Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2008

or

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

For the transition period from_____ to _____

Commission File No. 0-14710

XOMA Ltd.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

Table of Contents

XOMA Ltd.
FORM 10-Q
TABLE OF CONTENTS

Table of Contents

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

XOMA Ltd.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2008 (unaudited)	December 31, 2007 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,186	$ 22,500
Short-term investments	4,381	16,067
Restricted cash	13,878	6,019
Receivables	7,962	12,135
Prepaid expenses and other current assets	1,858	1,113
Debt issuance costs	398	254
Total current assets	34,663	58,088
Property and equipment, net	27,970	25,603
Debt issuance costs – long-term	1,436	722
Other assets	402	402
Total assets	$ 64,471	$ 84,815
LIABILITIES AND SHAREHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable	$ 9,270	$ 6,995
Accrued liabilities	8,095	7,710
Accrued interest	2,845	878
Deferred revenue	6,487	8,017
Other current liabilities	1,599	—
Total current liabilities	28,296	23,600
Deferred revenue – long-term	9,251	10,047
Interest bearing obligation – long-term	76,262	50,850
Other long-term liabilities	353	—
Total liabilities	114,162	84,497
Commitments and contingencies		
Shareholders' equity (net capital deficiency):		
Preference shares, $.05 par value, 1,000,000 shares authorized		
Series A, 210,000 designated, no shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	—	—
Series B, 8,000 designated, 2,959 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively; aggregate liquidation preference of $29.6 million	1	1
Common shares, $.0005 par value, 210,000,000 shares authorized, 132,429,517 and 131,957,774 shares outstanding at September 30, 2008 and December 31, 2007, respectively	66	66
Additional paid-in capital	745,410	740,119
Accumulated comprehensive loss	(82)	(9)
Accumulated deficit	(795,086)	(739,859)
Total shareholders' equity (net capital deficiency)	(49,691)	318
Total liabilities and shareholders' equity (net capital deficiency)	$ 64,471	$ 84,815

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

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

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

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

XOMA Ltd.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited, in thousands)

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

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

XOMA Ltd.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business

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

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

Basis of Presentation

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

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

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

Use of Estimates

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

In the third quarter of 2008, the National Institutes of Health ("NIH") completed an audit of the Company's billing rates related to the research and development contract with the National Institute of Allergy and Infectious Diseases ("NIAID"), a part of the NIH, which is being funded with federal funds under Contract No. HHSN26620060008C/N01-A1-60008l ("NIAID 2"). Prior to the NIH's audit, XOMA's billings were based on provisional fringe, overhead and general and administrative rates supported by XOMA's 2005 actual data; these provisional rates are subject to NIH audits annually at the discretion of NIAID's contracting office. In September of 2008, the NIH completed an audit of XOMA's 2007 actual data and developed billing rates for the period from January of 2007 to

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

Significant Accounting Policies

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

Fair Value Measurements

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

Fair Value Option for Financial Assets and Financial Liabilities

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

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

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

Concentration of Risk

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

The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the nine months ended September 30, 2008, three customers represented 48%, 34% and 11% of total revenues and two of these customers and two additional customers represented 57%, 13%, 12% and 11% of the $7.8 million trade receivables outstanding at September 30, 2008. For the nine months ended September 30, 2007 four customers represented 43%, 17%, 13%, and 10% of total revenues.

Royalty Revenue

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

Share-Based Compensation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comprehensive Income (Loss)

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

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

Net Income (Loss) Per Common Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Options for common shares	18,642	6,361	18,642	9,671
Convertible preference shares	3,818	—	3,818	3,818
Warrants for common shares[1]	—	125	—	125

(1) Expired in July of 2008

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

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

Cash and Cash Equivalents

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

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

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

Short-term Investments

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

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

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

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

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

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

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

Receivables

Receivables consist of the following (in thousands):

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

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

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

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

2. FAIR VALUE

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

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

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

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

3. COLLABORATIVE AND OTHER ARRANGEMENTS

NIAID 3

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

4. LONG-TERM DEBT

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

Goldman Sachs Term Loan

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

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

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

Novartis Note

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

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

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

Letter of Credit

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

Convertible Debt

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

5. LEGAL PROCEEDINGS, COMMITMENTS AND CONTINGENCIES

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

6. SUBSEQUENT EVENTS

Equity Line of Credit

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

Novartis

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

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

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

Overview

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

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

We have a premier antibody discovery and development platform that includes six antibody phage display libraries and our proprietary Human Engineering™ and bacterial cell expression ("BCE") technologies. For example, our BCE technology is a key biotechnology for the discovery and manufacturing of antibodies and other proteins. As a result, more than 50 pharmaceutical and biotechnology companies have signed BCE licenses with us.

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

Recent Developments

Review of Research and Development Priorities

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

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

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

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

XOMA 052

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

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

Other Developments

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

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

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

Results of Operations

Revenues

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

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

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

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

Contract revenues decreased by $5.4 million and $6.8 million for the three and nine months ended September 30, 2008 compared to the corresponding periods of 2007. The decreases are primarily due to the Company nearing the end of contracted service arrangements with AVEO Pharmaceuticals, Inc. (now with SPRI and referred to herein together as "SPRI/AVEO") and NIAID, a part of the NIH, Department of Health and Human Services which is being funded with federal funds under Contract No. HHSN26620060008C/N01-A1-60008l ("NIAID 2"). The decreases are partially offset by increased activity related to our contracts with SPRI and Takeda and may be further offset by new collaboration agreements and/or the expansion of existing agreements.

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

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

Research and Development Expenses

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

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

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

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

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

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

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

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

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

General and Administrative Expenses

General and administrative (“G&A”) expenses include salaries and related personnel costs, facilities costs and professional fees. G&A expenses were $6.7 million and $19.0 million for the three and nine months ended September 30, 2008, respectively, compared with $5.8 million and $15.1 million for the corresponding periods of 2007. The $0.9 million increase for the third quarter of 2008 compared with the third quarter of 2007 included an increase in salaries of $0.3 million, travel and related expenses of $0.2 million, consulting fees of $0.4 million related to employee training, legal fees supporting internal projects of $0.3 million and marketing and communications costs of $0.4 million. These increases were offset by a decrease in bonus expense of $0.4 million and share-based compensation expense of $0.3 million.

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

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

Other Income (Expense)

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

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

Accounting for Share-Based Compensation

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

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

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

Liquidity and Capital Resources

Cash, cash equivalents and short-term investments at September 30, 2008 was $10.6 million compared with $38.6 million at December 31, 2007. Net cash used in operating activities was $35.8 million for the nine months ended September 30, 2008, compared with cash provided of $7.4 million for the same period in 2007. The $43.2 million increase in cash used for operations during the nine months ended September 30, 2008, compared with the corresponding period of 2007, consisted of a net loss of $55.2 million with non-cash add-backs for depreciation and amortization of $4.9 million, equity related compensation of $5.0 million, accrued interest of $2.7 million and amortization of debt issuance costs of $1.1 million. During the nine month period, we collected $36.7 million in outstanding accounts receivable related to our revenue streams and made payments of $26.2 million relating to payroll, $4.0 million for the annual bonus paid in the first quarter, $48.8 million relating to payment of vendors and $34.0 million for loan-related payments including principal payments, interest payments and payment of debt issuance costs. During the nine months ended September 30, 2008, as compared to the same period in 2007, we substantially increased our spending on XOMA 052.

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

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

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

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

Goldman Sachs Term Loan

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

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

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

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

Novartis Note

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

Equity Line of Credit

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

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

Critical Accounting Policies

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

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

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

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

Subsequent Events

SPRI/ AVEO

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

RAPTIVA®

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

NEUPREX®

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

Lexicon

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

Novartis

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

Forward-Looking Information and Cautionary Factors That May Affect Future Results

Certain statements contained herein related to the sufficiency of our cash resources, levels of future revenues, losses, expenses and cash, future sales of approved products, as well as other statements related to current plans for product development and existing and potential collaborative and licensing relationships, or that otherwise relate to future periods, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on assumptions that may not prove accurate. Actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market. Among other things, the period for which our cash resources are sufficient could be shortened if expenditures are made earlier or in larger amounts than anticipated or are unanticipated, if anticipated revenues or cost sharing arrangements do not materialize, if funds are not otherwise available on acceptable terms; revenue levels may be other than as expected if sales of approved products are lower than expected; losses may be other than as expected for any of the reasons affecting revenues and expenses; expense levels and cash utilization may be other than as expected due to unanticipated changes in our research and development programs; and the sales efforts for approved products may not be successful if the parties responsible for marketing and sales fail to meet their commercialization goals, due to the strength of the competition, if physicians do not adopt the product as treatment for their patients or if remaining regulatory approvals are not obtained. These and other risks, including those related to the results of pre-clinical studies; the timing or results of pending and future clinical trials (including the design and progress of clinical trials; safety and efficacy of the products being tested; action, inaction or delay by the United States Food and Drug Administration ("FDA"), European or other regulators or their advisory bodies; and analysis or interpretation by, or submission to, these entities or others of scientific data); changes in the status of existing collaborative relationships; the ability of collaborators and other partners to meet their obligations; our ability to meet the demand of the United States government agency with which we have entered our first government contract; competition; market demands for products; scale-up and marketing capabilities; availability of additional licensing or collaboration opportunities; international operations; share price volatility; our financing needs and opportunities; uncertainties regarding the status of biotechnology patents; uncertainties as to the costs of protecting intellectual property; and risks associated with our status as a Bermuda company, are described in more detail in "Item 1A – Risk Factors".

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

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

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

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

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

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

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

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

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Controls and Procedures

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

Changes in Internal Control

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

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1a. RISK FACTORS

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

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

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

- research and development relating to our product candidates and production technologies,
- expansion of our production capabilities,
- various human clinical trials, and
- protection of our intellectual property.

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

- operations will generate meaningful funds,
- additional agreements for product development funding can be reached,
- strategic alliances can be negotiated, or
- adequate additional financing will be available for us to finance our own development on acceptable terms, or at all.

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

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

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

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

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

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

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

- making it more difficult for us to satisfy our obligations with respect to our obligations to other persons with respect to our other debt;
- limiting our ability to obtain additional financing or renew existing financing at maturity on satisfactory terms to fund our working capital requirements, capital expenditures, acquisitions, investments, debt service requirements and other general corporate requirements;
- increasing our vulnerability to general economic downturns, competition and industry conditions, which could place us at a competitive disadvantage compared with our competitors that are less leveraged;
- increasing our exposure to rising interest rates to the extent any of our borrowings are at variable interest rates;
- reducing the availability of our cash flow to fund our working capital requirements, capital expenditures, acquisitions, investments and other general corporate requirements because we will be required to use a substantial portion of our cash flow to service debt obligations; and
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- results of preclinical studies and clinical trials,
- information relating to the safety or efficacy of products or product candidates,
- developments regarding regulatory filings,
- announcements of new collaborations,
- failure to enter into collaborations,
- developments in existing collaborations,
- our funding requirements and the terms of our financing arrangements,
- technological innovations or new indications for our therapeutic products and product candidates,
- introduction of new products or technologies by us or our competitors,
- government regulations,
- developments in patent or other proprietary rights,
- the number of shares issued and outstanding,
- the number of shares trading on an average trading day,
- announcements regarding other participants in the biotechnology and pharmaceutical industries, and
- market speculation regarding any of the foregoing.

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

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

- testing,
- manufacturing,
- promotion and marketing, and
- exporting.

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

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

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

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

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

- our future filings will be delayed,
- our preclinical and clinical studies will be successful,
- we will be successful in generating viable product candidates to targets,
- we will be able to provide necessary additional data,
- results of future clinical trials will justify further development, or
- we will ultimately achieve regulatory approval for any of these product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Genentech's, Merck Serono's, Novartis' and UCB's willingness and ability to implement their marketing and sales effort and achieve sales;
- the strength of competition from other products being marketed or developed to treat psoriasis, age-related macular degeneration and Crohn's disease;
- the occurrence of adverse events which may give rise to safety concerns;
- physicians' and patients' acceptance of RAPTIVA® as a treatment for psoriasis, LUCENTIS® as a treatment for age-related macular degeneration and CIMZIA® as a treatment for Crohn's disease;
- manufacturer's ability to provide manufacturing capacity to meet demand for the products; and
- pricing and reimbursement issues.

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

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

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

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

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

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

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

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

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

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

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

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

- In March of 2004, we announced we had agreed to collaborate with Chiron Corporation (now Novartis) for the development and commercialization of antibody products for the treatment of cancer. In April of 2005, we announced the initiation of clinical testing of the first product candidate out of the collaboration, HCD122, an anti-CD40 antibody, in patients with advanced CLL. In October of 2005, we announced the initiation of the second clinical trial of HCD122 in patients with multiple myeloma. In November of 2008, we announced the restructuring of this product development collaboration, which involves six development programs including the ongoing HCD 122 program. In exchange for cash, contingent consideration and options for XOMA to develop or receive royalties on the four programs currently pending selection, Novartis will have control over the HCD 122 program and the additional ongoing program, as well as the right to expand the development of these programs into additional indications outside of oncology.
- In March of 2005, we entered into a contract with NIAID to produce three monoclonal antibodies designed to protect United States citizens against the harmful effects of botulinum neurotoxin used in bioterrorism. In July of 2006, we entered into an additional contract with NIAID for the development of an appropriate formulation for human administration of these three antibodies in a single injection. In September of 2008, we announced that we were rewarded an additional contract with NIAID to support our on-going development of drug candidates toward clinical trials in the treatment of botulism poisoning.
- We have licensed our BCE technology, an enabling technology used to discover and screen, as well as develop and manufacture, recombinant antibodies and other proteins for commercial purposes, to over 50 companies. As of September 30, 2008, we were aware of two antibody products manufactured using this technology that have received FDA approval, Genentech's LUCENTIS® (ranibizumab injection) for treatment of neovascular (wet) age-related macular degeneration and UCB's CIMZIA® (certolizumab pegol) for treatment of Crohn's disease.

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

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

- In September of 2004, we entered into a collaboration with Aphton for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In January of 2006, Aphton announced that its common stock had been delisted from Nasdaq. In May of 2006, Aphton filed for bankruptcy protection under Chapter 11, Title 11 of the United States Bankruptcy Code.
- In September of 2005, we signed a letter agreement with Cubist to develop production processes and to manufacture a novel two-antibody biologic in quantities sufficient to conduct Phase 3 clinical trials. In July of 2006, Cubist announced that it had decided to cease investment in this product candidate because of stringent FDA requirements for regulatory approval, and as a result we have terminated our letter agreement with Cubist.
- In September of 2006, we entered into an agreement with Taligen which formalized an earlier letter agreement, which was signed in May of 2006, for the development and Good Manufacturing Practices ("cGMP") manufacture of a novel antibody fragment for the potential treatment of inflammatory diseases. In May of 2007, we and Taligen entered into a letter agreement (the "letter agreement") which provides that we will not produce a cGMP batch at clinical scale pursuant to the terms of the agreement entered into in September of 2006. In addition, the letter agreement provides

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

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

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

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

- significantly greater financial resources,
- larger research and development and marketing staffs,
- larger production facilities,
- entered into arrangements with, or acquired, biotechnology companies to enhance their capabilities, or
- extensive experience in preclinical testing and human clinical trials.

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

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

XOMA 052

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

- Amgen Inc.'s Kineret® (anakinra) is an interleukin-1 receptor antagonist (IL-1ra) currently marketed to treat rheumatoid arthritis ("RA") and that has been evaluated over the years in multiple IL-1 mediated diseases, including Type 2 diabetes and other indications we are considering for XOMA 052.
- Amgen has been developing AMG 108, a fully human monoclonal antibody that targets inhibition of the action of IL-1. On April 28, 2008, Amgen discussed results from its recently completed Phase 2 study in RA. AMG 108 showed statistically significant improvement in the signs and symptoms of RA and was well tolerated. Amgen announced it is focusing on other opportunities for the antibody.

- In February of 2008, Regeneron Pharmaceuticals, Inc. (“Regeneron”) announced it had received marketing approval from the FDA for ARCALYST™ (rilonacept) Injection for Subcutaneous Use, an interleukin-1 blocker or IL-1 Trap, for the treatment of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome in adults and children 12 and older. In September of 2007, Regeneron also announced that treatment with rilonacept demonstrated a statistically significant reduction in patient pain scores in a single-blind, placebo run-in-controlled study of 10 patients with chronic active gout. In November of 2007, Regeneron announced it had initiated a Phase 2 safety and efficacy trial of rilonacept in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease. In September of 2008, Regeneron announced that the recently completed Phase 2 study of rilonacept demonstrated a statistically significant reduction in gout flares versus the placebo.
- Novartis has been developing ACZ885, a fully human anti-IL-1beta monoclonal antibody targeting interleukin-1 beta, and that they reported positive results in Phase 1 proof of concept clinical trials in rheumatoid arthritis and in Muckle-Wells Syndrome in June 2006. In July of 2007, they reported advancing ACZ885 into Phase 3 clinical trial for Muckle-Wells Syndrome and in December of 2007, they entered Phase 2 testing of ACZ885 in patients with Type 2 Diabetes Mellitus.

XOMA 629

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

RAPTIVA®

- In April of 2004, Amgen Inc. and its partner Wyeth Pharmaceuticals, a division of Wyeth, announced that their rheumatoid arthritis and psoriatic arthritis drug, Enbrel®, had been approved by the FDA for the same psoriasis indication as RAPTIVA® and, in September of 2004, they announced that the product received approval in the European Union in this same indication;
- On January 18, 2008, Abbott Labs announced that the FDA had approved Humira® (adalimumab) as a treatment for adult patients with moderate to severe chronic plaque psoriasis. Abbott Labs had previously announced in December of 2007 that Humira® (adalimumab) had received marketing authorization from the European Commission for use as a treatment for moderate-to-severe plaque psoriasis;
- In September of 2006, Centocor, Inc. (“Centocor”) , a unit of Johnson & Johnson, announced that its rheumatoid arthritis and Crohn’s disease drug, Remicade® (infliximab) had been approved by the FDA for the treatment of adult patients with chronic severe (i.e. extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. This drug had already been approved to treat plaque psoriasis in the European Union, psoriatic arthritis in the United States and, in combination with methotrexate, in the European Union;
- Biogen Idec Inc. (“Biogen”) sold its worldwide rights to Amevive®, which has been approved in the United States and Canada to treat the same psoriasis indication as RAPTIVA®, to Astellas Pharma US, Inc., in March of 2006;
- In June of 2008, Centocor announced that an advisory panel to the FDA has unanimously recommended approval of ustekinumab (CNTO 1275), a fully human monoclonal antibody that targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23) for the treatment of moderate-to-severe plaque psoriasis. The MAA regulatory submission for chronic moderate-to-severe plaque psoriasis was filed with the EMEA in the EU in December of 2007; and
- Other companies are developing monoclonal antibody or other products for treatment of inflammatory skin disorders.

LUCENTIS®

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

CIMZIA®

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

HCD122

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

Biodefense

- In May of 2006, the US Department of Health & Human Services (DHHS) awarded Cangene Corporation a five-year, $362 million contract under Project Bioshield. The contract requires Cangene to manufacture and supply 200,000 doses of an equine heptavalent botulism anti-toxin to treat individuals who have been exposed to the toxins that cause botulism.
- Emergent BioSolutions, Inc. is currently in development of a botulism immunoglobulin candidate that may compete with our anti-botulinum neurotoxin monoclonal antibodies
- We are aware of additional companies that are pursuing biodefense-related antibody products. PharmAthene, Elusys Therapeutics, Inc. and Human Genome Sciences, Inc. are developing anti-anthrax antibodies. Cangene and Emergent BioSolutions, Inc. are developing anti-anthrax immune globulin products. These products may compete with our efforts in the areas of other monoclonal antibody-based biodefense products, and the manufacture of antibodies to supply strategic national stockpiles.

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

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

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

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

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

- imposition of government controls,

- export license requirements,
- political or economic instability,
- trade restrictions,
- changes in tariffs,
- restrictions on repatriating profits,
- exchange rate fluctuations,
- withholding and other taxation, and
- difficulties in staffing and managing international operations.

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

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

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology, or
- permit us to gain or maintain a competitive advantage.

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

- whether any pending or future patent applications held by us will result in an issued patent, or that if patents are issued to us, that such patents will provide meaningful protection against competitors or competitive technologies,
- whether competitors will be able to design around our patents or develop and obtain patent protection for technologies, designs or methods that are more effective than those covered by our patents and patent applications, or
- the extent to which our product candidates could infringe on the intellectual property rights of others, which may lead to costly litigation, result in the payment of substantial damages or royalties, and/or prevent us from using technology that is essential to our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- "blacklisting" of our common shares by certain pension funds,
- legislation restricting certain types of transactions, and
- punitive tax legislation.

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

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

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

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

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

Our by-laws:

- require certain procedures to be followed and time periods to be met for any shareholder to propose matters to be considered at annual meetings of shareholders, including nominating directors for election at those meetings;
- authorize our Board of Directors to issue up to 1,000,000 preference shares without shareholder approval and to set the rights, preferences and other designations, including voting rights, of those shares as the Board of Directors may determine; and
- contain provisions, similar to those contained in the Delaware General Corporation Law that may make business combinations with interested shareholders more difficult.

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS

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

SIGNATURES

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

XOMA Ltd.

Date: November 10, 2008

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

Date: November 10, 2008

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

OMB Approval 2700-0042

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ▶	RATING	PAGE OF PAGES
		N/A	1 38

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
HHSN272200800028C	09/15/2008	687901

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
National Institutes of Health National Institute of Allergy and Infectious Diseases DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612		MID RCB-A RFP NIH-NIAID-DMID-08-21	N/A

7. NAME AND ADDRESS OF CONTRACTOR (No. street, county, state and ZIP Code)	8. DELIVERY
XOMA (US) LLC (VIN: 1108484) 2910 Seventh Street Berkeley, CA 94710	☐ FOB ORIGIN ☒ OTHER (See below) FOB Destination
	9. DISCOUNT FOR PROMPT PAYMENT N/A
	10. SUBMIT INVOICES ADDRESS SHOWN IN: Art. G.3

CODE	FACILITY CODE
	N/A

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
Article F.1		See Article G.3	N/A

13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304(c)( ) ☒ 41 U.S.C. 253(c)(1)

ACCOUNTING AND APPROPRIATION DATA :
EIN: 52-2154069 SOCC 25.55
CAN: 8470038 Obligation Amount: $19,916,229

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Title: Production of Monoclonal Antibody Based Therapeutics for Botulism Period: September 15, 2008 through September 14, 2014 Contract Type: Cost Reimbursement - CPFF - Completion	FY 2008 FY 2009 FY 2010 FY 2011 FY 2012	$11,201,141 $17,337,122 $14,782,297 $12,286,842 $ 8,808,598	FY 2013	$419,287

15G. TOTAL AMOUNT OF CONTRACT ▶ $64,835,287

16. TABLE OF CONTENTS

(✓)	SEC.	DESCRIPTION	PAGE(S)	(✓)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
☒	A	SOLICITATION/CONTRACT FORM	1	☒	I	CONTRACT CLAUSES	29
☒	B	SUPPLIES OR SERVICES AND PRICE/COST	4			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
☒	C	DESCRIPTION/SPECS./WORK STATEMENT	8	☒	J	LIST OF ATTACHMENTS	37
☒	D	PACKAGING AND MARKING	13			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
☒	E	INSPECTION AND ACCEPTANCE	14	☒	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	38
☒	F	DELIVERIES OR PERFORMANCE	15				
☒	G	CONTRACT ADMINISTRATION DATA	19	☐	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
☒	H	SPECIAL CONTRACT REQUIREMENTS	22	☐	M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return __2__ copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ AWARD *(Contractor is not required to sign this document.)* Your offer on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
Robert S. Tenerowicz	Yvette R. Brown

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
Robert S. Tenerowicz (Signature of person authorized to sign)	04SEP08	BY Yvette R Brown (Signature of Contracting Officer)	9/5/08

NSN 7540-01-152-8069
PREVIOUS EDITION UNUSABLE

26-107
Computer Generated

STANDARD FORM 26 (REV. 4-85)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

CONTRACT TABLE OF CONTENTS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this acquisition is to support the development of a safe human compatible MAb-based final drug product (FDP) that neutralizes the major subserotypes of BoNT/A/B/E (i.e. Al, A2, A3, B1, B2, El, and E3). This product should be acceptable for post exposure prophylaxis and treatment of BoNT intoxication, incurred by food borne or aerosol exposure.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $61,165,364.

b. The fixed fee for this contract is $3,669,923. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $64,835,287.

d. Total funds currently available for payment and allotted to this contract are $19,916,229, of which $18,721,255 represents the estimated costs, and of which $1,194,974 represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through December 31, 2009.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding the clause[s], ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

1. Acquisition, by purchase or lease, of any interest in real property;
2. Special rearrangement or alteration of facilities;
3. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
4. Travel to attend general scientific meetings;
5. Foreign travel - See subparagraph b. below;

6. Consultant costs;
7. Subcontracts;
8. Patient care costs;
9. Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property), regardless of acquisition value.

b. **Travel Costs**

1. Domestic Travel

a. Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $18,750 without the prior written approval of the Contracting Officer.

b. The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.2 - Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

2. Foreign Travel

Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project; (c) contract purposes to be served by the travel; (d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of NIH contract funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. **Establishment of Indirect Cost Rate**

Indirect costs are funded at a rate of 26.8%; however, the Contractor shall not bill or be reimbursed for indirect costs until such time as an indirect cost proposal has been submitted to the cognizant office responsible for negotiating the indirect cost rates, unless a temporary billing rate(s) has been included herein. Unless otherwise specified below, the indirect cost rate proposal shall be submitted no later than three (3) months after the date of contract award.

The Contractor may bill indirect costs at a temporary billing rate of 26.8%; until such time as indirect costs have been established.

b. **Subcontract**

1. To negotiate a cost reimbursement type subcontract with SRI International for invivo potency testing of antibodies and combination of antibodies for an amount not to exceed $5,509,920 for the period September 15, 2008 through September 14, 2014. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

2. To negotiate a cost reimbursement type subcontract with University of California at San Francisco for activity testing and toxin domain development and supply for an amount not to exceed $1,595,351 for the period September 15, 2008 through September 14, 2014. Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

c. **Consultants** Consultant fee(s) to be paid to the following individual(s):

NAME	RATE PER HOUR	NUMBER OF HOURS	TOTAL COST EXCLUDING TRAVEL NOT TO EXCEED
Hoi Leung	$ 300	160	$ 48,000.00
John Carpenter	$ 400	220	$ 88,000.00
Barbara Mathews	$ 300	160	$ 48,000.00

d. **Special Copyright Provisions**

1. In accordance with FAR Clause 52.227-14, Rights in Data General, the Contractor shall seek written permission from the Contracting Officer before establishing a copyright for any software and associated data generated under this contract. Additionally, the Government shall be provided a paid-up, world-wide, irrevocable, nonexclusive license to all rights under any copyright obtained.

e. **Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract as follows:

Contract No. HHSN272200800028C

f. **Advance Copies of Press Releases**

The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. In accordance with NIH Manual Chapter 1754, misrepresenting contract results or releasing information that is injurious to the integrity of NIH may be construed as improper conduct. The complete text of NIH Manual Chapter 1754 can be found at: http://www1.od.nih.gov/oma/manualchapters/management/1754/

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the project officer has received an advance copy of any press release related to this contract not less than two (2) working days prior to the issuance of the press release.

g. **Clinical Studies**

Clinical studies are not part of this contract, however, pre-IND package preparation, FDA communication and IND submission preparation are included in the contract SOW. Current NIAID policy requires the product sponsor to submit a request to NIAID to hold the IND for clinical studies to be performed with NIAID funding. It is therefore, currently not known whether NIAID or XOMA will hold the IND for products produced under this contract. XOMA's and NIAID's respective roles in the development and submission of documents to the FDA will be mutually agreed upon depending on which party holds the IND.

h. **Manufacturing Failure**

As a cost reimbursement contract, XOMA will only charge NIAID for the work performed. The $64,835,287 budget includes a 15% manufacturing failure rate.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated September 15, 2008, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

b. The following described document is attached hereto and hereby made a part of this contract: (SEE SECTION J- List of Attachments.)

Document Title	Date	Description of Document
XOMA Technical Proposal	June 26, 2008	Production of Monoclonal Antibody Based Therapeutics for Botulism, 208 pages

If there is any inconsistency between the attached portion of the proposal, identified in this subparagraph, and the work described in subparagraph a. of this ARTICLE, the terms and conditions of subparagraph a. of this ARTICLE shall control.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. **Technical Reports**

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer or the Contracting Officer. These reports shall be brief and factual and prepared in accordance with the format described below.

Format of Cover page - All reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project title
- Period of Performance Being Reported
- Contractor’s Name and Address
- Author(s)
- Date of Submission
- Delivery Address

1. **Monthly Progress Report**

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. In addition to the cover page the report shall include the following sections:

a. SECTION I - An INTRODUCTION covering the purpose and scope of the contract effort

b. SECTION II - PROGRESS

i. Section II Part A - OVERALL PROGRESS - a brief description of overall progress

ii. Section II Part B - MANAGEMENT AND ADMINISTRATION update - a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. establishing subcontractors; evaluating and managing subcontractor performance);

iii. Section II Part C - TECHNICAL PROGRESS - For each Milestone document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed correction action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned;

iv. Section II Part D - PROPOSED WORK - A summary of work proposed for the next reporting period; and

v. Section II Part E - PUBLICATIONS - Copies of abstracts, preprints and reprints of papers planned for presentation or publication.

2. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. An annual report will not be required for the period when the Final Report is due. A Monthly Report shall not be submitted when an Annual Report is due. In addition to the cover page the report shall include the following sections:

a. SECTION I - EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the current reporting period;

b. SECTION II - PROGRESS

i. Section II Part A - OVERALL PROGRESS - a brief description of overall progress;

ii. Section II Part B - MANAGEMENT AND ADMINISTRATION update - a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. establishing subcontractors; evaluating and managing subcontractor performance);

iii. Section II Part C - TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the Milestones. The report shall include a description of problems encountered and proposed correction action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned;

iv. Section II Part D - PROPOSED WORK - A summary of work proposed for the next year;

v. Section II Part E - PUBLICATIONS - Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting; and

vi. Section II Part F - INVENTIONS - A summary of any inventions developed during the course of the contract.

3. **Final Report**

This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. An Annual report will not be required for the period when the Final Report is due. In addition to the cover page the report shall include the following sections:

a. SECTION I - EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

b. SECTION II - RESULTS - A detailed description of the work performed, the results obtained, and the impact of the results on the scientific and/or public health community, including a listing of all manuscrips (published and in preparation) and abstracts presented during the entire period of performance, and a summary of all inventions.

The Contractor shall provide the Contracting Officer with three (3) copies of the Final Report in **draft** form (in accordance with the DELIVERIES Article in SECTION F of this contract 120 calendar days prior to the completion date of this contract.) The Project Officer will review the draft report and provide the Contracting Officer with comments within 45 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

4. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

b. **Other Reports/Deliverables**

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

1. Milestone Workplan

The Contractor shall submit a detailed Workplan for the activities they will perform to complete each Milestone. This report shall be submitted at least thirty (30) calendar days before work is planned to be initiated on the specific Milestone. The Project Officer shall review the workplan and either approve or provide feedback within 14 calendar days of submission. The Contractor shall be responsible for responding to the Project Officer’s feedback and revising the Workplan accordingly within fourteen (14) calendar days of receipt of the Project Officer’s feedback. The Milestone Workplan shall include the following specific information:

a. COVER PAGE that includes contract number and title; the type of report and period covered; the Contractor’s name, address, telephone number, fax number, and email address; and the date of submission

b. WORKPLAN that details:

i. Work to be performed

ii. Timelines

iii. Intermediate Milestones that will be used to track progress to completion of the Milestone

iv. Qualitative and quantitative criteria that will be used to track successful completion of Intermediate Milestones and final Milestone

v. An estimated total cost for all activities required to complete the Milestone.

2. Milestone Completion Report - Within thirty (30) days of completion of a Milestone the Contractor shall submit a report that includes the following specific information:

a. COVER PAGE that includes the contract number and title; the type of report and period covered; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;

b. An INTRODUCTION covering the scope of the contract effort and the specific Milestone completed.

c. RESULTS: Documentation and summary of the results of work undertaken that supports the completion of the stage of product development, including an analysis of the data as it relates to the qualitative and quantitative criteria established for successful completion of the Milestone. A summary of actual costs incurred in relation to costs estimated in the original Project Officer approved budget.

3. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance including adherence to GLP or GMP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP and GMP as identified in the final audit report to the Project Officer.

4. Site Visit Report

A report of the Site Visit Report shall be prepared by the Contractor and submitted to the Project and Contract Officers within 30 calendar days following the date of the meeting. These reports shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

5. Contract Initiation Meeting Report

A report of the Contract Initiation Meeting shall be prepared by the Contractor and submitted to the Project and Contract Officers within 30 calendar days following the date of the meeting. This report shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

6. Draft Transition Plan

A description of transition activities shall be provided in a Draft form to the Project and Contract Officers six months prior to the completion date of the contract.

7. Final Transition Plan

The Draft Transition Plan shall be approved and finalized and submitted as the Final Transition Plan to the Project and Contract Officers three months prior to the completion date of the contract.

8. Copies of FDA correspondence and meeting summaries

Within 30 calendar days of receiving correspondence from or meeting with the FDA, submit to the Project Officer copies of the correspondence or meeting minutes/summaries.

9. Other Reports

Within 30 calendar days of request, provide copies of other reports generated during the contract period related to performance of the contract including: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Chemistry, Manufacturing and Controls and other documents as requested for pre-IND and IND submissions to the FDA. These reports shall be provided at the request of the Project Officer, Draft Final Preclinical Safety and Toxicology Reports, Final Audited Preclinical Safety and Toxicology Reports.

10. Data

Within 30 calendar days of request, provide raw data or specific analysis of data generated with contract funding at the request of the Project Officer.

11. Monthly Teleconference and Extraordinary Meeting Minutes

Within 7 calendar days, provide minutes of monthly teleconferences and any other required extraordinary meetings at the request of the Project Officer.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisitions
6700-B Rockledge Drive
MSC 7612, Room 3214
Bethesda, Maryland 20892- 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed “Interagency Edison,” an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

ARTICLE D.1. PACKAGING

As required, packages shall be in a temperature controlled environment.

ARTICLE D.2. MARKING

All Hazardous Materials shall be marked appropriately for shipping.

ARTICLE D.3. SHIPPING

Shipments will be time sensitive/time critical.

Shipping insurance is required.

Shipping of select agents shall be in accordance with the DHHS regulations regarding the transfer of select agents (42CFR part 72; http://ww.cdc.gov/od/ohs/biosfty/shipregs.htm and shipping cGMP product and cell banks shall be in accordance with cGMP guidelines (as defined in the U.S. code of Federal Regulations - 21 CFR 211).

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the NIAID Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at: 6610 Rockledge Drive; Bethesda, Maryland 20892.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause ***52.246-9, Inspection of Research and Development (Short Form)*** *(April 1984).*

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

Item	Description	Quantity	Delivery Schedule
(1)	Monthly Progress Report	1 hard copy to PO 1 original to CO 1 electronic copy to PO and CO	The first report is due on/before the 15th of the month following the first full month of contract performance plus any fractional part of the initial month. Thereafter, each report is due on/before the 15th of each month following each reporting period.
(2)	Annual Progress Report	1 hard copy to PO 1 original to CO 1 electronic copy to PO and CO	The first report is due on/before 30 calendar days after the anniversary date of contract initiation. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract. Monthly Progress Reports will not be submitted the month the Annual Progress Report is due.
(3)	Final Invention Statement	1 copy to CO	Due on/before completion date of the contract.
(4)	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 copy to OPERA	As required by FAR Clause 52.227-11.
(5)	Draft Final and Final Report and Summary of Salient Results	1 hard copy to PO 1 original to CO 1 electronic copy to PO and CO	Draft Final Report is due 120 calendar days prior to the completion date of contract. Final Report and Summary of Salient Results is due on/before the completion date of the contract.

b. Other Reports and Deliverables (Delivery Schedule)

Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
1.	Milestone Workplan	SOW Part A	1 hard and electronic copy to PO	The Milestone 1 Workplan is due within 45 days of the initiation of contract performance. Subsequent Milestone Workplans are due within 30 days of the Contractor's intention to initiate a Milestone.
2.	Milestone Completion Report	SOW Part A	1 hard and electronic copy to PO	Within 30 calendar days of Milestone completion.
3.	Audit Reports	SOW Part C	1 hard and electronic copy to PO	Within 30 calendar days of Audit completion.
4.	Site Visit Reports	SOW Part D	1 hard and electronic copy to PO/CO	Within 30 calendar days of Site Visit.
5.	Contract Initiation Meeting Report	SOW Part D	1 hard and electronic copy to PO/CO	Within 30 calendar days of Contract Initiation meeting.
6.	Draft Transition Plan	SOW Part E	1 hard and electronic copy to PO/CO	Within 6 months of the completion date of the contract.
7.	Final Transition Plan	SOW Part E	1 hard and electronic copy to PO/CO	Within 3 months of the completion date of the contract.
8.	Other Reports; Data	SOW Part B	1 hard and electronic copy to PO	Within 30 calendar days of request of the PO or CO.
9.	Monthly Meeting Minutes; Extraordinary Meeting Minutes	SOW Part B	1 hard and electronic copy to PO	Within 7 calendar days of the meeting.
10.	Fifty (50) vials of cGMP MCB for each MAb	SOW Part B Milestone 12	To be specified 60 days prior to request to ship delivery	Within 120 calendar days of the acceptance of Milestone 12 Completion Report.

Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
11.	Anti-BoNT A FDP	SOW Part B Milestone 15	500 doses or 10% of the lot, whichever is less, to be specified 60 days prior to request to ship delivery	Within 120 calendar days of the acceptance of Milestone 15 Completion Report.
12.	Anti-BoNT B FDP	SOW Part B Milestone 15	500 doses or 10% of the lot, whichever is less, to be specified 60 days prior to request to ship delivery	Within 120 calendar days of the acceptance of Milestone 15 Completion Report.
13.	Anti-BoNT E FDP	SOW Part B Milestone 15	500 doses or 10% of the lot, whichever is less, to be specified 60 days prior to request to ship delivery	Within 120 calendar days of the acceptance of Milestone 15 Completion Report.
14.	Anti-BoNT A/B/E FDP	SOw Part B Milestone 15	500 doses or 10% of the lot, whichever is less, to be specified 60 days prior to request to ship delivery	Within 120 calendar days of the acceptance of Milestone 15 Completion Report.
15.	Lead Mab BDS	SOW Part B Milestone B	Contractor or FDP filing site	Within 120 calendar days of the acceptance of Milestone 15 Completion Report.

c. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.	Quantity
Project Officer Office of Biodefense Research Affairs Division of Microbiology and Infectious Diseases National Institute of Allergy and Infectious Diseases 6610 Rockledge Drive, MSC 6610, Room 5123 Bethesda, Maryland 20892	As stated in the tables above	As stated in the tables above

Addressee	Deliverable Item No.	Quantity
Contracting Officer	As stated in the tables above	As stated in the tables above
Division of Extramural Activities, Office of Acquisitions		
National Institute of Allergy and Infectious Diseases		
6700-B Rockledge Drive, MSC 7612, Room 3214		
Bethesda, Maryland 20892		
OPERA	(4)	As stated in the tables above
Office of Extramural Inventions and Technology Resources Branch		
6705 Rockledge Drive, MSC 7980, Room 1040-A		
Bethesda, Maryland 20892		

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

Katherine Taylor

6610 Rockledge Drive, MSC 6604

Bethesda, Maryland 20892

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
Milan Tomic, Ph.D.	Principal Investigator

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted as follows:

   a. One original to the following designated billing office:

      National Institutes of Health
      Office of Financial Management
      Commercial Accounts
      2115 East Jefferson Street, Room 4B-432, MSC 8500
      Bethesda, MD 20892-8500

   b. One copy to the following approving official:

      Contracting Officer
      Office of Acquisitions
      National Institute of Allergy and Infectious Diseases, NIH MSC 7612, Room 3214
      Bethesda, MD 20892

2. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases (NIAID).

   b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOAInvoices.

   c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26.*[Note: This only applies to new contracts awarded on/ after June 4, 2007, and any existing contract modified to include the number.]*

   d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.

   e. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a Two-Way match.

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) - 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

   "I hereby certify that the salaries charged in this invoice are in compliance with the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05

6100 Executive Boulevard, MSC-7540
Bethesda, MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted November 15, 2011.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed “Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption”, Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the “Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption”, Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.4. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

ARTICLE H.5. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.6. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.7. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/. *(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

ARTICLE H.8. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

http://grants1.nih.gov/grants/olaw/references/phspol.htm.

ARTICLE H.9. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

UNDER GOVERNING POLICY, FEDERAL FUNDS ADMINISTERED BY THE PUBLIC HEALTH SERVICE (PHS) SHALL NOT BE EXPENDED FOR RESEARCH INVOLVING LIVE VERTEBRATE ANIMALS WITHOUT PRIOR APPROVAL BY THE OFFICE OF LABORATORY ANIMAL WELFARE (OLAW), OF **AN ASSURANCE TO COMPLY WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS AND/OR A VALID INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) APPROVAL**. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES (e.g. COLLABORATING INSTITUTIONS, SUBCONTRACTORS, SUBGRANTEES) WITHOUT OLAW-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.

ARTICLE H.10. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.11. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002);
http://csrc.nist.gov/drivers/documents/FISMA-final.pdf

a. Information Type

[X] Administrative, Management and Support Information

[X] Mission Based Information

b. Security Categories and Levels

Confidentiality Level:	[ ]	Low	[X]	Moderate	[ ]	High
Integrity Level:	[X]	Low	[ ]	Moderate	[ ]	High
Availability Level:	[X]	Low	[ ]	Moderate	[ ]	High
Overall Level:	**[X]**	**Low**	**[ ]**	**Moderate**	**[ ]**	**High**

c. Position Sensitivity Designations

The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

[X] **Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov. **Note that NCI points of contact do not apply to this contract. Applicable NIAID contacts are designated within this contract (see ARTICLE G.1. Project Officer)**

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

Contractor/Subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/Subcontractor employee to work under the contract.

d. Information Security Training

The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: http://irtsectraining.nih.gov/ prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.

e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
3. Departing employees:
   - Provide the name, position title, and security clearance level held by or pending for the individual.
   - Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

1. Contractor Agreement

   The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

   - 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
   - 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
   - Public Law 96-511 (Paperwork Reduction Act)

2. Contractor-Employee Non-Disclosure Agreements

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

h. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems. (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

ARTICLE H.12. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause**352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272200800028C"

ARTICLE H.13. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.14. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant.

ARTICLE H.15. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients

of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : http:// ott.od.nih.gov/NewPages/64FR72090.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.16. SHARING RESEARCH DATA

The Contractor's data sharing plan, dated August 1, 2008 is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.17. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag selectagent/FinalRule3-18-05.pdf) as required, before using NIH funds for work involving a *Select Agent or Toxin*. **No NIH funds can be used for research involving a *Select Agent or Toxin* at a domestic institution without a valid registration certificate.**

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin*, before using NIH funds for any work directly involving a *Select Agent or Toxin*, the foreign institution must provide information satisfactory to the NIAID that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. **No NIH funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf.

Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag selectagent/index.html and:

http://www.aphis.usda.gov/programs/ag selectagent/ag bioterr forms.html

For foreign institutions, see the NIAID Select Agent Award information:

(http://www.niaid.nih.gov/ncn/clinical/default biodefense.htm).

ARTICLE H.18. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at:http://www.usfa.fema.gov/hotel/index.htm.

ARTICLE H.19. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.20. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

Beginning April 7, 2008, NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

General Clauses for a Cost-Reimbursement Research and Development Contract

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/farl.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions (Over $100,000)
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Sep 2007	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Apr 2008	Central Contractor Registration
52.204-10	Sep 2007	Reporting Subcontract Awards ($500,000,000 or more)
52.209-6	Sep 2006	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over$30,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100, 000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data (Over $650,000)
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $650, 000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Apr 2008	Small Business Subcontracting Plan (Over $550,000, $1,000,000 for Construction)

FAR CLAUSE NO.	DATE	TITLE
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $550,000, $1,000,000 for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Sep 2006	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over $100,000)
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Sep 2006	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over $100,000)
52.222-50	Aug 2007	Combating Trafficking in Persons
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	Dec 2007	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Dec 2007	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer—Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $650,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Jun 2007	Subcontracts, Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Mar 2007	Subcontracts for Commercial Items

FAR CLAUSE NO.	DATE	TITLE
52.245-1	Jun 2007	Government Property
52.245-9	Jun 2007	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2006)
352.216-72	Jan 2006	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Jan 2006	Withholding of Contract Payments
352.233-70	Jan 2006	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Jan 2006	Key Personnel
352.270-6	Jan 2006	Publications and Publicity
352.270-10	Jan 2006	Anti-Lobbying (Over $100,000)

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 08/2008].

ARTICLE 1.2 AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE 1.1. of this SECTION is hereby modified as follows:

a. **Alternate I** (October 1997) of FAR Clause **52.215-14, Integrity of Unit Prices** (October 1997) is added.

b. **Alternate IV** (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data - Modifications** (October 1997) is added.

c. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE 1.3. Additional Contract Clauses

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	**Obtain From"**
HHS Contractor Code of Ethics and Business Conduct Poster	http://www.oig.hhs.gov/hotline/OIG Hotline Poster.pdf

3. FAR Clause ***52.215-17, Waiver of Facilities Capital Cost of Money*** (October 1997).

4. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....
[ ] Offeror elects to waive the evaluation preference."

5. FAR Clause **52.227-14, Rights in Data-General** (December 2007).

6. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).

Specific data items that are not subject to paragraph (j) include:

a. XOMA's bioinformatics technology

b. XOMA's mammalian expression technology

c. XOMA's formulation technology

d. XOMA's transient transvection technology

7. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

8. FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

9. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).

10. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

*1. HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*

*2. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).*

*3. HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).*

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. NIH (RC)-7, Procurement of Certain Equipment (April 1984).

ARTICLE 1.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1)CLAUSES:

a. *FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees (December 2004)***

(a) Definition. As used in this clause—

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N. W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B–Compliance Evaluations, Complaint

Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to—

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that–

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall—

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).

For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B–Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated September 15, 2008, 8 pages.

2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4

Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (5/07), 6 pages.

3. Safety and Health

Safety and Health, HHSAR Clause 352.223-70, (1/06), 1 page.

4. Procurement of Certain Equipment

Procurement of Certain Equipment, NIH(RC)-7, 4/1/84, 1 page.

5. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 2 pages.

6. XOMA Technical Proposal

XOMA Technical Proposal, dated June 26, 2008, 208 pages.

7. Commitment To Protect Non-Public Information

Commitment To Protect Non-Public Information, 1 page. Located at: http://irm.cit.nih.gov/security/Nondisclosure.pdf

8. Roster of Employees Requiring Suitability Investigations

Roster of Employees Requiring Suitability Investigations, 1 page. Excel file located at: http://ais.nci.nih.gov/forms/Suitability-roster.xls

9. Employee Separation Checklist

Employee Separation Checklist, 1 page. Fillable PDF format located at: http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Annual Representations and Certifications completed and located at the Online Representations and Certifications Application (ORCA) website.
2. Animal Welfare Assurance Number 93-R-0451.

END of the SCHEDULE

(CONTRACT)

STATEMENT OF WORK

Production of Monoclonal Antibody-Based Therapeutics for Botulism

BACKGROUND AND INTRODUCTION:

Research conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Health (NIH), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of research grants and contracts. In this context, the NIAID's mission includes the development of new medical countermeasures against the biological agents that are most likely to be used in a terror attack on civilian populations. These biological agents have been prioritized as Category A, B, and C. Botulinum neurotoxins (BoNTs) are one of these biological threats and new therapies and diagnostics are needed to help counter the potential terrorist use of these toxins. Current treatment for exposure to BoNTs is despeciated polyclonal equine antitoxin. The disadvantages of this treatment include a risk of adverse reactions and a relatively short half-life in humans. Experience with human and human compatible monoclonal antibodies (MAbs) as therapies for other diseases has shown them to have a superior safety profile and longer half-life than equine antibodies. Through the proposed contract NIAID is seeking to advance the development of a human or human compatible MAb-based therapeutic product for the treatment of botulism caused by BoNT serotypes A, B and E (BoNT/A/B/E), which are Category A threat agents and account for >95% of naturally caused foodborne botulism

The NIAID is aware that no single organization may have the expertise and facilities required to perform all parts of the Statement of Work. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. The Contractor shall, however, be responsible for ALL work performed under this contract, including that performed by subcontractor(s).

The overall objective of this contract is to support the development of a safe human compatible MAb-based final drug product (FDP) that neutralizes the major subserotypes of BoNT/A/B/E (i.e. Al, A2, A3, BI, B2, El and E3). This product should be acceptable for post-exposure prophylaxis and treatment of BoNT intoxication, incurred by foodborne or aerosol exposure. The FDP should be stable for a minimum of 24 months at 4°C or room temperature.

The critical path for the development of a trivalent product (anti-BoNT/A/B/E) is likely to proceed through nonclinical and clinical evaluation of each of three monovalent products. The monovalent products are anticipated to be composed of multiple MAbs. It is, therefore, desirable that each monovalent product be formulated identically, and the final formulation for the trivalent product be a simple mixture of the three monovalent products. Through this contract NIAID seeks to support the development of three monovalent products, anti-BoNT/A, anti-BoNT/B and anti-BoNT/E, and a trivalent product, anti -BoNT/A/B/E.

Three human/human compatible MAbs that together potently neutralize BoNT/A subserotypes Al, A2 and A3 were developed in the laboratory of Dr. James Marks at the University of California, San Francisco under an NIAID-funded cooperative agreement. Under an NIAID contract NO1-AI-50004, XOMA (US) LLC ("XOMA"), Berkeley, CA, the variable region gene sequences of each MAb was fused to XOMA's proprietary modular antibody expression vector containing light and heavy chain constant regions. These MAbs were named NX01, NX02 and NX11. The contract supported the development of Master Cell Banks (MCB) and Working Cell

Banks (WCB) in a commercial Chinese Hamster Ovary (CHO) cell line according to current Good Manufacturing Practices (cGMP). The contract further supported preliminary manufacturing process development, manufacturing at the 130L scale, purification of bulk drug substance, and formulation studies for the individual MAbs. Under a subsequent contract (N01- AI-60008), NIAID is supporting the development of an anti-BoNT/A FDP that consists of a mixture of the three MAbs (NX01, NX02 and NX11). This three MAb mixture has also been shown to potently neutralize subserotype A3, although activity against subserotype A3 was not required under contract NO1-AI-60008. NIAID intends to evaluate the safety and pharmacokinetics of this FDP in laboratory animals and to then proceed to first-in-human testing of the product under other funding mechanisms. NIAID recognizes that further formulation of the monovalent anti-BoNT/A product currently under development may be required to ensure final compatibility with the anti-BoNT/B and anti-BoNT/E products.

The Contractor is expected to use knowledge, reagents, materials, WCB, MCB, BDS and FDP produced under contract N01-AI-50004 and N01-AI-60008 to most efficiently perform the activities outlined in this Statement of Work. Specifically, the Contractor shall utilize the anti-BoNT A MAb WCB, MCB, BDS and FDP developed under these two previous contracts.

The Contractor shall provide a panel of candidate MAbs with demonstrated activity against the major subserotypes of BoNT serotypes A, B and E.

SCOPE:

The major functions to be carried out under this contract include:

1) Evaluation of a panel of candidate MAbs for in vivo potency,*in vitro* safety, and their potential to be formulated into one of three monovalent products (i.e. anti-BoNT/A, anti-BoNT/B and anti-BoNT/E) and a single trivalent product (i.e. Anti-BoNT/A/B/E). Based on results from these studies, selection of lead MAbs to transition to cGMP manufacturing.

2) Production of cGMP master cell banks (MCB) and working cell banks (WCB) for each lead MAb

3) Development of a manufacturing process, manufacturing of non-GMP bulk drug substance at pilot and full-scale and cGMP bulk drug substance at full scale for each lead MAb

4) Production of three monovalent serotype-specific (anti-BoNT/A, anti-BoNT/B and anti-BoNT/E) FDPs and one trivalent FDP (anti-BoNT/A/B/E) according to cGMP and in sufficient amounts to support preclinical studies, long-term stability program, and Phase 1 and 2 clinical evaluation.

5) Assay development, qualification and validation (as required) for all of the assays needed to support nonclinical and clinical evaluation, manufacturing, and stability.

6) Performance of preclinical IND-enabling safety and pharmacology studies as required for IND approval.

7) Design, justification, and execution of an extended stability program for all BDS and FDP

8) Preparation of materials for submission to the Food and Drug Administration (FDA), participation in meetings with the FDA, including meetings to review pre-Investigational New Drug (IND) packages and IND applications.

TECHNICAL REQUIREMENTS

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below. Specifically, the Contractor shall:

A Milestone Workplans and Milestone Completion Reports

The Contractor shall submit a detailed Milestone Workplan for the activities they will perform to complete each Milestone. This report shall be submitted at least 30 calendar days before work is planned to be initiated on the specific Milestone and shall include:

A detailed description of work to be performed;

Timelines for initiation and completion of activities;

A description of Intermediate Milestones that will be used to track progress to completion of the Milestone;

Qualitative and quantitative criteria that will be used to track successful completion of Intermediate Milestones and the final Milestone; and

An estimated total cost for all activities required to complete the Milestone.

Project Officer will review the Milestone Workplan and either approve or provide feedback within 14 calendar days of submission. The Contractor shall be responsible for responding to the Project Officer's feedback and revising the Milestone Workplan accordingly, within 14 calendar days of receipt of the Project Officer's feedback.

The Contractor shall use Milestones and Intermediate Milestones as the basis for reporting technical progress in Monthly, Annual and Final Progress Reports

Within 30 days of completion of a Milestone the Contractor shall submit a Milestone Completion Report that includes:

Documentation and summary of the results of work undertaken that supports the completion of the stage of product development, including an analysis of the data as it relates to the qualitative and quantitative criteria established for successful completion of the Milestone

Actual costs incurred in relation to costs estimated in the original Project Officer approved budget

B Milestone Descriptions

Specifically, the Contractor shall perform all activities to accomplish:

Milestone 1: Selection of lead MAbs based on their potency, lack of tissue cross-reactivity in preliminary non-GLP screening studies both as single MAbs and as mixtures, and likelihood to be co-formulated. This shall include a clearly defined formulation strategy, for the three monovalent (Anti-BoNT/A, Anti-BoNT/B and anti-BoNT/E) and one trivalent (Anti-BoNT/A/B/E) FDP. This formulation strategy should be focused on meeting the formulation goals in the most efficient and cost effective manner possible. The goal for formulation is a sterile product, suitable for intravenous infusion that is stable for at least 24 months at 4°C or room temperature. However, should this not be feasible, NIAID will consider frozen, lyophilized or novel formulation strategies. Ideally, each monovalent product shall be formulated identically and the trivalent FDP shall be a simple mixture of the three monovalent products. The use of novel *in vivo* potency, *in vitro* safety, formulation and antibody engineering technologies may be employed to achieve this milestone.

With the exception of the three MAbs (NX01, NX02 and NX11) developed under contract no. N01-AI-60008, the Contractor may proceed to other Milestones, prior to the review and approval of the Milestone 1 report only with written approval of the Project Officer. For NX01, NX02 and NX11, Milestones 5 - 7 may be performed in parallel with Milestone 1.

Milestone 2: Develop and select high expression stable clones, suitable for MCB production in mammalian cell system for each lead MAb.

Milestones 2 - 6 may be performed in parallel for the lead MAbs.

Milestone 3: Production of a minimum of 200 vials of cGMP MCB and 200 vials of cGMP WCB for each lead MAb, and a certificate of analysis for each.

Milestone 4: Manufacturing process at pilot scale (e.g. 7 liter) to optimize yield and purity of each lead MAb and a plan for storage of BDS for each MAb.

Milestone 5: Prepare sterile and mycoplasma free non-GMP material using planned cGMP manufacturing process at full scale (approximately 150 - 2500L), perform viral clearance validations for x viral types for the final production process. Aliquot and store non-GMP BDS for each lead MAb. Non-GMP material produced during process development shall be used for final formulation development, assay development and IND-enabling studies.

Milestone 6: Master Production Record for full scale cGMP manufacturing for each MAb and plan for storage of cGMP BDS.

Milestone 7: Prepare sterile and mycoplasma free cGMP BDS at full scale for each MAb, and a certificate of analysis for each product. Aliquot and store cGMP BDS for each MAb.

Milestone 8: Final formulation studies for monovalent FDPs and trivalent FDP.

The Contractor shall not initiate Milestones 9 and 10 until completion and approval of Milestone 8.

Milestone 9: Final formulation, finishing, filling and labeling monovalent FDPs and provide a final formulation and product characterization report to the Project Officer. The FDPs produced under this contract should be suitable for clinical evaluation by sterile intravenous infusion. A single vial of each monovalent product shall contain an equal or greater number of neutralizing units for BoNT A, B, or E, as the Aventis-Pasteur (formerly Connaught) equine antitoxin products (i.e. 7,500 IU anti-Al; 5,500 IU anti-B1 and 8,500 IU anti-E3), unless otherwise agreed through discussions with the Project Officer. Neutralizing units for other subserotypes shall be agreed upon through discussions with the Project Officer.

Milestone 10: Final formulation, finishing, filling and labeling trivalent FDP and provide a final formulation and product characterization report to the Project Officer. The FDP produced under this contract should be suitable for clinical evaluation by sterile intravenous infusion. A single vial of each trivalent product shall contain an equal or greater number of neutralizing units for BoNT A, B, and E, as the Aventis-Pasteur (formerly Connaught) equine antitoxin products (i.e. 7,500 IU anti-A1; 5,500 IU anti-B1 and 8,500 IU anti-E3), unless otherwise agreed through discussions with the Project Officer or the FDA. Neutralizing units for other subserotypes shall be agreed upon through discussions with the Project Officer.

Milestone 11: Storage of cGMP BDS and FDP according to cGMP guidelines.

Milestone 12: Shipment of 50 vials cGMP MCB for each MAb, according to cGMP guidelines at the request of the Project Officer. The remaining MCB vials and all of the WCB vials will remain in the control and custody of the Contractor.

Milestone 13: Develop, qualify and validate (as required) analytical methods for concentration, identity, integrity, specificity, purity, potency, sterility, stability and contaminant identity and levels that are needed to fully characterize BDS and FDP, support lot release, formulation and stability studies.

Milestone 14: Develop, qualify and validate (as required) analytical methods to support nonclinical and clinical pharmacokinetic studies. For each assay the Contractor shall qualify and/or validate the assay, provide critical reagents; and submit a final assay qualification and/or validation report to the Project Officer.

Milestone 15: Shipment of cGMP BDS and FDP according to cGMP guidelines and the development plan agreed with the Project Officer.

Milestone 16: Develop and execute an extended stability program for BDS and FDP.

Milestone 17: Perform preclinical IND-enabling safety and pharmacology studies (under GLP). Provide draft and final animal study protocols for Project Officer review and approval, as well as draft unaudited final study reports and audited final study reports Audited final study reports shall be submitted to the Project Officer within 60 days of the draft unaudited final study report.

Milestone 18: Develop and review documents to be submitted to the FDA to support pre-IND document preparation and IND applications.

C Regulatory Compliance and Data Management

1) Provide data management and quality control systems/procedures, including data transmission, storage, and retrieval;

2) Provide for the statistical design and analysis of data resulting from the research undertaken;

3) Provide raw data or specific analyses of data generated with contract funding to the Project Officer;

4) Ensure strict adherence to FDA regulations and guidance, including requirements for the conduct of Good Laboratory Practices (GLP) and cGMP;

5) Arrange for independent audits as needed or as requested by the Project Officer. Audits may be requested to assure that Contractor and/or subcontractor facilities and all planned procedures meet the FDA regulations and guidance required to comply with GLP and cGMP. In addition, the Contractor shall ensure that all Contractor and/or subcontractor records and staff are available for site visits or audits. The Contractor shall provide interim and final audit reports to the Project Officer and the Contracting Officer within thirty (30) calendar days of the completion of the audit. The NIAID reserves the right to conduct independent audit of the Contractor and its subcontractors as needed to evaluate compliance with the FDA regulations and guidance required to meet GLP or cGMP standards; and

6) Prepare materials for and request, schedule and participate in all meetings with the FDA, including meetings to review pre-IND and IND packages. Submit all documentation to the FDA in a timely manner, consistent with timelines set out in the contract and by the FDA. Include NIAID staff, as designated by the Project Officer, in meetings and teleconferences with the FDA. Provide copies of all FDA correspondence and meeting minutes that are relevant to the product to the Project Officer.

D Project Management

A. Overall Project Management

The Contractor shall:

1. Provide for the overall scientific and financial management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontracts.

2. Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and timely completion within approved budgets of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer

3. Provide for a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on scientific and financial project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.

B. Subcontract Management and Reporting

1. Solicit, evaluate, award and manage subcontracts, including overseeing the technical, administrative and operational activities of subcontractors; audit subcontractor facilities, services, and financial expenditures; and track deliverables and reporting requirements

2. Assess and provide updates in Monthly and Annual Technical Progress Reports on subcontractor scientific and financial performance and progress toward achievement of defined tasks and responsibilities within established timelines; and identify and resolve problems with subcontractor performance

3. Ensure that subcontractor personnel, equipment and facilities are compliant with regulatory requirements in effect throughout the contract period of performance.

4. Ensure the complete and effective transfer of technology by the subcontractors to the Contractor, the Government, or a third party agreed upon by the Contractor.

5. Perform all necessary transition and closeout functions on each subcontract.

C. Meetings and Teleconferences

1. Contract Initiation Meeting

Plan and conduct a one-day Contract Initiation Meeting with the Contractor's PI, key personnel, key subcontractor personnel, consultants, the Project Officer, the Contracting Officer and other NIAID personnel designated by the Project Officer, to be held at the Contractor's site within 45 calendar days after the effective date of the contract. The Contractor shall have submitted the Milestone 1 Workplan 14 days before the Contract Initiation Meeting. The purpose of the Contract Initiation Meeting shall be to discuss the entire program, finalize the Milestone 1 Workplan and orient the Contractor to NIAID contract procedures. The Contractor shall provide a Contract Initiation Meeting Report within 30 calendar days of meeting. The report shall include copies of presentations and a summary of all discussions.

2. Monthly Meetings/Teleconferences

a) Plan and conduct meetings at a minimum of monthly intervals, either in person or via teleconference, with the Contractor's key personnel to review overall progress.

b) Plan and conduct monthly meetings of the Contractor's Principal Investigator, key personnel, key subcontractor personnel, consultants, and Project Manager with the Project Officer, Contracting Officer and other key NIAID staff, either in person or via teleconference. The purpose of this meeting will be to review Monthly Technical Progress Reports, any other reports that were delivered in the previous month, any matter that is relevant to the scientific and financial administration of the contract and future activities. The meeting shall be scheduled to occur within 14 calendar days of submission of the Monthly Technical Progress Report. The schedule for those meetings will be established by the PI, Project Officer and Contracting Officer after contract award. Prepare and distribute the agenda and meeting/teleconference materials to all participants. Provide a summary of all meetings and teleconferences to the Project Officer and Contracting Officer within seven calendar days of the teleconference

c) Organization of extraordinary teleconferences and meetings if issues arise that require more frequent communication and provision of meeting minutes for these teleconferences and meetings

3. Annual Site Visit

Arrange for a two day site visit on a yearly basis for NIAID contract and program staff, as requested by the Project Officer or Contracting Officer. These site visits shall be attended by the Principal Investigator, the Contractor's business representative, and all key personnel. The Contractor shall be responsible for:

a) Planning and submitting the agenda to the Project Officer for approval within 14 days of the site visit;

b) Developing written and oral presentation materials;

c) Arranging for the logistics associated with the site visits and for travel costs for all non-Government site visit attendees; and

d) Preparing and submitting Site Visit reports to the Project Officer and Contracting Officer within 30 calendar days of completion of each site visit. Reports shall include copies of all presentations and a summary of all discussions.

E Final Transition

If the Contractor is unable to reasonably fulfill the activities related to the next stage of development for the products developed under this contract, the Contractor shall ensure an orderly, secure and efficient transition of contract-related materials and activities to the successor contractor or to the Government. A description of transition activities shall be provided in a Draft and Final Transition Plan, which will be reviewed and approved by the Project Officer. The Draft Transition Plan is due six (6) months prior to the completion date of the contract, and a Final Transition Plan (approved by the Project Officer and Contracting Officer) is due three (3) months prior to the completion date of the contract

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR NIH COST-REIMBURSEMENT CONTRACTS, NIH(RC)-4

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, which are not set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request. ***All information must be legible or the invoice will be considered improper and returned to the Contractor.***

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (DUNS) or DUNS+4 number. The DUNS number must

identify the Contractor's name and address exactly as stated in the contract, and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid TIN or DUNS number, provide the Contractor's Vendor Identification Number (VIN), which appears after the Contractor's name on the face page of the award document. ***[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]*** When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

(c) **Invoice/Financing Request Number:** Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and will be returned to the contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the contractor chooses to reclaim those costs on a supplemental invoice, the contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised
(example: 8675309-05R).

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable). For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract.

   For Level of Effort contracts only, the Contractor shall provide the following information on a separate sheet of paper attached to the payment request:

   - hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and
   - hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Cite the rate(s) used to calculate fringe benefit costs, if applicable.

3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment.

   On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. An asterisk (*) shall precede the item if the equipment is below the $1,000 approval level. Include reference to the following (as applicable):

   - item number for the specific piece of equipment listed in the Property Schedule, and
   - COA number, if the equipment is not covered by the Property Schedule.

   The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

4) **Materials and Supplies:** Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

8) **Subcontract Costs:** List subcontractor(s) by name and amount billed.

9) **Other:** List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) Cost of Money (COM): Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(q) Indirect Costs: Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) Fixed-Fee: Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) Total Amounts Claimed: Insert the total amounts claimed for the current and cumulative periods.

(t) Adjustments: Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) Grand Totals

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions are keyed to the Columns on the sample invoice/financing request.

Column A - Expenditure Category: Enter the expenditure categories required by the contract.

Column B - Cumulative Percentage of Effort/Hrs. - Negotiated: Enter the percentage of effort or number of hours agreed to for each employee or labor category listed in Column A.

Column C - Cumulative Percentage of Effort/Hrs. - Actual: Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D - Amount Billed - Current: Enter amounts billed during the current period.

Column E - Amount Billed - Cumulative: Enter the cumulative amounts to date.

Column F - Cost at Completion: Enter data only when the Contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G - Contract Amount: Enter the costs agreed to for all expenditure categories listed in Column A.

Column H - Variance (Over or Under): Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications: Any modification in the amount negotiated for an item since the preceding report should be listed in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B432, MSC 8500
Bethesda, MD 20892-8500

(b) Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:

ABC CORPORATION
100 Main Street
Anywhere, U.S.A. Zip+4

Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent.

*DUNS or DUNS+4: _____
*TIN: _____

*Provide VIN only if Contractor does not have a valid TIN or DUNS number.

(c) Invoice/Financing Request No.: _____

(d) Date Invoice Prepared: _____

(e) Contract No. and Order No. (if applicable): _____

(f) Effective Date: _____

(g) Total Estimated Cost of Contract/Order: _____

(h) Total Fixed Fee (if applicable): _____

(i) Two-Way Match: _____
Three-Way Match: _____

(j) Office of Acquisitions: _____

(k) Central Point of Distribution: _____

(l) This invoice/financing request represents reimbursable costs for the period from _____ to _____.

Expenditure Category* A	Cumulative Percentage of Effort/Hrs Negotiated B	Cumulative Percentage of Effort/Hrs Actual C	Amount Billed (m) Current D	Amount Billed (n) Cumulative E	Cost at Completion F	Contract Value G	Variance H
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits __%							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money __%							
(q) Indirect Costs __%							
(r) Fixed Fee __%							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

_____ _____
(Name of (Title)

*Attach details as specified in the contract or requested by the Contracting Officer

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2006)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

1. In addition, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

   (1) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910. These regulations are available at: http://www.osha.gov/comp-links.html

   (2) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission,Washington, DC 20555–0001.

2. The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

   (1) Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available athttp://bmbl.od.nih.gov/index.htm.

   (2) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW., Lockbox 285, Washington, DC 20055 (ISBN 0–309–05229–7). This publication can be obtained by telephoning 800–624–8373. It also is available at http://www.nap.edu/catalog/4911.html.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the project or other appropriate officers, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of Clause)

Attachment 3

PROCUREMENT OF CERTAIN EQUIPMENT, NIH(RC)-7

Notwithstanding any other clause in this contract, the Contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting Officer.

67 - Photographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment.)
71 - Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Home-type Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Contractor and determined essential by the Contracting Officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost-reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

NIH(RC)-7 (4/1/84) Attachment 4
OMB Bulletin 81-16

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks “Subawardee,” then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizationallevel below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., “RFP-DE-90-001.”
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348-0046. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, DC 20503.

Attachment 5

DISCLOSURE OF LOBBYING ACTIVITIES
Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

Approved by OMB
0348-0046

1. Type of Federal Action: ☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	**2. Status of Federal Action:** ☐ a. bid/offer/application b. initial award c. post-award	**3. Report Type:** ☐ a. initial filing b. material change **For Material Change Only:** year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity: ☐ **Prime** ☐ **Subawardee** Tier _____, *if known*: **Congressional District**, *if known*: 4c	**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:** **Congressional District,** *if known*:
6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable*: _____
8. Federal Action Number, *if known*:	**9. Award Amount,** *if known*: $
10. a. Name and Address of Lobbying Registrant *(if individual, last name, first name, MI)*: XOMA undertook no lobbying activities in relationship to this contract. Therefore, Attachment 5 is not applicable.	**b. Individuals Performing Services** *(including address if different from No. 10a) (last name, first name, MI)*:
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____
Federal Use Only:	Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

Attachment 5

TECHNICAL PROPOSAL COVER SHEET

IN RESPONSE TO NIH-NIAID-DMID-08-21
TITLE: Production of Monoclonal Antibody Based Therapeutics for Botulism
OFFEROR: XOMA (US) LLC
Name and Address: XOMA (US) LLC, 2910 Seventh Street, Berkeley, CA 94710

DUNS # 05-134-0339

PRINCIPAL INVESTIGATOR: Milan Tomic, Ph.D.

OFFEROR PERSONNEL Name (Last, First, Initial) and Degree(s)*
Cafaro, Dan, B.A.
Dadson, Al, B.S.
Fall, Tom, A., B.A.
Freeberg, Joel, M.A.
Horwitz, Arnold, Ph.D.
Huang, Chin-Yi, Ph.D.
Ma, Jeremy K., B.S.
McGoogan, Calvin L., MBA
Meyer, Kathleen, Ph.D.
Rada, Beth M.S.
Tenerowicz, Robert, MBA
Tomic, Milan, T., Ph.D.
Wajid, Abdul, Ph.D.

SUBCONTRACTOR ORGANIZATIONS
Name and Address: SRI International, 333 Ravenswood, Menlo Park, CA 94025

PRINCIPAL INVESTIGATOR: Annalisa D'Andrea, Ph.D.

SUBCONTRACTOR PERSONNEL Name (Last, First, Initial) and Degree(s)*
Harrison, Travis, M., Ph.D.

Name and Address: University of California, San Francisco, CA 94143

PRINCIPAL INVESTIGATOR: James D. Marks, M.D., Ph.D.

SUBCONTRACTOR PERSONNEL Name (Last, First, Initial) and Degree(s)*
Lou, Jianlong, Ph.D.
Meng, Qi, Ph.D.

COLLABORATORS or CONSULTANTS:

Name [Last, First, Initial) Degree(s)] Organization
Carpenter, John C., Ph.D., University of Colorado, Formulations Consultant
Leung, Hoi, Ph.D., Biostatistics Consultant
Matthews, Barbara, M.D., MPH, BioDirect Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

PROJECT OBJECTIVES

SOLICITATION NUMBER: NIH-NIAID-DMID-08-21

CONTRACT NUMBER: (TO BE INSERTED BY THE CONTRACTING OFFICER):_____

OFFEROR NAME AND ADDRESS: **XOMA (US) LLC**
2910 Seventh Street
Berkeley, CA 94710

OFFEROR PHONE NUMBER (WITH AREA CODE) 510-204-7200

***DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT (i.e., Department Name):**
***MAJOR SUBDIVISION (i.e., "Dental School," "Medical School," etc., or Major Component Code, if known):**

RFP TITLE: Development of Therapeutic Agents for Select Biodefense Pathogens

PRINCIPAL INVESTIGATOR: Milan Tomic, Ph.D.

SUMMARY OF OBJECTIVES:

The goal of this proposal is to generate recombinant human compatible monovalent and trivalent antitoxins for the treatment and prevention of botulism due to botulinum neurotoxin serotypes A, B, and E (BoNT/A, B, and E). Each serotype-specific antitoxin will consist of 3 or 4 monoclonal antibodies (mAbs) in order to provide extraordinarily potent toxin neutralization. For this proposal, BoNT/A, B and E mAbs developed in the Marks Lab (UCSF) will be manufactured and formulated at XOMA to generate 3 monovalent BoNT/A, B, and E antitoxins and a potent trivalent BoNT/A, B, and E antitoxin for the treatment of botulism. XOMA is currently manufacturing three BoNT/A mAbs which can be used for a monovalent BoNT/A drug product. We will: 1) evaluate 9 and select 7 (3 BoNT/E and 4 BoNT/B) lead mAb candidates from parental BoNT mAbs provided by Dr. Marks. Lead mAbs will be selected based on stability, lack of cross reactivity to human tissue and potency in vivo when combined; 2) develop cell lines and production processes for each lead mAb and release engineering and GMP lots; 3) develop stable co-formulations and analytical tests for each monovalent BoNT/A, B, and E drug product and/or trivalent drug products; 4) perform IND enabling non-clinical studies on the monovalent and trivalent drug products; and 5) file an IND for the monovalent and/or the trivalent drug product. The high potency observed for BoNT/A, B and E mAbs in vivo may allow vialing of extremely small amounts of antibody (~ 5 mg total) as a therapeutic dose. At current yields for the BoNT/A mAbs, remarkably small fermentation volumes for each of 10 mAbs (3 BoNT/A, 4 BoNT/B, and 3 BoNT/E) could yield over 1 million doses!

INSTRUCTIONS: The information supplied on this form MUST meet the following requirements: The summary of objectives MUST fit in the space provided. The height of the letters must not be smaller than 10 point; Helvetica or Arial 12 point is the NIH-
suggested font. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi. No more than 6 lines of type within a vertical inch. Margins, in all directions, must be at least 1/2 inch.

THIS FORM MUST BE PLACED BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL ALONG WITH THE "GOVERNMENT NOTICE FOR HANDLING PROPOSALS."

*The insertion of the DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT (i.e., the Department Name) and MAJOR SUBDIVISION (i.e., "Dental School", "Medical School," etc., or the Major Component Code, if known) is required ONLY for INSTITUTIONS OF HIGHER EDUCATION.

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR 352.215-1.

(f) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(g) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

Exhibit 31.1

Certification
Pursuant to Section 302 Of The Sarbanes-Oxley Act Of 2002
(Chapter 63, Title 18 U.S.C. Section 1350(A) And (B))

I, Steven B. Engle, certify that:

1. I have reviewed this quarterly report on Form 10-Q of XOMA Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f))) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2008

/s/ STEVEN B. ENGLE

Steven B. Engle
Chairman, Chief Executive Officer and President

Exhibit 31.2

Certification
Pursuant to Section 302 Of The Sarbanes-Oxley Act Of 2002
(Chapter 63, Title 18 U.S.C. Section 1350(A) And (B))

I, Karen K. Thomas, certify that:

1. I have reviewed this quarterly report on Form 10-Q of XOMA Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f))) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2008

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

Exhibit 32.1

Certification
Pursuant to Section 906 Of The Sarbanes-Oxley Act Of 2002
(Chapter 63, Title 18 U.S.C. Section 1350(A) And (B))

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chapter 63, Title 18 U.S.C. Section 1350(a) and (b)), the undersigned hereby certifies in his capacity as an officer of XOMA Ltd. (the "Company") that the quarterly report of the Company on Form 10-Q for the period ended September 30, 2008, fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of and for the periods covered by such report.

Date: November 10, 2008

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

This certification will not be deemed filed for purposes of Section 18 of the Exchange Act (15 U.S.C. 78), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

Exhibit 32.2

Certification
Pursuant to Section 906 Of The Sarbanes-Oxley Act Of 2002
(Chapter 63, Title 18 U.S.C. Section 1350(A) And (B))

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chapter 63, Title 18 U.S.C. Section 1350(a) and (b)), the undersigned hereby certifies in his capacity as an officer of XOMA Ltd. (the "Company") that the quarterly report of the Company on Form 10-Q for the period ended September 30, 2008, fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of and for the periods covered by such report.

Date: November 10, 2008

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

This certification will not be deemed filed for purposes of Section 18 of the Exchange Act (15 U.S.C. 78), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

Exhibit 99.1

News Release

XOMA Reports Third Quarter 2008 Financial Results

Berkeley, CA – November 10, 2008 — XOMA Ltd. (NASDAQ: XOMA), a leader in the discovery and development of therapeutic antibodies, today announced its results for the quarter ended September 30, 2008.

“In the third quarter of 2008, XOMA presented encouraging results toward supporting one of the most significant medical advances in diabetes in decades – a move from insulin therapy to anti-inflammatory treatment. For the first time, XOMA showed that a single dose of an interleukin-1 beta blocker, XOMA 052, increased Type 2 diabetes patient insulin production over three months,” said Steven Engle, Chairman and Chief Executive Officer of XOMA. ”With these results, we are accomplishing what we promised in November of 2007 when we launched our new product-focused strategy, and we have begun laying the groundwork for a new disease-modifying approach to diabetes that could transform the lives of millions of patients.”

“In September 2008, XOMA presented interim Phase 1 data at the European Association for the Study of Diabetes (EASD) annual meeting that showed XOMA 052 is safe and well-tolerated in Type 2 diabetes patients and that use of XOMA 052 reduced glycosylated hemoglobin (HbA1c) levels, a standard measure of blood glucose control,” said Alan Solinger, M.D., XOMA’s Vice President of Clinical Immunology. “Interim results from the European trial showed that insulin production increased up to 91 days following a single dose of XOMA 052 – a remarkable finding supporting the disease-modifying and monthly dosing or longer potential of the anti-inflammatory approach.”

Engle continued, “In addition, we advanced our biodefense business by signing a $65 million contract with the U.S. Government, initiated new therapeutic antibody programs under the existing collaboration with Takeda Pharmaceutical Company Limited, signed a Memorandum of Understanding with the Texas A&M University System to jointly explore options for the development and manufacture of antibodies and protein-based therapeutics and recently presented positive XOMA 052 data in preclinical animal models of rheumatoid arthritis and gout at the American College of Rheumatology 2008 Annual Conference (ACR). Based on new clinical results, we began prioritizing our efforts including the restructuring of our Novartis partnership and established a new committed equity financing facility that provides additional financial flexibility. Finally, we are pleased to report receipt of the first royalty payments on Swiss sales of CIMZIA®, UCB’s recently approved drug for Crohn’s disease.”

XOMA Focuses On Highest Value Opportunities and Reduces Costs

“XOMA’s accomplishments in Q3 were indeed exceptional,” Engle continued, “In the last year, we gained clarity about which programs will generate the highest value and which antibody technologies will yield the most revenues. This knowledge and the recent unprecedented general economic conditions have given us the understanding and the opportunity to focus our resources and realize the full potential of XOMA’s assets. We are focusing our R&D spending on our most promising proprietary development programs, including XOMA 052 in Type 2 diabetes, while postponing spending on other indications and programs, and we will continue to develop and license the next generation antibody discovery and development technology.”

For the remainder of 2008 and in 2009, XOMA plans to:

- Complete ongoing Phase 1 clinical trials of XOMA 052 in Type 2 diabetes by mid 2009.
- Initiate a Phase 2 clinical study of XOMA 052 in Type 2 diabetes in mid 2009.
- Initiate a small XOMA 052 pharmacokinetic study in rheumatoid arthritis at the end of 2008 and postpone other rheumatoid arthritis studies. The company plans to leverage recent results and additional expected confirmatory results of studies with another IL-1 blocker in rheumatoid arthritis to validate the XOMA 052 approach in this indication, which are noted in the most recent events section below.
- Conduct XOMA 052 proof of concept trials in other indications.
- Seek to establish a partnership for development and worldwide marketing of XOMA 052.

Engle said, “Treating Type 2 diabetes with a potentially disease-modifying, anti-inflammatory therapy represents a large opportunity for patients and for XOMA. We recognize that to maximize the value of XOMA 052, and to offset our development costs, we need a pharmaceutical partner with strengths in worldwide development and marketing. Fortunately, large pharmaceutical companies need blockbuster potential drugs like XOMA 052 more than ever. Conversations are ongoing with several major pharmaceutical and biotechnology companies.”

Additionally, as part of focusing on the company’s most important proprietary programs, XOMA has:

- Restructured its product development collaboration with Novartis into a fully funded collaboration with an immediate cash payment of $6.2 million and reduction in debt, while maintaining the full potential to realize the value of a novel Phase 2 oncology compound, HCD122, through double-digit royalties.
- Suspended the XOMA 629 development program.
- Postponed a Phase 2 clinical study in gout.
- Postponed most planned capital expenses. Further spending will depend on timing of additional biodefense and other contracts.

Regarding biodefense activities, most of XOMA’s activity is generally covered by contract revenues from the U.S. government, and the company will therefore continue with its biodefense programs. The company will also continue its fully funded collaborations.

Third Quarter 2008 Financial Results

XOMA’s total revenues were $7.9 million in the third quarter of 2008, compared to $43.1 million in the third quarter of 2007. The decrease from 2007 was due primarily to a $30.0 million non-recurring license fee received from Pfizer Inc. (Pfizer) in the third quarter of 2007. In addition, XOMA is nearing the end of contracted service arrangements with the NIAID under contract No. HHSN26620060008C/N01-A1-60008l (“NIAID 2”) and Aveo Pharmaceuticals, Inc., which is now a part of the Schering Plough Research Institute (SPRI), so revenues under these contracts have decreased in the first three quarters of 2008 compared to the same period in 2007. These decreases were partially offset by higher royalty revenues and increased activities related to XOMA’s collaborations with Takeda and SPRI.

The operating loss for the third quarter was $18.5 million in 2008 compared to operating income of $22.7 million for the third quarter of 2007; the decrease was primarily due to the $30.0 million license fee recognized in 2007 from Pfizer as discussed above. Further contributing to the operating loss was an increase in operating expenses, reflecting increased R&D spending on the development of proprietary products, primarily XOMA 052. The net loss for the third quarter was $20.4 million or $0.15 per basic share for 2008, compared with net income of $21.8 million or $0.17 per basic share for the third quarter of 2007.

Cash, restricted cash, cash equivalents, and short-term investments at September 30, 2008 were $24.4 million of which $13.9 million was restricted cash reserved primarily for the payment of the semi-annual interest on a royalty-backed loan from Goldman Sachs. In October of 2008, Goldman Sachs withdrew $2.5 million from the restricted cash reserve as payment of interest and $4.6 million as payment of outstanding principal and returned $2.6 million in cash to XOMA. At December 31, 2007, cash, restricted cash, cash equivalents, and short-term investments were $44.6 million of which $6.0 million was restricted cash. A more detailed discussion of XOMA's third quarter 2008 financial results is provided below and in the company's Form 10-Q filing with the SEC. Subsequent to the third quarter, XOMA restructured its collaboration with Novartis and the new agreement provided XOMA with a $6.2 million cash payment and reduced XOMA's outstanding debt with Novartis by $7.5 million. In October 2008, XOMA entered into a committed equity financing facility and the company has sold 3.9 million shares for a net amount of $4.34 million.

Recent Highlights

- **Positive XOMA 052 Phase 1 diabetes data presented at EASD conference in September supports groundbreaking anti-inflammatory approach to Type 2 diabetes treatment:** Interim data from 48 patients demonstrated that a single dose of XOMA 052 reduced HbA1c, which is a validated marker of blood glucose control, and C-reactive protein levels, which is a protein indicative of systemic inflammation and associated with negative cardiovascular outcomes. In the European trial, additional tests were performed that showed that patients treated with a single dose of XOMA 052 demonstrated an increase in insulin production lasting 91 days or more. All human data on XOMA 052 generated to date support monthly or even less frequent dosing.
- **Positive XOMA 052 data in preclinical animal models of rheumatoid arthritis (RA) and gout presented at the ACR conference in October supports potential of XOMA 052 in additional inflammatory indications:** Treatment with XOMA 052 in the RA model showed improved disease scoring at all dosing levels. In the preclinical gout model, treatment with XOMA 052 blocked the inflammatory processes that occur following injection of monosodium urate crystals.
- **Data supporting the anti-inflammatory therapeutic approach of IL-1 beta blockers presented at ACR:** The positive clinical effect and safety of a class of drugs called IL-1 beta blockers, including XOMA 052, was demonstrated when Novartis reported positive Phase 2 data for its anti-IL-1 beta blocking antibody in cyropyrin-associated periodic syndrome that met the predefined endpoints of time to disease flare vs. placebo ($p<0.001$). Novartis also reported earlier stage data in systemic juvenile idiopathic arthritis (sJIA) that showed patients achieved substantial clinical improvement within 15 days and four patients achieved complete remission of the disease. These results continue to build evidence that offers promise for the class of IL-1 blocking antibodies to treat IL-1-mediated diseases.
- **New $65 million NIAID contract funds ongoing development of XOMA's anti-botulinum drug candidates, which is a key step to establish a national stockpiling contract:** In September of 2008, the Company announced that it had been awarded a $65 million multiple year contract funded with Federal funds from NIAID, a part of the NIH to support XOMA's ongoing development of drug candidates towards clinical trials in the treatment of botulism poisoning, a potentially deadly muscle paralyzing disease. The additional funding brings the program's total to nearly $100 million and enables initiation of human studies of anti-botulinum antibody products. Depending on positive results, continued government funding and additional human studies, XOMA plans to file the data package necessary to begin production of drug candidates for the Strategic National Stockpile.

- **Restructured agreement with Novartis provides immediate cash payment and debt reduction, eliminates planned project expenditures and will generate revenues in 2008 and 2009:** As announced today, XOMA restructured its agreement with Novartis involving research and development programs including the ongoing HCD122 program. The agreement provides XOMA with a $6.2 million cash payment and Novartis will fully fund all future R&D expenses related to the agreement and pay potential milestones and double-digit royalties related to the two ongoing programs. Further, XOMA's outstanding debt with Novartis has been reduced by $7.5 million. In exchange, Novartis assumes control over the HCD122 program and an additional ongoing program, as well as the right to expand the development of both programs into additional indications outside of oncology.
- **Biological manufacturing agreement with Texas A&M University System (TAMUS) may generate innovative processes and technologies, more manufacturing capacity, process development facilities and research personnel:** In September 2008, XOMA signed a memorandum of understanding with TAMUS designed to accelerate the translation of XOMA's innovative technologies into the practice of biological manufacturing. XOMA and TAMUS are exploring options for the development and manufacture of antibodies and protein-based therapeutics for human and veterinary applications.
- **First royalty payments received from UCB for Swiss sales of CIMZIA®, its recently approved drug for Crohn's disease:** Although initially small, as royalty payments are delayed three months, this royalty stream is XOMA's third. In April 2008, CIMZIA® was approved by the U.S. Food & Drug Administration (FDA) for the treatment of Crohn's disease, and commercial distribution of CIMZIA® started in April 2008. It is the second marketed therapeutic product manufactured under license using XOMA's proprietary bacterial cell expression technology. The company expects to realize an increase in royalty revenues from U.S. sales of CIMZIA® in the next quarter.
- **Committed equity financing facility provides financial options and flexibility:** In October 2008, XOMA entered into a committed equity financing facility under which it has the option to sell up to $60 million, in small amounts over two years, of its registered common shares to Azimuth Opportunity Ltd. The agreement gives XOMA flexibility to obtain money on the sale of its common shares based on an agreed upon formula from time to time. In the face of uncertain economic conditions, the company to date has sold 3.9 million shares for a net amount of $4.34 million. The company is not obligated to further utilize the facility, can use the facility at any time, remains free to enter other financing transactions, and did not pay a commitment fee or issue any warrants to secure the facility.
- **Newly appointed VP Research increases leadership in antibody development, collaboration activities and licensing:** In October 2008, XOMA appointed Steve Doberstein, Ph.D., to the position of Vice President of Research. Dr. Doberstein has extensive prior experience at antibody and protein companies including Xencor, Inc. and 5 PRIME, where he managed antibody discovery activities and the creation and implementation of pharmaceutical partnerships. At XOMA, Dr. Doberstein directs discovery and development of XOMA's preclinical drug candidates, supports clinical development of XOMA's portfolio of drug candidates and focuses on antibody discovery and cell line development.

Financial Discussion

Revenues

XOMA's total revenues were $7.9 million in the third quarter of 2008, compared to $43.1 million in the third quarter of 2007. Revenues for the first nine months of 2008 were $31.1 million compared to $69.5 million in the first nine months of 2007.

License and collaborative fee revenues were $1.3 million for the quarter ended September 30, 2008, compared with $31.3 million for the same period of 2007. The $30.0 million decrease is due to a $30.0 million non-recurring license fee received from Pfizer, Inc. in the third quarter of 2007.

Contract revenues for the third quarter totaled $2.0 million in 2008, compared with $7.4 million for the same period of 2007. The decrease of $5.4 million resulted primarily from XOMA nearing the completion of certain contracted service arrangements.

Royalties were $4.6 million for the third quarter of 2008 compared with $4.4 million in the third quarter of 2007. The $0.2 increase resulted primarily from higher sales of LUCENTIS® inside and outside the U.S. and RAPTIVA® outside the U.S.

Expenses

XOMA's research and development expense for the third quarter of 2008 totaled $19.7 million, compared with $14.6 million in the same period of 2007. The increase of $5.1 million primarily reflects spending on the development of XOMA 052 and XOMA 629 and work done to generate revenues under our contracts with Takeda and Schering-Plough Research Institute. Of the $5.1 million increase in research and development expenses in the third quarter of 2008 compared with the same period of 2007, $0.8 million related to an increase in salaries and related expenses including a $0.4 million increase in share-based compensation expense.

General and administrative expense for the third quarter of 2008 was $6.7 million compared with $5.8 million for the same period last year. This increase of $0.9 million includes a $0.3 million increase in salaries expense.

Interest expense for the third quarter of 2008 was $2.0 million compared with $1.2 million for the same period of 2007. The increase for the third quarter of 2008 compared with the same period of 2007 is due to the higher principal balance and interest rate associated with our new term loan facility with Goldman Sachs Specialty Lending Holdings, Inc.

Liquidity and Capital Resources

Cash, cash equivalents and short-term investments at September 30, 2008 were $10.6 million compared with $27.4 million at June 30, 2008. Cash used in operating activities during the third quarter of 2008 was $9.3 million compared with cash provided by operating activities of $22.6 million during the third quarter of 2007.

In August of 2008, XOMA sold its remaining auction rate securities. All sales were at par value, which was equal to recorded fair value, and no loss was incurred by the Company.

Long-term Debt

At September 30, 2008, XOMA had outstanding principal of $55.0 million on the 5-year term loan from Goldman Sachs established in May 2008 and $21.3 million of long-term debt to Novartis. The long-term debt to Novartis represents XOMA's borrowings under a $50.0 million loan facility established to facilitate XOMA's participation in its collaboration with Novartis. The Novartis loan is secured by XOMA's interest in the collaboration and is not due until 2015. The Goldman Sachs loan is secured by the company's royalty revenue for RAPTIVA®, LUCENTIS® and CIMZIA®. Under the restructured collaboration agreement with Novartis, the principal balance of this note has been reduced by $7.5 million to $13.8 million and no additional draw downs are available.

Guidance Update

As previously indicated, the company is planning on closing one or more major transactions by year end. Because there cannot be complete certainty as to the exact timing of these transactions, XOMA is updating its financial guidance for the full year 2008. The company expects that revenue for 2008 will be between $55 and $85 million. The company expects that research and development expense for 2008 will be between $83 and $87 million. General and administrative expense for 2008 is expected to be between $24 and $26 million. The company expects it will use cash of between $16 and $48 million in 2008 operating activities and will spend between $10 and $12 million in capital expenditures.

Product Highlights

XOMA 052: XOMA 052 is a potent monoclonal antibody with the potential to improve the treatment of patients with a wide variety of inflammatory diseases. XOMA 052 binds strongly to interleukin-1 beta (IL-1 beta), a pro-inflammatory cytokine that is involved in the development of diabetes, rheumatoid arthritis, gout and other diseases. By binding IL-1 beta, the drug blocks the activation of the IL-1 receptor, thereby preventing the cellular signaling events that produce inflammation. XOMA 052 is a humanized IgG2 antibody with a half-life of 22 days. Based on its binding properties, specificity to IL-1 beta and half-life, XOMA 052 may provide convenient dosing of once per month or longer. XOMA 052 was developed by XOMA using the Company's proprietary antibody technologies, capabilities and expertise. XOMA owns worldwide rights to the antibody and related intellectual property.

The central role of the IL-1 pathway in multiple diseases has been clinically validated by several inhibitors of the IL-1 pathway in development and by two FDA approved therapies based on IL-1 blockade. These disease indications include rheumatoid arthritis, systemic juvenile idiopathic arthritis, gout, Muckle-Wells syndrome, and others.

Based on the encouraging results from XOMA's initial trials for XOMA 052 in Type 2 diabetes, the company is planning and designing a large Phase 2 dose-ranging trial in a more narrowly defined type 2 diabetes population with the goal of establishing the data necessary to initiate a Phase 3 program. XOMA anticipates starting this Phase 2 randomized, double blind, placebo-controlled trial in mid-2009.

For rheumatoid arthritis, XOMA will initiate a clinical trial later this year to assess the safety and pharmacokinetics of XOMA 052 in this patient population. XOMA is putting a planned acute gout Phase 1 trial on hold and decelerated the start of clinical trials in systemic juvenile idiopathic arthritis, now estimated to start mid 2009.

RAPTIVA® (efalizumab) Collaboration with Genentech and Merck Serono - According to Genentech and Merck Serono SA, worldwide sales of RAPTIVA® in the third quarter of 2008 were $61 million, with $28 million coming from Genentech's sales in the U.S. and $33 million from Merck Serono SA's sales internationally. Third quarter sales grew 11 percent compared to $55 million in the third quarter of 2007, but declined 5 percent compared to $64 million in the second quarter of 2008. XOMA earns a mid single-digit royalty on worldwide sales of RAPTIVA®.

LUCENTIS® (ranibizumab injection) by Genentech - LUCENTIS® is an antibody fragment against Vascular Endothelial Growth Factor (VEGF) for the treatment of neovascular (wet) age-related macular degeneration, which causes vision loss in the elderly. LUCENTIS® is the first marketed therapeutic product manufactured under a license using XOMA's bacterial cell expression technology, an enabling technology used to discover and screen, as well as develop and manufacture, recombinant antibodies and other proteins for commercial purposes. LUCENTIS® was approved by the FDA in June of 2006 and in the European Union, where it is distributed by Novartis, in January of 2007.

According to Genentech and Novartis, worldwide sales of LUCENTIS® in the third quarter of 2008 were $446 million, with $225 million coming from Genentech's sales in the U.S and $221 million from Novartis' sales internationally. Third quarter sales grew 39 percent compared to $320 million in the third quarter 2007, but declined 3 percent compared to $458 million in the second quarter of 2008.

Certain European patents in our bacterial cell expression portfolio pertaining to LUCENTIS® expired in July 2008. As a result, XOMA's right to royalties on sales of LUCENTIS® outside of the U.S. ended in the third quarter of 2008.

CIMZIA® (certolizumab pegol) by UCB - CIMZIA® is an antibody fragment against Tumor Necrosis Factor alpha (TNF alpha) for the treatment of Crohn's disease and is the second marketed therapeutic product manufactured under license using XOMA's bacterial cell expression technology. CIMZIA® was approved by the FDA in April of 2008 for the treatment of moderate to severe Crohn's disease in adult patients who have not responded to conventional therapy and is currently under review for approval in rheumatoid arthritis by the FDA in the U.S and by the European Medicines Agency in Europe. XOMA expects that CIMZIA® could be approved in rheumatoid arthritis in the U.S. as early as year end 2008. Royalties from XOMA's bacterial cell expression licenses range from 0.5 percent to 3.0 percent of sales of covered products.

HCD122 with Novartis - HCD122 is a fully human anti-CD40 antibody with a unique, dual mechanism of action designed as an antagonist to CD40 and as a treatment for B-cell mediated diseases, including malignancies and autoimmune diseases. In April 2008, Novartis and XOMA started a Phase 1/2 clinical study of HCD122 for patients with lymphoma. In the open-label multi-site study, patients will receive HCD122 intravenously once a week for four weeks. This 50-patient study will evaluate highest tolerated dose, safety and activity of HCD122.

In April 2005, XOMA announced the initiation of a Phase 1 study of HCD122 for patients with advanced chronic lymphocytic leukemia, and in July 2008 this study was terminated due to limited patient availability and enrollment patterns. In October of 2005, XOMA and Novartis initiated a second Phase 1 study for patients with multiple myeloma. In December of 2006, the companies reported favorable preliminary results of these Phase 1 trials, as well as favorable pre-clinical results of comparisons of HCD122 with RITUXAN®.

Contract Development and Collaboration Agreements

NIAID Contract: Anti-Botulinum Neurotoxin Program

In July of 2006, XOMA was awarded a $16.3 million contract 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 contract work is being performed on a cost plus fixed fee basis over a three-year period and will be 100 percent funded with Federal funds from NIAID under Contract No. HHSN266200600008C.

In September of 2008, a new NIAID contract was awarded to continue development of XOMA's anti-botulinum antibody product candidates. As part of the new contract, XOMA will develop, evaluate and produce the clinical supplies to support an Investigational New Drug filing with the FDA and conduct preclinical studies required to support human clinical trials. The project is fully funded under Federal contract number HHSN272200800028C from NIAID.

Schering-Plough Research Institute Collaboration: Multiple Antibody Projects for Undisclosed Targets

In May of 2006, XOMA entered into a collaboration agreement with the Schering-Plough Research Institute (SPRI) to conduct multiple therapeutic monoclonal antibody discovery and development projects. During the collaboration, XOMA will discover therapeutic antibodies against targets selected by SPRI, use its phage display libraries to generate fully human antibodies and the company's proprietary Human Engineering technology to humanize antibody candidates generated by hybridoma techniques, perform pre-clinical studies to support regulatory filings, cell line and process development and produce antibodies for initial clinical trials. In January of 2007, XOMA announced that this collaboration had been expanded to include oncology targets. XOMA estimates that it could receive more than $75 million before royalties over the life of the agreement in aggregate upfront, R&D funding, milestone and other payments.

Takeda Pharmaceutical Collaboration: Multiple Antibody Projects for Undisclosed Targets

In November of 2006, the company entered into a collaboration agreement with Takeda to conduct multiple therapeutic monoclonal antibody discovery and development projects. During the collaboration, XOMA will discover therapeutic antibodies against multiple targets selected by Takeda. In February of 2007, XOMA announced that this collaboration had been expanded to include additional disease targets including those in oncology**.** In September of 2008, the company expanded the collaboration again to add new undisclosed targets to the collaborative effort. XOMA estimates that it could receive more than $230 million, before royalties, over the life of the agreement in aggregate upfront, R&D funding, milestone and other payments.

Investor Conference Call

XOMA will host a conference call and webcast to discuss its third quarter 2008 results today, November 10, 2008, at 4:30 p.m. Eastern. The webcast can be accessed via XOMA's website at www.xoma.com and will be available for replay until close of business on February 3, 2009. Telephone numbers for the live audiocast are 877-407-9205 (U.S. and Canada) and 201-689-8054 (International). Conference ID #: 300591. A telephonic replay will be available beginning approximately two hours after the conclusion of the call until close of business on February 3, 2009. Telephone numbers for the replay are 877-660-6853 (U.S./Canada) and 201-612-7415 (International). Two access numbers are required for the replay: account number 286 and conference ID # 300591.

About XOMA

XOMA discovers, develops and manufactures therapeutic antibody and other agents designed to treat inflammatory, autoimmune, infectious and cancerous diseases. The company's proprietary product pipeline includes XOMA 052, an anti-IL-1 beta antibody, and XOMA 3AB, a biodefense anti-botulism antibody candidate.

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

The company has a premier antibody discovery and development platform that incorporates leading antibody phage display libraries and XOMA's proprietary Human Engineering(TM) and bacterial cell expression and manufacturing technologies. Bacterial cell expression (BCE) is a key breakthrough biotechnology for the discovery and manufacturing of antibodies and other proteins. As a result, more than 50 pharmaceutical and biotechnology companies have signed BCE licenses.

In addition to developing its own products, XOMA develops products with premier pharmaceutical companies including Novartis AG, Schering-Plough Research Institute and Takeda Pharmaceutical Company Limited. XOMA has a fully integrated product development infrastructure, extending from pre-clinical science to approval, and a team of 335 employees at its Berkeley location. For more information, please visit http://www.xoma.com.

Forward Looking Statements

Certain statements contained herein concerning the anticipated levels of revenues, expenses and cash utilization, sales of approved products, expected payments under existing agreements and/or product development 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 anticipated levels of revenues, expenses and cash utilization may be other than as expected due to unanticipated changes in XOMA's research and development programs, unavailability of additional arrangements, lower than anticipated sales of approved products or failure of products to receive approval; 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 competition, if physicians do not adopt the products as treatments for their patients or if remaining regulatory approvals are not obtained or maintained; and XOMA will not receive the estimated total amounts of funds if it cannot successfully carry out its obligations under its existing contracts.

These and other risks, including those related to the results of discovery and 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 FDA, European or other regulators or their advisory bodies; and analysis or interpretation by, or submission to, these entities or others of scientific data); changes in the status of existing collaborative relationships; the ability of collaborators and other partners to meet their obligations; XOMA's ability to meet the demands of the United States government agency with which it has entered into its government contracts; competition; market demands for products; scale-up and marketing capabilities; availability of additional licensing or collaboration opportunities; international operations; share price volatility; XOMA's financing needs and opportunities; uncertainties regarding the status of biotechnology patents; uncertainties as to the costs of protecting intellectual property; and risks associated with XOMA's status as a Bermuda company, are described in more detail in XOMA's most recent filing on Form 10-K and in other SEC filings. Consider such risks carefully when considering XOMA's prospects.

Condensed Financial Statements Follow

###

XOMA Ltd.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2008 (unaudited)	December 31, 2007 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,186	$ 22,500
Short-term investments	4,381	16,067
Restricted cash	13,878	6,019
Receivables	7,962	12,135
Prepaid expenses and other current assets	1,858	1,113
Debt issuance costs	398	254
Total current assets	34,663	58,088
Property and equipment, net	27,970	25,603
Debt issuance costs – long-term	1,436	722
Other assets	402	402
Total assets	$ 64,471	$ 84,815
LIABILITIES AND SHAREHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)		
Current liabilities:		
Accounts payable	$ 9,270	$ 6,995
Accrued liabilities	8,095	7,710
Accrued interest	2,845	878
Deferred revenue	6,487	8,017
Other current liabilities	1,599	—
Total current liabilities	28,296	23,600
Deferred revenue – long-term	9,251	10,047
Interest bearing obligation – long-term	76,262	50,850
Other long-term liabilities	353	—
Total liabilities	114,162	84,497
Commitments and contingencies		
Shareholders' equity (net capital deficiency):		
Preference shares, $.05 par value, 1,000,000 shares authorized Series A, 210,000 designated, no shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	—	—
Series B, 8,000 designated, 2,959 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively; aggregate liquidation preference of $29.6 million	1	1
Common shares, $.0005 par value, 210,000,000 shares authorized, 132,429,517 and 131,957,774 shares outstanding at September 30, 2008 and December 31, 2007, respectively	66	66
Additional paid-in capital	745,410	740,119
Accumulated comprehensive loss	(82)	(9)
Accumulated deficit	(795,086)	(739,859)
Total shareholders' equity (net capital deficiency)	(49,691)	318
Total liabilities and shareholders' equity (net capital deficiency)	$ 64,471	$ 84,815

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

.

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

Media & Investors Contact:
Carolyn Hawley
Porter Novelli Life Sciences for XOMA
619-849-5375
chawley@pnlifesciences.com