \$8.8 million drawdown on our Novartis loan facility and \$0.1 million in proceeds from the issuance of common shares partially offset with capital lease payments and payments of short-term loan obligations of \$0.1 million each.

In February of 2006, we completed an exchange offer with holders of our 6.5% convertible senior notes due 2012 in which we exchanged \$60.0 million aggregate principal amount of our new 6.5% Convertible SNAPS<sub>SM</sub> due 2012 (the New Notes ) for all \$60.0 million aggregate principal amount of our then outstanding convertible senior notes due 2012. We also issued an additional \$12.0 million of New Notes to the public for cash at a public offering price of 104% of principal, or \$12.5 million. The New Notes are initially convertible into approximately 38.4 million common shares at a conversion rate of 533.4756 of common shares per \$1,000 principal amount of New Notes, which is equivalent to a conversion price of approximately \$1.87 per common share. Before February 10, 2010, we may not redeem the New Notes. On or after February 10, 2010, we may redeem any or all of the New Notes at 100% of the principal amount, plus accrued and unpaid interest. In addition, we may automatically convert some or all of the New Notes on or prior to the maturity date if the closing price of our common shares has exceeded 150% of the conversion price then in effect for at least 20 trading days during any consecutive 30 trading day period ending within five trading days prior to the notice of auto-conversion. If we elect to automatically convert, or if holders elect to voluntarily convert, some or all of the New Notes on or prior to February 10, 2010, we must pay or provide for additional interest equal to four years' worth of interest less any interest paid or provided for, on the principal amount so converted, prior to the date of conversion. Additional interest, if any, shall be paid in cash or, solely at our option and subject to certain limitations, in our common shares valued at the conversion price then in effect.

In accounting for the New Notes, we applied guidance as set forth in EITF 96-19, Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities, as amended ( SFAS 133 ), EITF 05-7, EITF 00-19, and EITF 01-6 as follows. The exchange offer is a modification of existing debt, rather than an extinguishment. The additional interest payment upon conversion is an embedded derivative requiring separate accounting. We considered the provisions of EITF 05-2 and concluded that this is not conventional convertible debt.



## **Table of Contents**

In accordance with SFAS 133, we have separately accounted for the additional interest payment feature of the New Notes as an embedded derivative instrument, which is measured at fair value and classified on the balance sheet with the convertible debt. Changes in the fair value of the embedded derivative are recognized in earnings as a component of other income (expense). At the time of issuance, we estimated the fair value of the additional interest payment feature to be \$5.8 million, including approximately \$1.0 million related to the New Notes issued for cash, based on current information including share price. For the New Notes issued in the exchange offer and in the new money offering, this amount was subtracted from the carrying value of the debt, reflected as a debt discount, which is amortized as interest expense using the effective interest method through the date the notes are scheduled to mature, and separately reported as a derivative liability.

The additional New Notes were issued to the initial purchasers for net proceeds of \$11.8 million. Debt issuance costs related to the New Notes of approximately \$0.7 million are being amortized on a straight-line basis over the 72 month life of the notes. Additional debt issuance costs of \$2.0 million, related to the modification of the existing debt, were expensed as incurred with \$1.1 million and \$0.9 million expensed during the quarters ended March 31, 2006 and December 31, 2005, respectively.

For the three months ended September 30, 2006, \$20,000 of New Notes were converted into 13,097 common shares including 2,427 shares related to the additional interest payment feature of the notes. We recorded a \$176,000 charge to interest expense during the quarter ended September 30, 2006, as a result of an increase in the fair value of the embedded derivative on our convertible debt including \$2,000 related to the converted notes.

For the nine months ended September 30, 2006, \$15.5 million of New Notes were converted into 10,398,267 common shares including 2,145,398 shares related to the additional interest payment feature of the notes. We recorded a \$4.1 million charge to interest expense during the nine months ended September 30, 2006, as a result of an increase in the fair value of the embedded derivative on our convertible debt including \$2.7 million related to the converted notes.

For the three months ended September 30, 2006 and 2005, we incurred \$0.9 million and \$1.0 million, respectively, in interest expense payable on our convertible debt. For the nine months ended September 30, 2006 and 2005, we incurred \$2.8 million and \$2.5 million, respectively, in interest expense payable on our convertible debt. Interest expense is payable on a semi-annual basis. Additionally, we amortized a net of \$0.3 million and \$0.7 million, respectively, in debt issuance costs, premium and discount for the three and nine months ended September 30, 2006, and amortized \$0.1 million and \$0.3 million, respectively, in debt issuance costs for the three and nine months ended September 30, 2005.

We expect our cash, cash equivalents and short-term investments to increase during the fourth quarter of 2006 as a result of our recent financing partially offset by the use of cash to fund ongoing operations and capital investments.

Based on current spending levels, anticipated revenues, collaborator funding, proceeds from our convertible note offerings in February of 2005 and February of 2006, our November 2006 term loan and other sources of funding we believe to be available, we estimate that we have sufficient cash resources to meet our anticipated net cash needs through at least 2008. Any significant revenue shortfalls, increases in planned spending on development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. Progress or setbacks by potentially competing products may also affect our ability to raise new funding on acceptable terms.

## **Critical Accounting Policies**

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition and recognition of research and development expenses to be critical policies. There have been no significant changes in our critical accounting policies, except as noted below, during the nine months ended September 30, 2006, as compared with those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 8, 2006.

### *Contract Revenue*

Contract revenue for research and development involves our providing research and development for manufacturing processes to collaborative partners or others. We recognize revenue under these arrangements as the related research and development costs are incurred and collectibility is reasonably assured. Revenues for certain contracts are accounted for by a proportional performance, or output based, method where performance is based on agreed progress toward elements defined in the contract.



## **Table of Contents**

### *Share Based Compensation*

On January 1, 2006, we adopted SFAS 123R, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors, including employee share options and employee share purchases related to the Employee Share Purchase Plan, on estimated fair values. We are using the modified prospective method. Under this method, we are required to record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. To estimate the value of an award, we use the Black-Scholes option pricing model. This model requires inputs such as expected life, expected volatility and risk-free interest rate. Further, 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 our historical data, the risk-free rate is based on the yield available on U.S. Treasury zero-coupon issues. We review our valuation assumptions quarterly and, as a result, it is likely we will change our valuation assumptions used to value share based awards granted in future periods.

### **Recent Accounting Pronouncements**

In July of 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes ( FIN 48 ), an interpretation of FASB Statement No. 109, Accounting for Income Taxes ( FAS 109 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FAS 109 and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 will be effective beginning with the first annual period after December 15, 2006. We are still evaluating what impact, if any, the adoption of this standard will have on our financial position or results of operations.

### **Subsequent Events**

On November 2, 2006, we announced that we had entered into a collaboration agreement with Takeda Pharmaceutical Company Limited ( Takeda ) for therapeutic monoclonal antibody discovery and development. Under the agreement, Takeda will make upfront and milestone payments to us, fund our R&D and manufacturing activities for preclinical and early clinical supplies and pay us royalties on sales of products resulting from the collaboration. During the collaboration, we will discover therapeutic antibodies against multiple targets selected by Takeda. We will recognize revenue on the upfront payment on a straight-line basis over the term of the contract, on the services as they are performed and on the milestones and royalties as they are received.

On November 9, 2006, XOMA (US) LLC entered into a five-year, \$35.0 million term loan facility ( the facility ) with Goldman Sachs Specialty Lending Holdings, Inc. and borrowed the full amount thereunder. The loan is guaranteed by us. Indebtedness under the facility will bear interest at an annual rate equal to six-month LIBOR plus 5.25% and is secured by all rights to receive payments due XOMA (US) LLC relating to RAPTIVA®, LUCENTIS and CIMZIA . Payments received by XOMA (US) LLC in respect of these payment rights will be used to make semi-annual interest payments under the facility, and amounts in excess of interest requirements may be used to pay down principal at the discretion of the lender. XOMA (US) LLC may prepay indebtedness under the facility at any time, subject to certain prepayment premiums. Proceeds from the loan will be used for general corporate purposes.

### **Forward-Looking Information And Cautionary Factors That May Affect Future Results**

Certain statements contained herein related to the sufficiency of our cash resources, levels of future expenses and cash, future sales of approved products, as well as other statements related to current plans for product development and existing and potential collaborative and licensing relationships, or that otherwise relate to future periods, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on assumptions that may not prove accurate. Actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market. Among other things, the period for which our cash resources are sufficient could be shortened if expenditures are made earlier or in larger amounts than anticipated or are unanticipated, if anticipated revenues or cost sharing arrangements do not materialize, if funds are not otherwise available on acceptable terms; expense levels and cash utilization may be other than as expected due to unanticipated changes in our research and development programs; and the sales efforts for approved products may not be successful if the parties responsible for marketing and sales fail to meet their commercialization goals, due to the strength of the competition, if physicians do not adopt the product as treatment for their patients or if remaining regulatory approvals are not obtained. These and other risks, including those related to the results of pre-clinical 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 Food and Drug Administration ( FDA ), European or other regulators or their advisory bodies; and analysis or interpretation by, or submission to,





**Table of Contents**

these entities or others of scientific data); changes in the status of existing collaborative relationships; the ability of collaborators and other partners to meet their obligations; our ability to meet the demand of the United States government agency with which we have entered our first government contract; competition; market demands for products; scale-up and marketing capabilities; availability of additional licensing or collaboration opportunities; international operations; share price volatility; our financing needs and opportunities; uncertainties regarding the status of biotechnology patents; uncertainties as to the costs of protecting intellectual property; and risks associated with our status as a Bermuda company, are described in more detail in the remainder of this section.

**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 facility. By policy, we make our investments in high quality debt securities, limit the amount of credit exposure to any one issuer, limit duration by restricting the term of the instrument and hold investments to maturity except under rare circumstances. We do not invest in derivative financial instruments.

In February of 2006, we completed an exchange offer for all \$60.0 million of our 6.5% convertible senior notes due 2012 for \$60.0 million of 6.5% convertible SNAPS<sup>SM</sup> due 2012 (the New Notes) and issued an additional \$12.0 million of New Notes to the public for cash. The interest rate and amount of principal of the previously outstanding notes were, and of the New Notes are, fixed. The New Notes include an additional interest rate feature which is accounted for as an embedded derivative which is measured at fair value. Changes in the fair value of the embedded derivative are recognized in earnings as interest expense.

As of September 30, 2006, we have drawn down \$15.8 million against the Novartis \$50.0 million loan facility that is due in 2015 at an interest rate based on six month LIBOR plus 2 percent which was 7.53% at September 30, 2006. We estimate that a hypothetical 100 basis point change in interest rates could increase or decrease our interest expense by approximately \$160,000 on an annualized basis.

In November of 2006, we entered into a five-year senior term loan facility in the aggregate amount of \$35.0 million. Interest on the facility will be at a rate of USD six month LIBOR plus 5.25% with the principal due at maturity.

We hold interest-bearing instruments that are classified as cash, cash equivalents and short-term investments. Fluctuations in interest rates can affect the principal values and yields of fixed income investments. If interest rates in the general economy were to rise rapidly in a short period of time, our fixed income investments could lose value. The following table presents the amounts and related weighted interest rates of our cash and investments at September 30, 2006 and December 31, 2005 (in thousands, except interest rate):

		Carrying		Average
	Maturity	Amount	Fair Value	Interest Rate
September 30, 2006				
Cash and cash equivalents	Daily	\$ 10,517	\$ 10,517	4.17%
Short-term investments	Less than 1 year	12,942	12,986	4.65%
December 31, 2005				
Cash and cash equivalents	Daily	\$ 20,804	\$ 20,804	2.82%
Short-term investments	Less than 1 year	22,801	22,732	4.23%

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

Under the supervision and with the participation of our management, including our Chairman of the Board, President and Chief Executive Officer 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 of the Board, President and Chief Executive Officer and our Vice President, Finance and Chief Financial Officer concluded that our disclosure controls and procedures are



## **Table of Contents**

effective 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 September of 2004, XOMA (US) LLC entered into a collaboration with Aphton for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In May of 2006, Aphton filed for bankruptcy protection under Chapter 11, Title 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, No. 06-10510 (CSS). XOMA (US) LLC filed a proof of claim in the proceeding, as an unsecured creditor of Aphton, for approximately \$594,000. It is not presently known what, if any, distributions will be made to holders of unsecured claims.

### **ITEM 1a. RISK FACTORS**

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

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

Currently, our revenues rely significantly upon sales of RAPTIVA® and LUCENTIS®, in which we have only a royalty interest. RAPTIVA® was approved by the FDA on October 27, 2003, for the treatment of chronic moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Genentech and Serono SA (Serono), Genentech's international marketing partner for RAPTIVA®, are responsible for the marketing and sales effort in support of this product. In September of 2004, Serono announced that RAPTIVA® had received approval for use in the European Union and the product was launched in several European Union countries in the fourth quarter of 2004. LUCENTIS® was approved by the FDA on June 30, 2006, for the treatment of AMD. Genentech and Novartis AG, Genentech's international marketing partner for LUCENTIS®, are responsible for the marketing and sales effort in support of this product. We have no role in marketing and sales efforts, and neither Genentech nor Serono has an express contractual obligation to us regarding the marketing or sales of RAPTIVA® or LUCENTIS®.

Under our current arrangements with Genentech, we are entitled to receive royalties on worldwide sales of RAPTIVA® and LUCENTIS®. Successful commercialization of this product is subject to a number of risks, including, but not limited to:

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

the strength of competition from other products being marketed or developed to treat psoriasis;

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

physicians' and patients' acceptance of RAPTIVA® as a treatment for psoriasis;

physicians' and patients' acceptance of LUCENTIS as a treatment for AMD;

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

pricing and reimbursement issues.

## **Table of Contents**

According to Genentech, U.S. sales of RAPTIVA® for the first nine months of 2006 were \$66.2 million, compared with \$58.8 million for the first nine months of 2005. According to Serono, sales of RAPTIVA® outside of the U.S. for the first nine months of 2006 were \$48.7 million, compared with \$21.8 million for the first nine months of 2005. According to Genentech, U.S. sales of LUCENTIS through September 30, 2006, were \$162.9 million including sales during the third quarter of 2006 of \$152.5 million. LUCENTIS sales outside the U.S. were \$6.4 million, of which \$3.9 million occurred during the third quarter of 2006. This was the first full quarter for sales. Given our current reliance on RAPTIVA® and LUCENTIS as principal sources of our revenues, any material adverse developments with respect to the commercialization of RAPTIVA® or LUCENTIS may cause our revenues to decrease and may cause us to incur losses in the future.

**Because our products 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 which could adversely affect your investment.**

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 products and production technologies,

expansion of our production capabilities,

various human clinical trials and

protection of our intellectual property.

Based on current spending levels, anticipated revenues, collaborator funding, proceeds from our convertible note offerings in February of 2005 and February of 2006, our November 2006 term loan and other sources of funding we believe to be available, we estimate that we have sufficient cash resources to meet our anticipated net cash needs through at least 2008. Any significant revenue shortfalls, increases in planned spending on development programs or more rapid progress of development programs than anticipated, as well as the unavailability of anticipated sources of funding, could shorten this period. Progress or setbacks by potentially competing products may also affect our ability to raise new funding on acceptable terms. As a result, we do not know when or whether:

operations will generate meaningful funds,

additional agreements for product development funding can be reached,

strategic alliances can be negotiated or

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

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

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

As of September 30, 2006, we (including our subsidiaries) had approximately \$74.2 million, including our embedded derivative, of indebtedness outstanding. We may not be able to generate cash sufficient to pay the principal of, interest on and other amounts due in respect of our indebtedness when due. We and our subsidiaries may also incur additional debt that may be secured. In connection with our collaboration with

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

Novartis, Novartis has extended a line of credit to us (through our United States subsidiary) for \$50.0 million to fund up to 75% of our expenses thereunder, of which \$15.8 million was drawn as of September 30, 2006. This line of credit is secured by a pledge of our interest in the collaboration.

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 convertible notes and our obligations to other persons with respect to our other debt;

## Table of Contents

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.

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

Our products 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 products, including:

testing,

manufacturing,

promotion and marketing and

exporting.

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



which may have a material impact on the FDA product approval process.

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

Our potential products 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

## **Table of Contents**

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 products.

For example,

In 1996, in conjunction with Genentech, we began testing RAPTIVA® in patients with moderate-to-severe plaque psoriasis. In April of 2002, we announced with Genentech that a pharmacokinetic study conducted on RAPTIVA® comparing XOMA-produced material and Genentech-produced material did not achieve the pre-defined statistical definition of comparability, and the FDA requested that another Phase III study be completed before the filing of a Biologics License Application for RAPTIVA®, delaying the filing beyond the previously-planned time frame of the summer of 2002. In March of 2003, we announced completion of enrollment in a Phase II study of RAPTIVA® in patients suffering from rheumatoid arthritis. In May of 2003, Genentech and we announced our decision to terminate Phase II testing of RAPTIVA® in patients suffering from rheumatoid arthritis based on an evaluation by an independent Data Safety Monitoring Board that suggested no overall net clinical benefit in patients receiving the study drug. We also completed enrollment in a Phase II study of RAPTIVA® as a possible treatment for patients with psoriatic arthritis. In March of 2004, we announced that the study did not reach statistical significance.

In December of 1992, we began human testing of our NEUPREX® product, a genetically engineered fragment of a particular human protein, and licensed certain worldwide rights to Baxter in January of 2000. In April of 2000, members of the FDA and representatives of XOMA and Baxter discussed results from the Phase III trial that tested NEUPREX® in pediatric patients with a potentially deadly bacterial infection called meningococemia, and senior representatives of the FDA indicated that the data presented were not sufficient to support the filing of an application for marketing approval at that time.

In 2003, we completed two Phase I trials of XMP.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 II clinical testing in patients with mild-to-moderate acne. In August of 2004, we announced the results of a Phase II trial with XMP.629 gel. The results were inconclusive in terms of clinical benefit of XMP.629 compared with vehicle gel.

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

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

We have experienced significant losses and, as of September 30, 2006, we had an accumulated deficit of \$713.0 million.

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

For the nine months ended September 30, 2006, we had a net loss of approximately \$37.4 million or \$0.40 per common share (basic and diluted). For the year ended December 31, 2005, as a result of the restructuring of our Genentech arrangement and subsequent extinguishment of our obligation to pay \$40.9 million under a development loan and related one-time credit to other income, we had net income of approximately \$2.8 million or \$0.03 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 products and entering into new agreements for product development, manufacturing and commercialization, all of

---

## **Table of Contents**

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 products 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.

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

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

In April of 1996, we entered into an agreement with Genentech whereby we agreed to co-develop Genentech's humanized monoclonal antibody product RAPTIVA®. In April of 1999, March of 2003, and January of 2005, the companies amended the agreement. In October of 2003, RAPTIVA® was approved by the FDA for the treatment of adults with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and, in September of 2004, Serono announced the product's approval in the European Union. In January of 2005, we entered into a restructuring of our collaboration agreement with Genentech which ended our existing cost and profit sharing arrangement related to RAPTIVA® in the United States and entitles us to a royalty interest on worldwide net sales.

In November of 2001, we entered into a collaboration with Millennium to develop two of Millennium's products for certain vascular inflammation indications. In October of 2003, we announced that we had discontinued one of these products, MLN2201. In December of 2003, we announced the initiation of Phase I testing on the other product, MLN2222. As of May 2006, we completed the transfer of the data from the Phase I study to Millennium as per our amended agreement.

In March of 2004, we announced we had agreed to collaborate with Chiron Corporation (now Novartis) for the development and commercialization of antibody products for the treatment of cancer. Under the terms of the agreement, the companies will jointly research, develop, and commercialize multiple antibody product candidates. In April of 2005, we announced the initiation of clinical testing of the first product candidate out of the collaboration, HCD122, an anti-CD40 antibody, in patients with advanced CLL. In October of 2005, we announced the initiation of the second clinical trial of HCD122 in patients with multiple myeloma.

In October of 2004, we announced the licensing of our ING-1 product to Triton for use with their TNT System.

In March of 2005, we entered into a contract with the NIAID, a part of the National Institutes of Health, to produce three monoclonal antibodies designed to protect United States citizens against the harmful effects botulinum neurotoxin of used in bioterrorism. In July of 2006, we entered into an additional contract with NIAID for the development of an appropriate formulation for human administration of these three antibodies in a single injection.

In June of 2005, we announced the formation of a collaboration to jointly develop and commercialize antibody drugs for certain targets discovered by Lexicon.

We have licensed our BCE technology, an enabling technology used to discover and screen, as well as develop and manufacture, recombinant antibodies and other proteins for commercial purposes, to approximately 45 companies. As of June 30, 2006, we were aware of one antibody product manufactured using this technology that has received FDA approval, Genentech's LUCENTIS (ranibizumab injection) for treatment of neovascular (wet) age-related macular degeneration, and one antibody manufactured using this technology that is in late-stage clinical testing, UCB's CIMZIA (CDP870) anti-TNF alpha antibody fragment for rheumatoid arthritis and Crohn's disease.

Because our collaborators and licensees are independent third parties, they may be subject to different risks than we are and have significant discretion in determining the efforts and resources they will apply. If these collaborators and licensees do not successfully develop and market these products, we may not have the capabilities, resources or rights to do so on our own. We do not know whether our collaborators or licensees

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

will successfully develop and market any of the products that are or may become the subject of one of our collaboration or licensing arrangements. In particular, each of these arrangements provides for either sharing of collaboration expenses, which means that not only we but our collaborators must have sufficient available funds for the collaborations to continue, or funding solely by our collaborators or licensees. In addition, our collaboration with Novartis provides for funding by it in the form of a line of credit to us, and we cannot be certain that Novartis will provide the necessary funds available when we attempt to draw on the line of credit. Furthermore, our contracts with NIAID contain numerous standard terms and conditions provided for in the applicable federal acquisition regulations and customary in many government contracts. Uncertainty exists as to whether we will be able to comply with these terms and conditions in a timely manner, if at all. In addition, given that this is our first program under contract with NIAID or any other governmental agency, we are uncertain as to the extent of NIAID's demands and the flexibility that

## **Table of Contents**

will be granted to us in meeting those demands. Lastly, CIMZIA (CDP870) has not received marketing approval from the FDA or any foreign governmental agency, and therefore we cannot assure you that it will prove to be safe and effective, will be approved for marketing or will be successfully commercialized.

In April of 2006, Novartis AG completed its acquisition of Chiron. Although we are continuing to evaluate the impact of this acquisition, we do not yet know what effects this transaction will have on our collaboration.

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

In December of 2003, we agreed to collaborate with Alexion Pharmaceuticals, Inc. ( Alexion ) for the development and commercialization of an antibody to treat chemotherapy-induced thrombocytopenia. The TPO mimetic antibody was designed to mimic the activity of human thrombopoietin, a naturally occurring protein responsible for platelet production. In November of 2004, in conjunction with Alexion, we determined that the lead molecule in our TPO mimetic collaboration did not meet the criteria established in the program for continued development. In the first quarter of 2005, the companies determined not to continue with this development program and in the second quarter of 2005, the collaboration was terminated.

In November of 2004, we announced the licensing of our BPI product platform, including our NEUPREX® product, to Zephyr Sciences, Inc. In July of 2005, we announced our decision to terminate the license agreement with Zephyr due to Zephyr not meeting the financing requirements of the license agreement.

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

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

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

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

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

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

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

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, 2005 through November 6, 2006, our share price has ranged from a high of \$2.74 to a low of \$0.98.

**Table of Contents**

On November 6, 2006, the closing price of the common shares as reported on the Nasdaq National Market was \$2.23 per share. Factors contributing to such volatility include, but are not limited to:

sales and estimated or forecasted sales of products,

results of preclinical studies and clinical trials,

information relating to the safety or efficacy of products,

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,

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.



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

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

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

Although RAPTIVA® was approved in the United States in October of 2003 and in the European Union in 2004 and LUCENTIS was approved in June of 2006, their acceptance in the marketplace may not continue. Furthermore, even if other products in which we have an interest receive approval in the future, they may not be accepted in the marketplace. In addition, we or our collaborators or licensees may experience difficulties in launching new products, many of which are novel and based on technologies that are unfamiliar to the healthcare community. We have no assurance that healthcare providers and patients will accept such products, if developed. For example, physicians and/or patients may not accept a product for a particular indication because it

## **Table of Contents**

has been biologically derived (and not discovered and developed by more traditional means) or if no biologically derived products are currently in widespread use in that indication. Similarly, physicians may not accept a product, such as RAPTIVA® or LUCENTIS, if they believe other products to be more effective or are more comfortable prescribing other products. Safety concerns may also arise in the course of on-going clinical trials or patient treatment as a result of adverse events or reactions.

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

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

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

significantly greater financial resources,

larger research and development and marketing staffs,

larger production facilities,

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

extensive experience in preclinical testing and human clinical trials.

These factors may enable others to develop products and processes competitive with or superior to our own or those of our collaborators. In addition, a significant amount of research in biotechnology is being carried out in universities and other non-profit research organizations. These entities are becoming increasingly interested in the commercial value of their work and may become more aggressive in seeking patent protection and licensing arrangements. Furthermore, positive or negative developments in connection with a potentially competing product may have an adverse impact on our ability to raise additional funding on acceptable terms. For example, if another product is perceived to have a competitive advantage, or another product's failure is perceived to increase the likelihood that our product will fail, then investors may choose not to invest in us on terms we would accept or at all.

Without limiting the foregoing, we are aware that:

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

Abbott Laboratories has presented data from a Phase II psoriasis trial showing clinical benefits of its rheumatoid arthritis and psoriatic arthritis drug Humira® for the treatment of psoriasis;

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

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

## **Table of Contents**

Biogen and Fumapharm AG have taken their psoriasis-treating pill, BG-12, through a Phase III trial in Germany in which, according to the companies, the product significantly reduced psoriasis symptoms in patients, and Biogen acquired Fumapharm in June of 2005;

Isotechnika, Inc. has completed a Canadian Phase III trial of ISA247, a trans-isomer of a cyclosporine analog, in 450 patients with moderate to severe psoriasis, achieving all efficacy endpoints, as well as a Phase III extension trial, and has announced plans to conduct a 500-patient second Canadian/European phase III trial; and

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

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

There are at least two competitors developing a complement inhibitor which may compete with MLN2222. Alexion and its partner Proctor & Gamble reported in November 2005 that preliminary results in a second Phase III trial of pexelizumab, a monoclonal antibody, did not achieve its primary endpoint in patients undergoing coronary artery bypass graft surgery. TP10 is a complement inhibitor developed by AVANT Immunotherapeutics, Inc. (AVANT) for applications including the limitation of complement-mediated damage following surgery on cardiopulmonary by-pass. AVANT has completed a Phase II study where the drug demonstrated treatment benefits in males.

Currently, there are at least two companies developing topical peptide treatments for acne which may compete with XMP.629. Migenix Inc. and its partner Cutanea Life Sciences, Inc. are developing MBI 594AN, a topical peptide that has completed two Phase II trials for the treatment of acne, and Helix Biomedix, Inc. is developing several peptide compounds.

In collaboration with Novartis, we are co-developing an antibody to the target CD40, and, at the current time, there are several CD40-related programs under development, mostly focused on the development of CD40 ligand products. For example, SGN-40 is a humanized monoclonal antibody under development by Seattle Genetics, Inc. which is targeting CD40 antigen. SGN-40 is currently in Phase I studies in multiple myeloma, non-Hodgkin's lymphoma, and in a Phase I/II study in chronic lymphocytic leukemia.

It is possible that other companies may be developing other products based on the same human protein as our NEUPREX® product, and these products may prove to be more effective than NEUPREX®. It is also possible that other companies may be developing other products based on the same therapeutic target as our XOMA 052 product and these products may prove to be more effective than XOMA 052.

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

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

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

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

prevent our competitors from duplicating our products;

---

## **Table of Contents**

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

permit us to gain or maintain a competitive advantage.

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

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

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

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

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

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

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

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

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



---

## **Table of Contents**

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

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

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

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

### **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.

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

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

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

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

We may not be able to successfully operate in any foreign market. We believe that, because the pharmaceutical industry is global in nature, international activities will be a significant part of our future business activities and that, when and if we are able to generate income, a substantial portion of that income will be derived from product sales and other activities outside the United States. Foreign regulatory agencies often establish standards different from those in the United States, and an inability to obtain foreign regulatory approvals on a timely basis could put us at a competitive disadvantage or make it uneconomical to proceed with a product's development. International operations and sales may be limited or disrupted by:

imposition of government controls,

export license requirements,



political or economic instability,

trade restrictions,

changes in tariffs,

---

## **Table of Contents**

restrictions on repatriating profits,

exchange rate fluctuations,

withholding and other taxation and

difficulties in staffing and managing international operations.

**Because we are a relatively small biopharmaceutical company with limited resources, we may not be able to attract and retain qualified personnel, and the loss of key personnel could delay or prevent achieving our objectives.**

Our success in developing marketable products and achieving a competitive position will depend, in part, on our ability to attract and retain qualified scientific and management personnel, particularly in areas requiring specific technical, scientific or medical expertise. There is intense competition for such personnel. Our research, product development and business efforts could be adversely affected by the loss of one or more key members of our scientific or management staff, particularly our executive officers: John L. Castello, our Chairman of the Board, President and Chief Executive Officer; Patrick J. Scannon, M.D., Ph.D., our Executive Vice President and Chief Biotechnology Officer; J. David Boyle II, our Vice President, Finance and Chief Financial Officer; and Christopher J. Margolin, our Vice President, General Counsel and Secretary. We currently have no key person insurance on any of our employees.

We had approximately 243 employees as of September 30, 2006, and we anticipate that we will require additional experienced executive, accounting, research and development, legal, administrative and other personnel in the future. There is intense competition for the services of these personnel, especially in California. Moreover, we expect that the high cost of living in the San Francisco Bay Area, where our headquarters and manufacturing facilities are located, may impair our ability to attract and retain employees in the future. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to implement our current initiatives or grow effectively.

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

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

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

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

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

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

blacklisting of our common shares by certain pension funds;

legislation restricting certain types of transactions; and

punitive tax legislation.

## **Table of Contents**

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

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

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

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

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

Our bye-laws:

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

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

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

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

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

We are authorized to issue, without shareholder approval, 1,000,000 preference shares, of which 2,959 were issued and outstanding as of September 30, 2006, 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, without shareholder approval, up to 210,000,000 common shares, of which 97,569,353 were issued and outstanding as of September 30, 2006. If we issue additional equity securities, the price of our common shares and, in turn, the price of our convertible notes may be materially and adversely affected. In addition, as of September 30, 2006, there were \$56.5 million aggregate principal amount of New Notes outstanding, which were convertible into an aggregate of 30,157,376 common shares, with an aggregate of 3,346,798 additional shares issuable in lieu of the additional interest that would be due on such conversion.

## **Table of Contents**

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

If we do not continue to comply with the continued listing requirements for The Nasdaq National 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 SmallCap Market.

We cannot be sure that our price will comply with the requirements for continued listing of our common shares on The Nasdaq National 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 National Market and we are not successful in obtaining a listing on The Nasdaq SmallCap Market, our common shares would likely trade in the over-the-counter market.

If our common shares are neither listed for trading on a United States national or regional securities exchange nor approved for trading on The Nasdaq National Market, Nasdaq SmallCap Market or any other established United States system of automated dissemination or quotations of securities prices, it would be deemed a fundamental change under the indenture governing our convertible notes, giving the holders thereof the right to require us to repurchase such notes. Our failure to repurchase our convertible notes would constitute an event of default under the notes indenture, which might constitute an event of default under the terms of our other debt.

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 National 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 National 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.

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

None.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

On May 23, 2006, the Company held its annual general meeting of shareholders. The following persons (the only nominees) were elected as the Company's directors, having received the indicated votes:

<b>Name</b>	<b>Votes For</b>	<b>Votes Withheld</b>
James G. Andress	73,987,128	9,842,398
William K. Bowes, Jr.	73,729,012	10,100,514

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

John L. Castello	73,809,950	10,019,576
Peter Barton Hutt	73,964,094	9,865,432
Arthur Kornberg, M.D.	73,993,388	9,836,138
Patrick J. Scannon, M.D., Ph.D.	74,035,252	9,794,274
W. Denman Van Ness	74,034,763	9,794,763
Patrick J. Zenner	70,031,941	13,797,585

## **Table of Contents**

The proposal to appoint Ernst & Young LLP to act as the Company's independent auditors for the 2006 fiscal year and authorize the Board to agree to such auditors' fee was approved, having received 81,063,390 votes for, 2,115,183 votes against, 650,953 abstentions and zero broker non-votes.

The proposal to amend the Company's Restricted Share Plan to eliminate the provisions thereof that permitted the issuance of shares at a price, and the granting of options with an exercise price, representing a discount to the fair market price of the common shares on the date of issuance or grant, as the case may be, was approved, having received 22,767,676 votes for, 10,186,654 votes against, 233,214 abstentions and 50,641,982 broker non-votes.

The proposal to amend the Company's 1981 Share Option Plan and Restricted Share Plan to increase the number of shares issuable over the terms of the two plans by 3,450,000 shares to 14,600,000 shares in the aggregate was approved, having received 21,790,332 votes for, 11,109,870 votes against, 287,342 abstentions and 50,641,982 broker non-votes.

The proposal to amend the Company's Restricted Share Plan to increase the number of shares issuable over the term of the plan by 750,000 shares (which shares will come out of the 3,450,000 share increase referred above) to 2,250,000 shares in the aggregate was approved, having received 21,756,632 votes for, 11,170,953 votes against, 259,959 abstentions and 50,641,982 broker non-votes.

### **ITEM 5. OTHER INFORMATION**

None.

### **ITEM 6. EXHIBITS**

#### **(a) Exhibits**

##### **Exhibit**

##### **Number**

31.1	Certification of John L. Castello, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of J. David Boyle II, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of John L. Castello, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of J. David Boyle II, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1	Press Release dated November 9, 2006, furnished herewith

**Table of Contents**

**XOMA Ltd.**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XOMA Ltd.

Date: November 9, 2006

By: /s/ JOHN L. CASTELLO  
John L. Castello  
Chairman of the Board, President and

Chief Executive Officer

Date: November 9, 2006

By: /s/ J. DAVID BOYLE II  
J. David Boyle II  
Vice President, Finance and

Chief Financial Officer