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

FORM 10-Q

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

For the quarterly period ended June 30, 2006

Commission File No. 0-14710

**XOMA Ltd.**

(Exact name of registrant as specified in its charter)

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

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

**2910 Seventh Street, Berkeley,  
California 94710**  
(Address of principal executive offices,  
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. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer  Accelerated Filer  Non-Accelerated filer

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

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

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Class	Outstanding at August 3, 2006
Common shares US\$.0005 par value	97,410,508

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## PART I - FINANCIAL INFORMATION

## ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	June 30, 2006 <u>(unaudited)</u>	December 31, 2005 <u>(note 1)</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,798	\$ 20,804
Short-term investments	23,054	22,732
Receivables, net	5,602	5,186
Related party receivables	96	98
Prepaid expenses	1,217	975
Debt issuance costs	477	493
Total current assets	42,244	50,288
Property and equipment, net	21,940	19,056
Related party receivables – long-term	75	93
Debt issuance costs – long-term	2,187	2,683
Deposits	457	457
Total assets	<u>\$ 66,903</u>	<u>\$ 72,577</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY (NET CAPITAL DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$ 3,525	\$ 5,648
Accrued liabilities	5,613	5,717
Accrued interest	1,472	1,652
Deferred revenue	4,849	3,527
Total current liabilities	15,459	16,544
Deferred revenue – long-term	5,075	4,333
Convertible debt – long-term	58,109	60,000
Interest bearing obligation – long-term	15,793	12,373
Total liabilities	94,436	93,250
Commitments and contingencies	—	—
Shareholders' equity (net capital deficiency):		
Preference shares, \$.05 par value, 1,000,000 shares authorized		
Series A, 135,000 designated, no shares issued and outstanding	—	—
Series B, 8,000 designated, 2,959 shares issued and outstanding; aggregate liquidation preference of \$29.6 million	1	1
Common shares, \$.0005 par value, 210,000,000 shares authorized, 97,409,289 and 86,312,712 shares outstanding at June 30, 2006 and December 31, 2005, respectively	49	43
Additional paid-in capital	674,698	655,041
Accumulated comprehensive income	(71)	(66)
Accumulated deficit	(702,210)	(675,692)
Total shareholders' equity (net capital deficiency)	(27,533)	(20,673)
Total liabilities and shareholders' equity (net capital deficiency)	<u>\$ 66,903</u>	<u>\$ 72,577</u>

*See accompanying notes to condensed consolidated financial statements.*

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
<b>Revenues:</b>				
License and collaborative fees	\$ 731	\$ 2,655	\$ 1,385	\$ 3,180
Contract and other revenue	4,681	933	7,775	2,192
Royalties	2,100	1,571	3,956	2,780
Total revenues	<u>7,512</u>	<u>5,159</u>	<u>13,116</u>	<u>8,152</u>
<b>Operating costs and expenses:</b>				
Research and development (including contract related of \$2,672 and \$4,611, respectively, for the three and six months ended June 30, 2006, and \$974 and \$1,785 for the three and six months ended June 30, 2005)	12,104	9,547	24,285	19,549
General and administrative	4,386	3,709	9,439	7,460
Total operating costs and expenses	<u>16,490</u>	<u>13,256</u>	<u>33,724</u>	<u>27,009</u>
Loss from operations	(8,978)	(8,097)	(20,608)	(18,857)
<b>Other income (expense):</b>				
Investment and interest income	385	418	842	987
Interest expense	2,681	(1,117)	(6,745)	(1,778)
Other income (expense)	(3)	252	(7)	41,184
Net income (loss) from operations before taxes	(5,915)	(8,544)	(26,518)	21,536
Provision for income taxes	—	38	—	38
Net income (loss)	<u>\$ (5,915)</u>	<u>\$ (8,582)</u>	<u>\$ (26,518)</u>	<u>\$ 21,498</u>
Basic net income (loss) per common share	<u>\$ (0.06)</u>	<u>\$ (0.10)</u>	<u>\$ (0.29)</u>	<u>\$ 0.25</u>
Diluted net income (loss) per common share	<u>\$ (0.06)</u>	<u>\$ (0.10)</u>	<u>\$ (0.29)</u>	<u>\$ 0.20</u>
Shares used in computing basic net income (loss) per common share	<u>96,661</u>	<u>86,253</u>	<u>92,326</u>	<u>85,997</u>
Shares used in computing diluted net income (loss) per common share	<u>96,661</u>	<u>86,253</u>	<u>92,326</u>	<u>115,332</u>

*See accompanying notes to condensed consolidated financial statements.*

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

	Six Months Ended June 30,	
	2006	2005
Cash flows from operating activities:		
Net income (loss)	\$(26,518)	\$ 21,498
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	2,383	2,218
Common shares contribution to 401(k) and management incentive plans	1,088	1,304
Share-based compensation expense	647	—
Accrued interest on convertible notes and other interest bearing obligations	237	1,563
Revaluation of embedded derivative	3,968	—
Amortization of discount, premium and issuance costs of convertible debt	493	205
Amortization of premium on short-term investments	35	—
Gain on extinguishment of debt	—	(40,935)
Loss on disposal/retirement of property and equipment	4	2
Gain on sale of investments	—	(271)
Other non-cash adjustments	(4)	—
Changes in assets and liabilities:		
Receivables and related party receivables	(396)	(3,805)
Prepaid expenses	(242)	(166)
Deposits	—	(297)
Accounts payable	(2,123)	(103)
Accrued liabilities	(104)	(13,658)
Deferred revenue	2,064	120
Net cash used in operating activities	<u>(18,468)</u>	<u>(32,325)</u>
Cash flows from investing activities:		
Proceeds from sales/maturities of investments	15,734	502
Purchase of investments	(16,091)	—
Purchase of property and equipment	(5,271)	(1,461)
Net cash used in investing activities	<u>(5,628)</u>	<u>(959)</u>
Cash flows from financing activities:		
Principal payments of short-term loan	—	(115)
Payments under capital lease obligations	—	(133)
Proceeds from issuance of long-term debt	3,003	8,844
Proceeds from issuance of convertible notes	11,969	56,553
Proceeds from issuance of common shares	118	96
Net cash provided by financing activities	<u>15,090</u>	<u>65,245</u>
Net increase (decrease) in cash and cash equivalents	(9,006)	31,961
Cash and cash equivalents at the beginning of the period	20,804	23,808
Cash and cash equivalents at the end of the period	<u>\$ 11,798</u>	<u>\$ 55,769</u>

*See accompanying notes to condensed consolidated financial statements.*

**XOMA Ltd.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

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

**Business**

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

**Basis of Presentation**

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

In the opinion of management, the unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which are necessary to present fairly the Company's consolidated financial position as of June 30, 2006, the consolidated results of the Company's operations for the three and six months ended June 30, 2006 and 2005, and the Company's cash flows for the six months then ended. The condensed consolidated balance sheet amounts at December 31, 2005, have been derived from audited consolidated financial statements. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year or future periods.

**Critical Accounting Policies**

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

*Contract Revenue*

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

*Share Based Compensation*

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), "Stock-Based Payment" ("SFAS 123R"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors, including employee share options and employee share purchases related to the Employee Share Purchase Plan, on estimated fair values. The Company is using the modified prospective method. Under this method, the Company is required to record compensation expense for all awards granted after the date of adoption and for the unvested portion of previously granted awards that remain outstanding at the date of adoption. To estimate the value of an award, the Company uses the Black-Scholes option pricing model. This model requires inputs such as expected life, expected volatility and risk-free interest rate. Further, the forfeiture rate also impacts the amount of aggregate compensation. These inputs are subjective and generally require significant analysis and judgment to develop. While estimates of expected life, volatility and forfeiture rate are

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

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

**Estimates**

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

**Concentration of Risk**

Cash, cash equivalents, short-term investments and accounts receivable are financial instruments, which potentially subject the Company to concentrations of credit risk. The Company maintains money market funds and short-term investments that bear minimal risk. The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the six months ended June 30, 2006, two customers represented 56% and 30% of total revenues and, as of June 30, 2006, there were billed and unbilled receivables of \$5.1 million outstanding from these customers representing 54% and 37% of the balance. For the six months ended June 30, 2005, four customers represented 47%, 25%, 13% and 12% of total revenues and, as of June 30, 2005, there were billed and unbilled receivables of \$4.1 million from three of these customers representing 44%, 27% and 19% of the balance.

**Share-Based Compensation**

The Company grants qualified and non-qualified share options, shares and other share related awards under various plans to directors, officers, employees and other individuals. To date, share-based compensation issued under these plans consists of qualified and non-qualified incentive share options and shares. Share options are granted at exercise prices of not less than the fair market value of the Company's common shares on the date of grant. Generally, share options granted to employees fully vest four years from the grant date and expire ten years from the date of the grant or three months from the date of termination of employment (longer in case of death or certain retirements). Certain options granted to directors fully vest on the date of grant and certain options may fully vest upon a change of control of the Company. Additionally, the Company has an Employee Share Purchase Plan ("ESPP") that allows employees to purchase Company shares at a purchase price equal to 95% of the closing price on the exercise date. For ESPP periods beginning prior to December 31, 2004, the purchase price per common share is 85% of fair market value at the lower of either the first day of the 24 month offering period or the last day of the period. As of June 30, 2006, the Company had approximately 6.5 million shares of common shares reserved for future issuance under its share option plans and ESPP.

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

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

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

	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
Net income (loss) — as reported	\$ (8,582)	\$ 21,498
Deduct: Total share-based employee compensation expense under SFAS 123	(2,733)	(3,163)
Pro forma net income (loss)	<u>\$ (11,315)</u>	<u>\$ 18,335</u>
Net income (loss) per common share:		
Basic — as reported	\$ (0.10)	\$ 0.25
Basic — pro forma	\$ (0.13)	\$ 0.21
Diluted — as reported	\$ (0.10)	\$ 0.20
Diluted — pro forma	\$ (0.13)	\$ 0.17

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

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

	Three Months Ended June 30, 2006	Six Months Ended June 30, 2006
Research and development	\$ 114	\$ 270
General and administrative	143	377
Total share-based compensation expense	<u>\$ 257</u>	<u>\$ 647</u>

Basic and diluted net income (loss) per common share is (.01) lower for the six months ended June 30, 2006, than if the Company had not adopted SFAS 123R. There was no capitalized share-based compensation cost as of June 30, 2006. There were no recognized tax benefits during the three and six months ended June 30, 2006. The adoption of SFAS 123R had no impact on cash flows from operations or financing.

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

The fair value of share based awards was estimated using a Black-Scholes model with the following weighted-average assumptions for the three and six months ended June 30, 2006 and 2005.

	Three Months Ended June 30,		Six Months Ended June 30,		
	2006	2005	2006	2005	
Dividend yield	0%	0%	0%	0%	0%
Expected volatility	78%	83%	80%	83%	83%
Risk-free interest rate	5.18%	3.70%	4.67%	4.10%	4.10%
Expected life	5.3 years	4.1 years	5.3 years	4.3 years	4.3 years

Prior to the adoption of SFAS 123R, the Company's Board of Directors approved the acceleration of vesting of all outstanding employee share options with an exercise price greater than \$3.00 per share. Because the exercise price of all the accelerated options exceeded the market price per share of the common shares as of the new measurement date, the acceleration had no impact on the

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**(unaudited)**

Company's earnings in 2005. Since the accelerated options had exercise prices in excess of the current market value of the Company's common shares, the options had limited economic value and were not fully achieving their original objective of incentive compensation and employee retention. The modification allows expense recognized after the adoption of SFAS 123R to better reflect the Company's compensation strategies.

Share option activity for the six months ended June 30, 2006, is as follows:

	<u>Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value (in thousands)</u>
Options outstanding at December 31, 2005	5,422,096	\$ 4.96		
Granted	1,222,300			
Forfeited, expired or cancelled	(563,828)			
Options outstanding at June 30, 2006	<u>6,080,568</u>	<u>\$ 4.30</u>	<u>6.77</u>	<u>\$295,066</u>
Options exercisable at June 30, 2006	<u>4,122,323</u>	<u>\$ 5.57</u>	<u>5.58</u>	<u>\$115,369</u>

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

	<u>Six Months Ended June 30,</u>			
	<u>2006</u>		<u>2005</u>	
	<u>Unvested Number of Shares</u>	<u>Weighted-Average Grant-Date Fair Value</u>	<u>Unvested Number of Shares</u>	<u>Weighted-Average Grant-Date Fair Value</u>
Unvested balance at December 31	1,234,838	\$ 1.56	1,890,034	\$ 5.50
Granted	1,222,300	1.68	1,167,100	1.45
Vested	(401,211)	1.52	(1,693,630)	5.58
Forfeited	(97,682)	1.61	(246,804)	3.73
Unvested balance at June 30	<u>1,958,245</u>	<u>\$ 1.64</u>	<u>1,116,700</u>	<u>\$ 1.54</u>

At June 30, 2006, there was \$1.2 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 gains or losses on the Company's available-for-sale securities are included in other comprehensive income (loss). Comprehensive income (loss) and its components for the three and six months ended June 30, 2006 and 2005, are as follows (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2006</u>	<u>2005</u>	<u>2006</u>	<u>2005</u>
Net income (loss)	\$(5,915)	\$(8,582)	\$(26,518)	\$21,498
Unrealized gain (loss) on securities available-for-sale	5	—	(5)	(280)
Comprehensive income (loss)	<u>\$(5,910)</u>	<u>\$(8,582)</u>	<u>\$(26,523)</u>	<u>\$21,218</u>

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

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

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**XOMA Ltd.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

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

	June 30,	
	2006	2005
Options for common shares	6,081	5,610
Warrants for common shares	125	125
Convertible preference shares, notes, and related interest, as if converted	37,335	38,827

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
<b>Numerator</b>				
Net income (loss)	\$ (5,915)	\$ (8,582)	\$ (26,518)	\$ 21,498
Interest on convertible long-term debt	—	—	—	1,754
Net income (loss) used for diluted net income (loss) per share	<u>\$ (5,915)</u>	<u>\$ (8,582)</u>	<u>\$ (26,518)</u>	<u>\$ 23,252</u>
<b>Denominator</b>				
Weighted average shares outstanding used for basic net income (loss) per share	96,661	86,253	92,326	85,997
Effect of dilutive share options	—	—	—	52
Effect of convertible preference shares	—	—	—	3,818
Effect of convertible long-term debt	—	—	—	25,465
Weighted-average shares outstanding and dilutive securities used for diluted net income (loss) per share	<u>96,661</u>	<u>82,253</u>	<u>92,326</u>	<u>115,332</u>

**Receivables**

Receivables consist of the following (in thousands):

	June 30, 2006	December 31, 2005
Trade receivables	\$3,167	\$ 2,880
Collaborations	2,138	1,916
Other receivables	297	390
Total	<u>\$5,602</u>	<u>\$ 5,186</u>

**Accrued Liabilities**

Accrued liabilities consist of the following (in thousands):

	June 30, 2006	December 31, 2005
Accrued payroll costs	\$1,919	\$ 2,084
Accrued management incentive compensation	1,091	1,758
Accrued legal fees	1,064	813
Customer advances	1,000	750
Accrued collaborations	272	—
Other	267	312
Total	<u>\$5,613</u>	<u>\$ 5,717</u>

**XOMA Ltd.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**2. CONVERTIBLE DEBT**

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

In accounting for the New Notes, the Company applied guidance as set forth in EITF 96-19, SFAS 133, EITF 05-7, EITF 00-19, and EITF 01-6 as follows. The exchange offer is a modification of existing debt, rather than extinguishment. The additional interest payment upon conversion is an embedded derivative requiring separate accounting. The Company considered the provisions of EITF 05-2 and concluded that this is not conventional convertible debt.

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

Convertible debt consisted of the following (in thousands):

	<u>June 30, 2006</u>	<u>December 31, 2005</u>
Convertible debt	\$52,229	\$ 60,000
Embedded derivative	5,528	—
Premium	352	—
Total	<u>\$58,109</u>	<u>\$ 60,000</u>

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

For the three months ended June 30, 2006, \$2.9 million of New Notes were converted into 1,972,847 shares of common shares including 407,096 shares related to the additional interest payment feature of the notes. The Company recorded (\$4.1) million in interest expense/(benefit) during the quarter ended June 30, 2006, as a benefit arising from the decrease in the fair value of the embedded derivative on its convertible debt of which (\$4.3) million of benefit related to the recovery of interest expense from the increase in the fair value of the embedded derivative during the quarter ended March 31, 2006, partially offset by \$0.2 million in expense related to the converted notes.

For the six months ended June 30, 2006, \$15.5 million of New Notes were converted into 10,385,171 shares of common shares including 2,142,971 shares related to the additional interest payment feature of the notes. The Company recorded \$4.0 million in

**XOMA Ltd.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

interest expense during the six months ended June 30, 2006, as a result of an increase in the fair value of the embedded derivative on its convertible debt including \$2.7 million related to the converted notes.

For the three months ended June 30, 2006 and 2005, the Company incurred \$0.9 million and \$1.0 million, respectively, in interest expense payable on its convertible debt. For the six months ended June 30, 2006 and 2005, the Company incurred \$1.9 million and \$1.5 million, respectively, in interest expense payable on its convertible debt. Interest expense is payable on a semi-annual basis. Additionally, the Company amortized a net of \$0.3 million and \$0.5 million, respectively, in debt issuance costs, premium and discount for the three and six months ended June 30, 2006, and amortized \$0.1 million and \$0.2 million, respectively, in debt issuance costs for the three and six months ended June 30, 2005.

### **3. COLLABORATIVE AND OTHER ARRANGEMENTS**

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

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

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

### **4. LEGAL PROCEEDINGS**

In April of 2005, a complaint was filed in the Circuit Court of Cook County, Illinois, in a lawsuit captioned Hanna v. Genentech, Inc. and XOMA (US) LLC, No. 2005004386, by an alleged participant in one of the clinical trials of RAPTIVA®. The lawsuit was thereafter removed to the United States District Court, Northern District of Illinois, No. 05C 3251. The complaint asserted claims for alleged strict product liability and negligence against Genentech and the Company based on injuries alleged to have occurred as a result of plaintiff’s treatment in the clinical trials. The complaint sought unspecified compensatory damages alleged to be in excess of \$100,000. In April of 2006, the claimant filed a motion seeking voluntary dismissal of the lawsuit and, in May of 2006, the complaint was dismissed with prejudice.

In September of 2004, XOMA (US) LLC entered into a collaboration with Aphton for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In May of 2006, Aphton filed for bankruptcy protection under Chapter 11, Title 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, No. 06-10510 (CSS). XOMA (US) LLC intends to file a proof of claim in this proceeding, as a creditor of Aphton, for approximately \$594,000.

### **5. SUBSEQUENT EVENTS**

On July 28, 2006, the Company announced that it had placed its production process development work for Cubist Pharmaceuticals, Inc. (“Cubist”) on hold and issued a notice of contract termination because of Cubist’s decision to cease investment in its HepeX-B™ product as a result of stringent FDA requirements for regulatory approval. As a result of this termination, the company will recognize all Cubist deferred revenue and a termination fee in the quarter ending September 30, 2006.

On July 31, 2006, the Company announced that it had been awarded a \$16.3 million dollar contract (Contract No. HHSN266200600008C/N01-A1-60008) funded with Federal funds from the National Institute of Allergy and Infectious Diseases (“NIAID”), a part of the National Institutes of Health, Department of Health and Human Services, to produce botulinum neurotoxin monoclonal antibodies for the treatment of botulism to protect U.S. citizens against the harmful effects of botulinum neurotoxins used in bioterrorism.

## ITEM 2 – MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

### Results of Operations

#### *Revenues*

Total revenues for the three and six months ended June 30, 2006, were \$7.5 million and \$13.1 million, respectively, compared with \$5.2 million and \$8.2 million, respectively, for the same periods of 2005.

License and collaborative fee revenues were \$0.7 million and \$1.4 million, respectively, for the three and six months ended June 30, 2006, compared with \$2.7 million and \$3.2 million, respectively, for the same periods of 2005. These revenues include amortization of upfront payments, milestone revenues and licensing revenues related to the outlicensing of our products and technologies and other collaborative arrangements. The decreases of \$2.0 million and \$1.8 million, respectively, for the three and six months ended June 30, 2006, resulted primarily from an outlicensing agreement with Merck & Co. Inc. in the quarter ended June 30, 2005.

Contract revenues were \$4.7 million and \$7.8 million, respectively, for the three and six months ended June 30, 2006, compared with \$0.9 million and \$2.2 million, respectively, for the same periods of 2005. The increases of \$3.8 million and \$5.6 million, respectively, for the three and six months ended June 30, 2006, resulted primarily from an increase in contract manufacturing services performed under our contract with the National Institute of Allergy and Infectious Diseases (“NIAID”) entered into in March of 2005 to develop three anti-botulinum neurotoxin monoclonal antibody therapeutics offset by a reduction in clinical trial services performed on behalf of Genentech, Inc. (“Genentech”). The NIAID contract work is being performed over an eighteen month period and is 100% funded with federal funds from NIAID under Contract No. HHSN266200500004C. We are recognizing revenue over the life of the contract as the services are performed on a proportional performance basis and, as per the terms of the contract, a 10% retention on all revenue is being deferred and classified as a receivable until completion of the contract.

Royalties were \$2.1 million and \$4.0 million, respectively, for the three and six months ended June 30, 2006, compared with \$1.6 million and \$2.8 million, respectively, for the same periods of 2005. The increases of \$0.5 million and \$1.2 million, respectively, for the three and six months ended June 30, 2006, resulted primarily from RAPTIVA® royalties earned under our royalty arrangement with Genentech.

#### *Operating Costs and Expenses*

Research and development expenses consist of direct and research-related allocated overhead costs such as salaries and related personnel costs, patents, materials and supplies in addition to costs related to clinical trials to validate our testing processes and procedures and related overhead expenses. Research and development expenses include independent research and development and costs associated with collaborative research and development as well as contract research and development arrangements. Research and development expenses were \$12.1 million and \$24.3 million, respectively, for the three and six months ended June 30, 2006, compared with \$9.5 million and \$19.5 million, respectively, for the same periods of 2005, an increase of 27% and 24%, respectively. These increases primarily reflect increases in spending on our contract with NIAID, our development of XOMA 052 and NEUPREX®, and our collaborations with Lexicon Genetics Incorporated (“Lexicon”) and Schering Plough Research Institute (“SPRI”), partially offset by decreased spending on our collaboration agreements with Novartis AG (“Novartis” formerly Chiron Corporation), Genentech and Millennium Pharmaceuticals, Inc. In addition, for the three and six months ended June 30, 2006, we recorded \$0.1 million and \$0.3 million, respectively, of share-based compensation expense. No share based compensation expense was recorded in 2005.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Earlier stage programs	\$ 9,777	\$ 7,080	\$ 19,044	\$ 15,712
Later stage programs	2,327	2,467	5,241	3,837
Total	<u>\$ 12,104</u>	<u>\$ 9,547</u>	<u>\$ 24,285</u>	<u>\$ 19,549</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Internal projects	\$ 7,387	\$ 4,965	\$ 15,184	\$ 11,258
Collaborative arrangements	4,717	4,582	9,101	8,291
Total	<u>\$ 12,104</u>	<u>\$ 9,547</u>	<u>\$ 24,285</u>	<u>\$ 19,549</u>

For the three months ended June 30, 2006, three development programs (HCD122 (formerly CHIR12.12), NIAID and XOMA 052) accounted for more than 10% but less than 20% and no development program accounted for more than 20% of our total research and development expenses. For the six months ended June 30, 2006, two development programs (HCD122 and NEUPREX®) accounted for more than 10% but less than 20%, one development program (XOMA 052) accounted for more than 20% but less than 30%, one development program (NIAID) accounted for more than 30% but less than 40% and no development program accounted for more than 40% of our total research and development expenses. For the three months ended June 30, 2005, one development program (HCD122) accounted for more than 30% but less than 40% and no development program accounted for more than 40% of our total research and development expenses. For the six months ended June 30, 2005, one development program (HCD122) 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.

We currently anticipate that research and development expenses will continue to increase in 2006 as compared with 2005. We expect our spending on our oncology collaboration with Novartis, including HCD122, to continue as well as increases in spending on our collaborations with Lexicon and SPR1, our contract with NIAID, our development of XOMA 052 and NEUPREX® and other new projects. Future research and development spending may also be impacted by potential new licensing or collaboration arrangements, as well as the termination of existing agreements. Beyond this, the scope and magnitude of future research and development expenses are difficult to predict at this time.

General and administrative expenses include salaries and related personnel costs, facilities costs and professional fees. General and administrative expenses for the three and six months ended June 30, 2006, were \$4.4 million and \$9.4 million, respectively, compared with \$3.7 million and \$7.5 million, respectively, for the same periods of 2005. The increase of \$0.7 million for the three months ended June 30, 2006, compared with the three months ended June 30, 2005, resulted primarily from increased legal and consulting expenses. The increase of \$1.9 million for the six months ended June 30, 2006, compared with the six months ended June 30, 2005, resulted primarily from increased professional fees of which \$1.1 million related to our February debt exchange. In addition, for the three and six months ended June 30, 2006, we recorded \$0.1 million and \$0.4 million, respectively, of share-based compensation expense. No share-based compensation expense was recorded in 2005.

### *Other Income (Expense)*

Investment and interest income for the three and six months ended June 30, 2006, was \$0.4 million and \$0.8 million, respectively, compared with \$0.4 million and \$1.0 million, respectively, for the same periods of 2005. Investment and interest income consists primarily of interest earned on our cash and investment balances. The six month period ended June 30, 2005, includes a \$0.3 million one-time gain on the sale of short-term investments.

Interest expense/(benefit) for the three and six months ended June 30, 2006, was (\$2.7) million and \$6.7 million, respectively, compared with \$1.1 million and \$1.8 million, respectively, for the same periods of 2005. Interest expense/(benefit) for the three

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months ended June 30, 2006, consists of (\$4.1) million from the revaluation of the embedded derivative from our convertible debt, \$0.9 million of interest payable on our convertible debt, \$0.3 million in net amortization of debt issuance costs, discount and premium on our convertible debt and \$0.2 million of interest payable on our note with Novartis. Interest expense for the six months ended June 30, 2006, consists of \$4.0 million from the revaluation of the embedded derivative from our convertible debt, \$1.9 million of interest payable on our convertible debt, \$0.5 million in net amortization of debt issuance costs, discount and premium on our convertible debt and \$0.4 million of interest payable on our note with Novartis. Our 2005 interest expense consisted primarily of interest payable on our convertible notes.

Other income (expense) for the three months and six months ended June 30, 2006, was zero, compared with \$0.3 million and \$41.2 million, respectively for the three and six months ended June 30, 2005. The amount for the six months ended June 30, 2005, consists primarily of a one-time gain related to the extinguishment of the Genentech development loan as a result of the restructuring of the Genentech agreement, which occurred in January of 2005.

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

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

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

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

During the three and six months ended June 30, 2006, we recognized \$0.3 million and \$0.6 million, respectively, in share-based compensation expense. At June 30, 2006, there was \$1.2 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 June 30, 2006, was \$34.9 million compared with \$43.5 million at December 31, 2005. This \$8.6 million decrease reflects cash used in operations of \$18.5 million and cash used in the purchase of fixed assets of \$5.3 million partially offset by cash provided by financing activities \$15.1 million, primarily from the \$12.5 million in New Notes issued for cash in our convertible debt exchange.

Net cash used in operating activities was \$18.5 million for the six months ended June 30, 2006, compared with \$32.3 million for the same period in 2005.

Cash used in operations for the six months ended June 30, 2006, consisted of a net loss of \$26.5 million with non-cash addbacks for the revaluation of our embedded derivative of \$4.0 million, depreciation and amortization of \$2.9 million, equity related compensation of \$1.7 million and accrued interest of \$0.2 million partially offset by an increase in assets of \$0.6 million and a net

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decrease in liabilities of \$0.2 million. During the six months ended June 30, 2006, we made payments of \$2.6 million for debt issuance costs on our convertible debt, \$2.0 million for interest on our convertible debt and \$1.1 million for our Management Incentive Compensation Program ("MICP"), which is paid in March of each year.

Cash used in operations for the three months ended June 30, 2005, consisted of a net income of \$21.5 million with non-cash deductions of \$40.9 million for a gain on the extinguishment of our debt with Genentech and a \$0.3 million gain on a sale of investments along with an increase in assets of \$4.3 million and a net decrease in liabilities of \$13.6 million partially offset by non-cash addbacks for depreciation and amortization of \$2.4 million, equity related compensation of \$1.3 million and accrued interest of \$1.6 million. During the six months ended June 30, 2005, we made payments of \$4.0 million on our Genentech collaboration liability, \$2.9 million on our Novartis collaboration liability and \$1.3 million for our MICP.

Net cash used in investing activities for the six months ended June 30, 2006 and 2005, was \$5.6 million and \$1.0 million, respectively. The \$4.6 million increase in cash used in 2006 compared with 2005 reflected a \$0.9 million increase in purchases, net of sales, of investments and a \$3.8 million increase in purchases of property and equipment.

Net cash provided by financing activities for the six months ended June 30, 2006 and 2005, was \$15.1 million and \$65.2 million, respectively. Financing activities for the six months ended June 30, 2006, consisted of \$12.5 million in proceeds from the issuance of convertible notes, offset by \$0.5 million in debt issuance costs, a \$3.0 million advance on our line of credit with Novartis and \$0.1 million in proceeds from the issuance of common shares. Financing activities for the six months ended June 30, 2005, consisted of an issuance of \$60.0 million of convertible senior notes for net proceeds of \$56.6 million, an \$8.8 million drawdown on our Novartis loan facility and \$0.1 million in proceeds from the issuance of common shares partially offset with capital lease payments and payments of short-term loan obligations of \$0.1 million each.

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

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

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

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

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For the three months ended June 30, 2006, \$2.9 million of New Notes were converted into 1,972,847 shares of common shares including 407,096 shares related to the additional interest payment feature of the notes. We recorded (\$4.1) million in interest expense/(benefit) during the quarter ended June 30, 2006, as a benefit arising from the decrease in the fair value of the embedded derivative on our convertible debt of which (\$4.3) million of benefit related to the recovery of interest expense from the increase in the fair value of the embedded derivative during the quarter ended March 31, 2006, partially offset by \$0.2 million in expense related to the converted notes.

For the six months ended June 30, 2006, \$15.5 million of New Notes were converted into 10,385,171 shares of common shares including 2,142,971 shares related to the additional interest payment feature of the notes. We recorded \$4.0 million in interest expense during the six months ended June 30, 2006, as a result of an increase in the fair value of the embedded derivative on our convertible debt including \$2.7 million related to the converted notes.

For the three months ended June 30, 2006 and 2005, we incurred \$0.9 million and \$1.0 million, respectively, in interest expense payable on our convertible debt. For the six months ended June 30, 2006 and 2005, we incurred \$1.9 million and \$1.5 million, respectively, in interest expense payable on our convertible debt. Interest expense is payable on a semi-annual basis. Additionally, we amortized a net of \$0.3 million and \$0.5 million, respectively, in debt issuance costs, premium and discount for the three and six months ended June 30, 2006, and amortized \$0.1 million and \$0.2 million, respectively, in debt issuance costs for the three and six months ended June 30, 2005.

We expect our cash, cash equivalents and short-term investments to continue to decrease in 2006 with the use of cash to fund ongoing operations and capital investments, partially offset by proceeds from our Novartis loan facility.

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

### **Critical Accounting Policies**

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

#### *Contract Revenue*

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

#### *Share Based Compensation*

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

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### **Subsequent Events**

On July 28, 2006, we announced that we had placed our production process development work for Cubist Pharmaceuticals, Inc. ("Cubist") on hold and issued a notice of contract termination because of Cubist's decision to cease investment in its HepeX-B™ product as a result of stringent FDA requirements for regulatory approval. As a result of this termination, we will recognize all Cubist deferred revenue and a termination fee in the quarter ending September 30, 2006.

On July 31, 2006, we announced that we had been awarded a \$16.3 million dollar contract (Contract No. HHSN266200600008C/N01-AI-60008) funded with Federal funds from NIAID, a part of the National Institutes of Health, Department of Health and Human Services, to produce botulinum neurotoxin monoclonal antibodies for the treatment of botulism to protect U.S. citizens against the harmful effects of botulinum neurotoxins used in bioterrorism.

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

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

## **ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

### ***Interest Rate Risk***

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio and our loan facility. By policy, we make our investments in high quality debt securities, limit the amount of credit exposure to any one issuer, limit duration by restricting the term of the instrument and hold investments to maturity except under rare circumstances. We do not invest in derivative financial instruments.

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

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

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

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related weighted interest rates of our cash and investments at June 30, 2006 and December 31, 2005 (in thousands, except interest rate):

	<u>Maturity</u>	<u>Carrying Amount</u>	<u>Fair Value</u>	<u>Average Interest Rate</u>
June 30, 2006				
Cash and cash equivalents	Daily	\$11,798	\$ 11,798	3.88%
Short-term investments	Less than 1 year	23,124	23,054	4.40%
December 31, 2005				
Cash and cash equivalents	Daily	\$20,804	\$ 20,804	2.82%
Short-term investments	Less than 1 year	22,801	22,732	4.23%

## ITEM 4 – CONTROLS AND PROCEDURES

### *Evaluation of Controls and Procedures*

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

### *Changes in Internal Control*

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

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### **PART II – OTHER INFORMATION**

#### **ITEM 1. LEGAL PROCEEDINGS**

In April of 2005, a complaint was filed in the Circuit Court of Cook County, Illinois, in a lawsuit captioned *Hanna v. Genentech, Inc. and XOMA (US) LLC*, No. 2005004386, by an alleged participant in one of the clinical trials of RAPTIVA®. The lawsuit was thereafter removed to the United States District Court, Northern District of Illinois, No. 05C 3251. The complaint asserted claims for alleged strict product liability and negligence against Genentech and us based on injuries alleged to have occurred as a result of plaintiff's treatment in the clinical trials. The complaint sought unspecified compensatory damages alleged to be in excess of \$100,000. In April of 2006, the claimant filed a motion seeking voluntary dismissal of the lawsuit and, in May of 2006, the complaint was dismissed with prejudice.

In September of 2004, XOMA (US) LLC entered into a collaboration with Aphton for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In May of 2006, Aphton filed for bankruptcy protection under Chapter 11, Title 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, No. 06-10510 (CSS). XOMA (US) LLC intends to file a proof of claim in this proceeding, as a creditor of Aphton, for approximately \$594,000.

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

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

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

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

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

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

According to Genentech, United States sales of RAPTIVA® for the first half of 2006 were \$43.6 million, compared with \$37.9 million for the first half of 2005. According to Serono, sales of RAPTIVA® outside of the United States for the first half of 2006 were \$30.6 million, compared with \$11.8 million for the first half of 2005. Given our current reliance on RAPTIVA® as one of the principal sources of our revenue, any material adverse developments with respect to the commercialization of RAPTIVA® may cause our revenue to decrease and may cause us to incur losses in the future.

We expect future revenues to rely similarly on sales of approved products in which we have only a royalty interest. For example, on June 30, 2006, Genentech announced FDA approval of LUCENTIS™ (ranibizumab) for treatment of neovascular (wet)

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age-related macular degeneration, and we have a royalty interest in this product arising from Genentech's license to our bacterial cell expression ("BCE") technology. Because we will have no role in marketing or sales of these products, our future revenues will be subject to risks similar to those described above.

### **Because our products are still being developed, we will require substantial funds to continue; we cannot be certain that funds will be available and, if they are not available, we may have to take actions which could adversely affect your investment.**

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

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

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

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

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

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

As of June 30, 2006, we (including our subsidiaries) had approximately \$73.9 million, including our embedded derivative, of indebtedness outstanding. We may not be able to generate cash sufficient to pay the principal of, interest on and other amounts due in respect of our indebtedness when due. We and our subsidiaries may also incur additional debt that may be secured. In connection with our collaboration with Novartis, Novartis has extended a line of credit to us (through our United States subsidiary) for \$50.0 million to fund up to 75% of our expenses thereunder, of which \$15.8 million was drawn as of June 30, 2006. This line of credit is secured by a pledge of our interest in the collaboration.

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

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

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- reducing the availability of our cash flow to fund our working capital requirements, capital expenditures, acquisitions, investments and other general corporate requirements because we will be required to use a substantial portion of our cash flow to service debt obligations; and
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

Our ability to satisfy our debt obligations will depend upon our future operating performance and the availability of refinancing debt. If we are unable to service our debt and fund our business, we may be forced to reduce or delay capital expenditures, seek additional debt financing or equity capital, restructure or refinance our debt or sell assets. We cannot assure you that we would be able to obtain additional financing, refinance existing debt or sell assets on satisfactory terms or at all.

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

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

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

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

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

Our potential products will require significant additional research and development, extensive preclinical studies and clinical trials and regulatory approval prior to any commercial sales. This process is lengthy and expensive, often taking a number of years. As clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals, the length 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

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- we will ultimately achieve regulatory approval for any of these products.

For example,

- In 1996, in conjunction with Genentech, we began testing RAPTIVA® in patients with moderate-to-severe plaque psoriasis. In April of 2002, we announced with Genentech that a pharmacokinetic study conducted on RAPTIVA® comparing XOMA-produced material and Genentech-produced material did not achieve the pre-defined statistical definition of comparability, and the FDA requested that another Phase III study be completed before the filing of a Biologics License Application for RAPTIVA®, delaying the filing beyond the previously-planned time frame of the summer of 2002. In March of 2003, we announced completion of enrollment in a Phase II study of RAPTIVA® in patients suffering from rheumatoid arthritis. In May of 2003, Genentech and we announced our decision to terminate Phase II testing of RAPTIVA® in patients suffering from rheumatoid arthritis based on an evaluation by an independent Data Safety Monitoring Board that suggested no overall net clinical benefit in patients receiving the study drug. We also completed enrollment in a Phase II study of RAPTIVA® as a possible treatment for patients with psoriatic arthritis. In March of 2004, we announced that the study did not reach statistical significance.
- In December of 1992, we began human testing of our NEUPREX® product, a genetically engineered fragment of a particular human protein, and licensed certain worldwide rights to Baxter in January of 2000. In April of 2000, members of the FDA and representatives of XOMA and Baxter discussed results from the Phase III trial that tested NEUPREX® in pediatric patients with a potentially deadly bacterial infection called meningococemia, and senior representatives of the FDA indicated that the data presented were not sufficient to support the filing of an application for marketing approval at that time.
- In 2003, we completed two Phase I trials of XMP.629, a BPI-derived topical peptide compound targeting acne, evaluating the safety, skin irritation and pharmacokinetics. In January of 2004, we announced the initiation of Phase II clinical testing in patients with mild-to-moderate acne. In August of 2004, we announced the results of a Phase II trial with XMP.629 gel. The results were inconclusive in terms of clinical benefit of XMP.629 compared with vehicle gel.

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

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

We have experienced significant losses and, as of June 30, 2006, we had an accumulated deficit of \$702.2 million.

For the six months ended June 30, 2006, we had a net loss of approximately \$26.5 million or \$0.29 per common share (basic and diluted). For the year ended December 31, 2005, as a result of the restructuring of our Genentech arrangement and subsequent extinguishment of our obligation to pay \$40.9 million under a development loan and related one-time credit to other income, we had net income of approximately \$2.8 million or \$0.03 per common share (basic and diluted).

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

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

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

- In April of 1996, we entered into an agreement with Genentech whereby we agreed to co-develop Genentech's humanized monoclonal antibody product RAPTIVA®. In April of 1999, March of 2003, and January of 2005, the companies amended the agreement. In October of 2003, RAPTIVA® was approved by the FDA for the treatment of adults with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and, in September of 2004, Serono announced the product's approval in the European Union. In January of 2005, we entered into a restructuring of our

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collaboration agreement with Genentech which ended our existing cost and profit sharing arrangement related to RAPTIVA® in the United States and entitles us to a royalty interest on worldwide net sales.

- In November of 2001, we entered into a collaboration with Millennium to develop two of Millennium's products for certain vascular inflammation indications. In October of 2003, we announced that we had discontinued one of these products, MLN2201. In December of 2003, we announced the initiation of Phase I testing on the other product, MLN2222. As of May 2006, we completed the transfer of the data from the Phase I study to Millennium as per our amended agreement.
- In March of 2004, we announced we had agreed to collaborate with Chiron Corporation (now Novartis) for the development and commercialization of antibody products for the treatment of cancer. Under the terms of the agreement, the companies will jointly research, develop, and commercialize multiple antibody product candidates. In April of 2005, we announced the initiation of clinical testing of the first product candidate out of the collaboration, HCD122, an anti-CD40 antibody, in patients with advanced CLL. In October of 2005, we announced the initiation of the second clinical trial of HCD122 in patients with multiple myeloma.
- In October of 2004, we announced the licensing of our ING-1 product to Triton for use with their TNT™ System.
- In March of 2005, we entered into a contract with the NIAID, a part of the National Institutes of Health, to produce three botulinum neurotoxin monoclonal antibodies designed to protect United States citizens against the harmful effects of biological agents used in bioterrorism. In July of 2006, we entered into an additional contract with NIAID for the development of an appropriate formulation for human administration of these three antibodies in a single injection.
- In June of 2005, we announced the formation of a collaboration to jointly develop and commercialize antibody drugs for certain targets discovered by Lexicon.
- We have licensed our BCE technology, an enabling technology used to discover and screen, as well as develop and manufacture, recombinant antibodies and other proteins for commercial purposes, to approximately 45 companies. As of June 30, 2006, we were aware of one antibody product manufactured using this technology that has received FDA approval, Genentech's LUCENTIS™ (ranibizumab) for treatment of neovascular (wet) age-related macular degeneration, and one antibody manufactured using this technology that is in late-stage clinical testing, UCB's CIMZIA™ (CDP870) anti-TNF alpha antibody fragment for rheumatoid arthritis and Crohn's disease.

Because our collaborators and licensees are independent third parties, they may be subject to different risks than we are and have significant discretion in determining the efforts and resources they will apply. If these collaborators and licensees do not successfully develop and market these products, we may not have the capabilities, resources or rights to do so on our own. We do not know whether our collaborators or licensees will successfully develop and market any of the products that are or may become the subject of one of our collaboration or licensing arrangements. In particular, each of these arrangements provides for either sharing of collaboration expenses, which means that not only we but our collaborators must have sufficient available funds for the collaborations to continue, or funding solely by our collaborators or licensees. In addition, our collaboration with Novartis provides for funding by it in the form of a line of credit to us, and we cannot be certain that Novartis will provide the necessary funds available when we attempt to draw on the line of credit. Furthermore, our contracts with NIAID contain numerous standard terms and conditions provided for in the applicable federal acquisition regulations and customary in many government contracts. Uncertainty exists as to whether we will be able to comply with these terms and conditions in a timely manner, if at all. In addition, given that this is our first program under contract with NIAID or any other governmental agency, we are uncertain as to the extent of NIAID's demands and the flexibility that will be granted to us in meeting those demands. Lastly, CIMZIA™ (CDP870) has not received marketing approval from the FDA or any foreign governmental agency, and therefore we cannot assure you that it will prove to be safe and effective, will be approved for marketing or will be successfully commercialized.

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

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

- In December of 2003, we agreed to collaborate with Alexion for the development and commercialization of an antibody to treat chemotherapy-induced thrombocytopenia. The TPO mimetic antibody was designed to mimic the activity of human thrombopoietin, a naturally occurring protein responsible for platelet production. In November of 2004, in conjunction with Alexion, we determined that the lead molecule in our TPO mimetic collaboration did not meet the criteria established in the

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program for continued development. In the first quarter of 2005, the companies determined not to continue with this development program and in the second quarter of 2005, the collaboration was terminated.

- In November of 2004, we announced the licensing of our BPI product platform, including our NEUPREX® product, to Zephyr. In July of 2005, we announced our decision to terminate the license agreement with Zephyr due to Zephyr not meeting the financing requirements of the license agreement.
- In September of 2004, we entered into a collaboration with Apton for the treatment of gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies. In January of 2006, Apton announced that its common stock had been delisted from Nasdaq. In May of 2006, Apton filed for bankruptcy protection under Chapter 11, Title 11 of the U.S. Bankruptcy Code.
- In September of 2005, we signed a letter agreement with Cubist to develop production processes and to manufacture a novel two-antibody biologic in quantities sufficient to conduct Phase III clinical trials. In July of 2006, Cubist announced that it had decided to cease investment in this product because of stringent FDA requirements for regulatory approval, and as a result we have terminated our letter agreement with Cubist.

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

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

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

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

There can be no assurance that the market price of our common shares will not decline below its present market price or that there will be an active trading market for our common shares. The market prices of biotechnology companies have been and are likely to continue to be highly volatile. Fluctuations in our operating results and general market conditions for biotechnology stocks could have a significant impact on the volatility of our common share price. We have experienced significant volatility in the price of our common shares. From January 1, 2005 through August 3, 2006, our share price has ranged from a high of \$2.74 to a low of \$0.98. On August 3, 2006, the closing price of the common shares as reported on the Nasdaq National Market was \$1.80 per share. Factors contributing to such volatility include, but are not limited to:

- sales and estimated or forecasted sales of products,
- results of preclinical studies and clinical trials,
- information relating to the safety or efficacy of products,
- developments regarding regulatory filings,
- announcements of new collaborations,
- failure to enter into collaborations,
- developments in existing collaborations,

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- our funding requirements and the terms of our financing arrangements,
- technological innovations or new indications for our therapeutic products,
- introduction of new products or technologies by us or our competitors,
- government regulations,
- developments in patent or other proprietary rights,
- the number of shares issued and outstanding,
- the number of shares trading on an average trading day,
- announcements regarding other participants in the biotechnology and pharmaceutical industries and
- market speculation regarding any of the foregoing.

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

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

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

Although RAPTIVA® was approved in the United States in October of 2003 and in the European Union in 2004, its acceptance in the marketplace may not continue. In addition, although LUCENTIS™ was approved in the United States in July of 2006, 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® or LUCENTIS™, if they believe other products to be more effective or are more comfortable prescribing other products. Safety concerns may also arise in the course of on-going clinical trials or patient treatment as a result of adverse events or reactions.

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

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

Developments by others may render our products or technologies obsolete or uncompetitive. Technologies developed and utilized by the biotechnology and pharmaceutical industries are continuously and substantially changing. Competition in the areas of genetically engineered DNA-based and antibody-based technologies is intense and expected to increase in the future as a number of established biotechnology firms and large chemical and pharmaceutical companies advance in these fields. Many of these competitors

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may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

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

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

Without limiting the foregoing, we are aware that:

- in April of 2004, Amgen Inc. and its partner Wyeth Pharmaceuticals, a division of Wyeth, announced that their rheumatoid arthritis and psoriatic arthritis drug, Enbrel<sup>®</sup>, had been approved by the FDA for the same psoriasis indication as RAPTIVA<sup>®</sup> and, in September of 2004, they announced that the product received approval in the European Union in this same indication;
- Abbott Laboratories has presented data from a Phase II psoriasis trial showing clinical benefits of its rheumatoid arthritis and psoriatic arthritis drug Humira<sup>™</sup> for the treatment of psoriasis;
- Biogen Idec Inc. ("Biogen") sold its worldwide rights to Amevive<sup>®</sup>, which has been approved in the United States and Canada to treat the same psoriasis indication as RAPTIVA<sup>®</sup>, to Astellas Pharma US, Inc. in March of 2006;
- Centocor, Inc., a unit of Johnson & Johnson, has tested its rheumatoid arthritis and Crohn's disease drug, Remicad<sup>®</sup>, in phase III clinical trials of patients with moderate to severe plaque psoriasis and has announced the FDA has accepted its license application for the drug in this indication and that the drug has 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 and Fumapharm AG have taken their psoriasis-treating pill, BG-12, through a Phase III trial in Germany in which, according to the companies, the product significantly reduced psoriasis symptoms in patients, and Biogen announced in May of 2006 that it is acquiring Fumapharm;
- Isotechnika, Inc. has completed a Canadian Phase III trial of ISA247, a trans-isomer of a cyclosporine analog, in 450 patients with moderate to severe psoriasis, achieving all efficacy endpoints; and
- other companies are developing monoclonal antibody or other products for treatment of inflammatory skin disorders.

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

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

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

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

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

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

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

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

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

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

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

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

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- whether competitors will be able to design around our patents or develop and obtain patent protection for technologies, designs or methods that are more effective than those covered by our patents and patent applications or
- the extent to which our products could infringe on the intellectual property rights of others, which may lead to costly litigation, result in the payment of substantial damages or royalties, and/or prevent us from using technology that is essential to our products.

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

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

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

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

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

### **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.

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

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

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

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

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

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

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

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

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

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

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We had approximately 232 employees as of June 30, 2006, and we anticipate that we will require additional experienced executive, accounting, research and development, legal, administrative and other personnel in the future. There is intense competition for the services of these personnel, especially in California. Moreover, we expect that the high cost of living in the San Francisco Bay Area, where our headquarters and manufacturing facilities are located, may impair our ability to attract and retain employees in the future. If we do not succeed in attracting new personnel and retaining and motivating existing personnel, our operations may suffer and we may be unable to implement our current initiatives or grow effectively.

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

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

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

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

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

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

- “blacklisting” of our common shares by certain pension funds;
- legislation restricting certain types of transactions; and
- punitive tax legislation.

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.

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

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

Our bye-laws:

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

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

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

We are authorized to issue, without shareholder approval, 1,000,000 preference shares, of which 2,959 were issued and outstanding as of June 30, 2006, which may give other shareholders dividend, conversion, voting, and liquidation rights, among other rights, which may be superior to the rights of holders of our common shares. In addition, we are authorized to issue, without shareholder approval, up to 210,000,000 common shares, of which 97,409,289 were issued and outstanding as of June 30, 2006. If we issue additional equity securities, the price of our common shares and, in turn, the price of our convertible notes may be materially and adversely affected. In addition, as of June 30, 2006, there were \$56.6 million aggregate principal amount of New Notes outstanding, which were convertible into an aggregate of 30,168,045 common shares, with an aggregate of 3,349,225 additional shares issuable in lieu of the additional interest that would be due on such conversion.

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

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

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

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

If our shares were to trade on the over-the-counter market, selling our common shares could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and security analysts' coverage of us may be reduced. In addition, in the event our common shares are delisted, broker-dealers have certain regulatory burdens imposed upon them,

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which may discourage broker-dealers from effecting transactions in our common shares, further limiting the liquidity thereof. These factors could result in lower prices and larger spreads in the bid and ask prices for common shares.

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

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

None.

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

None.

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

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

<u>Name</u>	<u>Votes For</u>	<u>Votes Withheld</u>
James G. Andress	73,987,128	9,842,398
William K. Bowes, Jr.	73,729,012	10,100,514
John L. Castello	73,809,950	10,019,576
Peter Barton Hutt	73,964,094	9,865,432
Arthur Kornberg, M.D.	73,993,388	9,836,138
Patrick J. Scannon, M.D., Ph.D.	74,035,252	9,794,274
W. Denman Van Ness	74,034,763	9,794,763
Patrick J. Zenner	70,031,941	13,797,585

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

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

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

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

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

None.

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**ITEM 6. EXHIBITS**

(a) Exhibits

<u>Exhibit Number</u>	
10.58	Fifth amendment to lease of premises at 2910 Seventh Street, Berkeley, California dated June 1, 2006
10.59	Collaboration Agreement, dated as of May 22, 2006, by and between Schering Corporation, acting through its Schering-Plough Research Institute division, and XOMA (US) LLC (with certain confidential information omitted, which omitted information is the subject of a confidential treatment request and has been filed separately with the Securities and Exchange Commission)
10.60	Agreement dated July 28, 2006, between XOMA (US) LLC and the National Institute of Allergy and Infectious Diseases
31.1	Certification of John L. Castello, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of J. David Boyle II, filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of John L. Castello, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of J. David Boyle II, furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1	Press Release dated August 9, 2006, furnished herewith

**XOMA Ltd.**

**SIGNATURES**

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

XOMA Ltd.

Date: August 9, 2006

By: /s/ JOHN L. CASTELLO

John L. Castello  
Chairman of the Board, President and  
Chief Executive Officer

Date: August 9, 2006

By: /s/ J. DAVID BOYLE II

J. David Boyle II  
Vice President, Finance and  
Chief Financial Officer

**FIFTH AMENDMENT TO OFFICE LEASE**

THIS FIFTH AMENDMENT TO OFFICE LEASE (the "Fifth Amendment") is dated as of June 1, 2006 (the "Effective Date") and is entered into by and between 7th Street Property General Partnership ("Landlord") and XOMA Ltd. and XOMA (US) LLC, a Delaware limited liability company (collectively, "Tenant"), with reference to the following facts:

A. Landlord and Tenant entered into that certain Lease dated as March 25, 1992 with respect to the Premises described therein comprised of 21,425 rentable square feet located on the first floor ("First Floor") of the Building known as 2910 Seventh Street, Berkeley, Ca.

B. The lease as amended by (i) that certain Amendment to Office Lease dated as of December 31, 1997, (ii) that certain Second Amendment to Office Lease dated April 10, 2000, (iii) that certain Amendment to Office Lease Agreement dated April 16, 2001, and (iv) that certain letter amendment dated March 15, 2005 is hereinafter referred to as the "Lease".

C. The term of the Lease is fixed to expire as of September 30, 2007.

D. Landlord and Tenant desire to amend the Lease to provide, among other provisions, for the incorporation of 22,334 rentable square feet located on the second floor of the Building into the Premises (the "Second Floor Premises"), for the extension of the Term, for the modification of the Base Rent and for the modification of certain other terms in the Lease, all as more particularly set forth below.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and other good and valuable consideration, the receipt whereof and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Scope of Fifth Amendment and Defined Terms. Except as expressly provided in this Fifth Amendment, the Lease shall remain in full force and effect. Except as expressly provided in this Fifth Amendment, the term "Lease" shall mean the Lease as modified by this Fifth Amendment. Capitalized terms used in this Fifth Amendment and not otherwise defined herein shall have the respective meanings set forth in the Lease.

2. Modifications to Lease. Notwithstanding anything in the Lease to the contrary, the Lease is hereby modified as follows:

(a) Second Floor Premises. The Second Floor Premises as more particularly described on Exhibit A which is attached hereto, are hereby incorporated into the Premises. All of the terms and conditions of the Lease shall be applicable to the Second Floor Premises, except as specifically set forth in this Fifth Amendment. Landlord and Tenant have agreed upon the rentable square feet of the Second Floor Premises and of the Building for all purposes of this Lease.

(b) Second Floor Premises Commencement Date. The Second Floor Premises Commencement Date shall be the Effective Date.

(c) Extension of Term. The Termination Date shall be May 31, 2014 .

(d) Premises Rentable Area: From and after the Effective Date, the rentable square feet of the Premises shall be 43,759.

(e) First Floor Base Rent. From and after the Effective Date, Base Rent for the First Floor shall be paid as follows:

<u>Months</u>	<u>Monthly Base Rent</u>
1-24	\$ 61,489.75
25-36	\$ 63,334.45
37-48	\$ 65,234.48
49-60	\$ 67,191.51
61-72	\$ 69,207.25
73-84	\$ 71,283.47
85-96	\$ 73,421.98

(f) First Floor Operating Expense Credit and Utility Credit

(i) Operating Expenses Credit: \$113,380.00 per year based on a 1992 Base Year.

(ii) Utility Credit: \$0.13 per rentable square foot per month

(g) Second Floor Base Rent. From and after the Effective Date, Base Rent for the Second Floor shall be paid as follows:

<u>Months</u>	<u>Monthly Base Rent</u>
1-24	\$ 27,917.50
25-36	\$ 28,755.03
37-48	\$ 29,617.68
49-60	\$ 30,506.21
61-72	\$ 31,421.39
73-84	\$ 32,364.03
85-96	\$ 33,334.95

(h) Second Floor Operating Expense Credit \$0.035 per rentable square foot per month.

(g) Allowance: Condition of Premises.

(i) Landlord will provide a tenant improvement allowance in the amount of \$150,000 ("Allowance") with respect to the Second Floor Premises. All repairs and alterations to the Premises, including the Second Floor Premises shall be performed in accordance with Article 7 of the Lease ("Tenant Improvements"). Tenant shall submit plans and specifications ("Plans and Specifications") for the Tenant Improvements for Landlord's review and approval, which approval shall not be unreasonably withheld. Landlord shall have the right to approve Tenant's contractor and subcontractors (collectively, "Contractors"), which approval shall not be unreasonably withheld. Landlord shall have five (5) business days to approve the Plans and Specifications and Contractors and the failure to issue a disapproval within this time period shall be deemed an approval of the submitted items.

(ii) Tenant will accept the Premises, including the Second Floor Premises as of the Second Floor Commencement Date in its "as-is" condition, with no additional obligation on the part of Landlord to repair, remodel or refurbish the Premises, including the Second Floor Premises.

(iii) The Allowance shall be disbursed by Landlord after the completion of all tenant improvements within thirty (30) days after delivery by Tenant to Landlord of (i) invoices marked paid and other evidence as Landlord shall reasonably require of the cost of the design of the tenant improvements and the cost of the tenant improvements; (ii) evidence reasonably satisfactory to Landlord that all of the Tenant Improvements constructed to date have been satisfactorily completed in accordance with the plans and specifications approved by Landlord, upon certifications reasonably satisfactory to Landlord delivered by Tenant and Tenant's architect; (iii) unconditional final lien releases from the general contractor and each subcontractor; (iv) a cost breakdown of Tenant's final and total construction costs incurred in connection with the Tenant Improvements, together with receipted invoices showing evidence of full payment therefor; (v) copies of permits required in connection with the Tenant Improvements and all governmental approvals, sign offs and certificates of occupancy with respect to the Tenant Improvements, and (vi) the Lease shall be in full force and effect and there shall exist no event of default under the Lease.

(h) Option to Extend Term. The following section is incorporated into the Lease:

(i) Tenant is hereby granted an option to extend the term of the Lease (the "Option Term") from the Termination Date to May 31, 2019 (the "Extended Termination Date") by giving written notice to Landlord of Tenant's intent to exercise such option (the "Option Notice") no later than May 31, 2013. The Option Term shall be on the same terms and conditions in effect immediately before the commencement of the Option Term, except that the rent shall be set at 95% of the Fair Market Lease Rate (as hereinafter defined) for comparable space in the Berkeley area; provided that in no event shall the rental rate for the Option Term be less than the rental rate as of the last day immediately before the commencement of the Option Term. Notwithstanding anything to the contrary above, if Tenant is in default in the payment of rent, in the making of other payments required to be made by Tenant under this Lease, or otherwise under this Lease on the date the Option Notice is delivered to Landlord or on the date the Option Term is to commence, the Option Term shall not commence and this Lease shall expire as of the Termination Date.

(ii) Fair Market Lease Rate. Landlord shall give Tenant notice ("Landlord's Notice") of the fair market lease rate (including fair market increases during the Option Term) after receiving Tenant's written notice of intent to exercise the Option, provided that Landlord's Notice shall not be delivered later than 120 days prior to the commencement of the Option Term. If Tenant believes that the fair market lease rate as established by Landlord is incorrect, Tenant shall notify Landlord in writing within 20 days of Tenant's receipt of the notice from Landlord that Tenant desires to submit the matter to appraisal with a designation of a commercial real estate broker with at least three years experience in the office leasing market in Berkeley and Emeryville. If Landlord agrees with the identity of such appraiser, it shall within 10 days notify the appraiser and Tenant that such appraiser shall determine the fair market lease rate (including fair market increases during the Option Term). If not, Landlord shall submit the name of its appraiser with the same qualifications set forth above to Tenant within said 10 days. The two appraisers so selected shall choose a third appraiser with the same qualifications set forth above and the three together shall determine the fair market lease rate (including fair market increases during the Option Term). If the two appraisers cannot select a third appraiser within 20 days after Landlord submits the name of its appraiser, either party may at any time apply to the presiding judge of any court of competent jurisdiction for the appointment of the third appraiser. If the three appraisers are unable to agree on the fair market lease rate they shall each determine the fair market lease rate assuming annual CPI increases during the Option Term and then average their determinations by tossing out the high and low appraisal and accepting the middle appraisal as the fair market lease rate. The costs of the appraisal process shall be borne by Tenant unless the fair market lease rate as determined by the appraisal is more than 10% below the lease rate set forth in Landlord's Notice in which case Landlord and Tenant shall share the reasonable costs of the appraisal process equally. The appraisal process shall be completed as quickly as reasonably possible. If for any reason the Option Term commences prior to the conclusion of the appraisal process, Tenant shall continue to pay the monthly base rent then in effect to Landlord plus 5% of such amount, pending completion of the appraisal process, at which time all surplus funds, if any, shall be distributed to Tenant in accordance with the outcome of the appraisal process, and Tenant shall subsequently be bound by the lease rate as determined by the appraisal process. The rent during the Option Term shall continue to be adjusted as agreed upon between Landlord and Tenant or as determined by the appraisal process.

(iii) Payment of Commission. In connection with the Option, Tenant shall not use the services of a broker or other real estate licensee, except solely for determining fair market rent as more particularly specified above. In the event of a claim for broker's fee, finder's fee, commission or other similar compensation in connection with the exercise of such option based on a relationship with or through Tenant, Tenant hereby agrees to protect, defend and indemnify Landlord against and hold Landlord harmless from any and all damages, liabilities, costs, expenses and losses (including, without limitation, reasonable attorneys' fees and costs) which Landlord may sustain or incur by reason of such claim. Landlord hereby agrees to protect, defend and indemnify Tenant against and hold Tenant harmless from any and all damages, liabilities, costs, expenses and losses (including, without limitation, reasonable attorneys' fees and costs) which Tenant may sustain or incur by reason of a claim for broker's fee, finder's fee, commission or other similar compensation in connection with the exercise of the Option based on a relationship with or through Landlord.

3. Payment of Commission. In connection with this Fifth Amendment, Tenant acknowledges that it has not used the services of a broker or other real estate licensee. In the event of a claim for broker's fee, finder's fee, commission or other similar compensation in connection herewith based on a relationship with or through Tenant, Tenant hereby agrees to protect, defend and indemnify Landlord against and hold Landlord harmless from any and all damages, liabilities, costs, expenses and losses (including, without limitation, reasonable attorneys' fees and costs) which Landlord may sustain or incur by reason of such claim. Landlord hereby agrees to protect, defend and indemnify Tenant against and hold Tenant harmless from any and all damages, liabilities, costs, expenses and losses (including, without limitation, reasonable attorneys' fees and costs) which Tenant may sustain or incur by reason of a claim for broker's fee, finder's fee, commission or other similar compensation in connection herewith based on a relationship with or through Landlord.

4. Waiver. No failure or delay by a party to insist upon the strict performance of any term, condition or covenant of this Fifth Amendment, or to exercise any right, power or remedy hereunder shall constitute a waiver of the same or any other term of this Fifth Amendment or preclude such party from enforcing or exercising the same or any such other term, conditions, covenant, right, power or remedy at any later time.

5. Representations and Acknowledgments. Tenant hereby acknowledges that Landlord has performed all of its obligations with respect to the Premises. Tenant further acknowledges that as of the date hereof, to its best knowledge, Landlord is not in default under any of the terms of the Lease. Landlord hereby acknowledges that Tenant has performed all of its obligations with respect to the Premises. Landlord further acknowledges that as of the date hereof, to its best knowledge, Tenant is not in default under any of the terms of the Lease. Notwithstanding the foregoing, Landlord has not provided the reconciliation for Operating Expenses for calendar year 2005 and each party reserves its rights with respect to such reconciliation.

6. California Law. This Fifth Amendment shall be construed and governed by the laws of the State of California.

7. Authority. This Fifth Amendment shall be binding upon and inure to the benefit of the parties, their respective heirs, legal representatives, successors and assigns. Each party hereto and the persons signing below warrant that the person signing below on such party's behalf is authorized to do so and to bind such party to the terms of this Fifth Amendment.

8. Attorneys' Fees and Costs. In the event of any action at law or in equity between the parties to enforce any of the provisions hereof, any unsuccessful party to such litigation shall pay to the successful party all costs and expenses, including reasonable attorneys' fees (including costs and expenses incurred in connection with all appeals) incurred by the successful party, and these costs, expenses and attorneys' fees may be included in and as part of the judgment. A successful party shall be any party who is entitled to recover its costs of suit, whether or not the suit proceeds to final judgment.

9. Entire Agreement; No Amendment. This Fifth Amendment constitutes the entire agreement and understanding between the parties with respect to the subject of this amendment

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and shall supersede all prior written and oral agreements concerning this subject matter. This Fifth Amendment may not be amended, modified or otherwise changed in any respect whatsoever except by a writing duly executed by authorized representatives of Landlord and Tenant. Each party acknowledges that it has read this Fifth Amendment, fully understands all of this Fifth Amendment's terms and conditions, and executes this Fifth Amendment freely, voluntarily and with full knowledge of its significance. This Fifth Amendment is entered into by the parties with and upon advice of counsel.

10. Severability. If any provision of this Fifth Amendment or the application thereof to any person or circumstances shall be invalid or unenforceable to any extent, the remainder of this Fifth Amendment and the application of such provision to other persons or circumstances, other than those to which it is held invalid, shall not be affected and shall be enforced to the furthest extent permitted by law.

11. Counterparts. This Fifth Amendment may be executed in counterparts, and such counterparts together shall constitute but one original of the Fifth Amendment. Each counterpart shall be equally admissible in evidence, and each original shall fully bind each party who has executed it.

12. Agreement to Perform Necessary Acts. Each party agrees that upon demand, it shall promptly perform all further acts and execute, acknowledge, and deliver all further instructions, instruments and documents which may be reasonably necessary or useful to carry out the provisions of this Fifth Amendment.

13. Captions and Headings. The titles or headings of the various paragraphs hereof are intended solely for convenience of reference and are not intended and shall not be deemed to modify, explain or place any construction upon any of the provisions of this Fifth Amendment.

[Signatures on separate page]



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EXHIBIT A  
SECOND FLOOR PREMISES  
PLAN OF THE PREMISES INSERTED HERE.

[\*] indicates that a confidential portion of the text of this agreement has been omitted. The non-public information has been filed separately with the Securities and Exchange Commission.

**EXHIBIT 10.59**

## **COLLABORATION AGREEMENT**

This Collaboration Agreement (this "Agreement") is dated as of May 22, 2006 (the "Effective Date") and is made by and between Schering Corporation, acting through its Schering-Plough Research Institute division, a New Jersey corporation having offices at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033 (hereinafter "SPRI"); and XOMA (US) LLC, a Delaware limited liability company having offices at 2910 Seventh Street, Berkeley, California 94710 (hereinafter "XOMA"). SPRI and XOMA are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

### **RECITALS**

WHEREAS, SPRI and XOMA are each in the business of, among other things, discovering and developing products for the prevention or treatment of human diseases and conditions;

WHEREAS, SPRI (a) has technology for and expertise in the identification and validation of targets for use in the discovery of such products, and has identified and validated, and continues to identify and validate, target antigens for use in the discovery of antibodies potentially useful for such purposes, and (b) has personnel with expertise in the development of such products;

WHEREAS, XOMA has technology for and expertise in the discovery, optimization, development and manufacturing of antibodies potentially useful for such purposes;

WHEREAS, SPRI and XOMA are interested in collaborating (a) in the discovery of antibodies to target antigens identified and validated by SPRI and (b) in the development of such antibodies for use in the prevention or treatment of human diseases and conditions; and

WHEREAS, it is anticipated that XOMA will have primary responsibility for research and development activities relating to the target antigens that are the subject of the Parties' collaboration from antibody discovery through Investigational New Drug application filing(s);

NOW, THEREFORE, in consideration of the premises and of the covenants herein contained, the Parties hereto mutually agree as follows:

### **ARTICLE 1**

#### **DEFINITIONS**

For purposes of this Agreement, the terms defined in this Article 1 shall have the respective meanings specified below:

1.1 "Adverse Drug Reaction" means any untoward medical occurrence in a patient or subject who is administered a Collaboration Product, whether or not considered related to the Collaboration

Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Collaboration Product.

1.2 “Affiliate” means any corporation, company, partnership, joint venture and/or firm that controls, is controlled by or is under common control with a Party to this Agreement. For purposes hereof, “control” means (a) in the case of a corporate entity, direct or indirect ownership of more than fifty percent (50%) of the stock or shares entitled to vote for the election of directors; (b) in the case of a non-corporate entity, direct or indirect ownership of more than fifty percent (50%) of the equity interests with the power to direct the management and policies of such non-corporate entity; or (c) possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.3 “Annual Maintenance Fee” has the meaning specified in Section 7.2 hereof.

1.4 “Antibody” means any immunoglobulin molecule whether in monospecific or any other form and shall include, without limitation, immunoglobulin fragments, such as Fv, Fab, F(ab’) and single-chain antibodies.

1.5 “Antibody Product” means any composition of matter or article of manufacture consisting essentially of an Antibody (a) alone or (b) integrally associated with a composition of matter or article of manufacture (including without limitation conjugates bound to a toxin, label or other moiety) providing therapeutic, half-life, safety or other advantages to the Antibody.

1.6 “Antibody Related Claims” has the meaning specified in Section 9.2.1 hereof.

1.7 “Bankruptcy Code” has the meaning specified in Section 14.3 hereof.

1.8 “Batch” means a specific volume, produced in a 130L or larger size bioreactor, of cell culture fluid processed through to bulk drug substance that is intended to have a uniform character and quality, within specified limits, and that is produced according to a single manufacturing order during the same cycle of manufacture.

1.9 “Batch Price” means the price associated with the production of each Batch (excluding internal analytical testing and Third Party costs as provided in Section 7.6.2), which, for [\*], shall be as follows: [\*] for each 130L scale Batch; [\*] for each 500L scale Batch; and [\*] for each 2,750L scale Batch. Batch Prices shall be adjusted annually by XOMA, [\*].

1.10 “BLA” means a Biologics Licensing Application (as defined in the FDC Act) and any other equivalent marketing authorization application or other license, registration or application seeking approval from a Regulatory Authority to market a Collaboration Product in the Field in the Territory.

1.11 “Cancer” means a condition or disease primarily characterized by uncontrolled growth or spread of abnormal and anaplastic cells, metastases, neoplasm, malignant tumors and/or invasion by abnormal and anaplastic cells into tissues regardless of cause. For the avoidance of doubt, Cancer shall not include inflammation, infection or conditions characterized solely by hypertrophy or hyperplasticity of normal cells.

1.12 “cGMP Guidelines” means the FDA’s current good manufacturing practice guidelines as promulgated under the FDC Act and 21 C.F.R. (parts 210 and 211), and as further defined by FDA guidance documents, as amended from time to time.

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1.13 “Chiron Agreement” has the meaning specified in Section 1.14 hereof.

1.14 “Chiron Exclusivity Period” shall mean the exclusivity period provided for in Section 3.2 of the May 26, 2005 Research, Development and Commercialization Agreement between Chiron Corporation and XOMA (the “Chiron Agreement”). As of the Effective Date, the Chiron Exclusivity Period expires on February 27, 2007.

1.15 “Collaboration” has the meaning specified in Section 2.1.1 hereof.

1.16 “Collaboration Committee” means the Joint Steering Committee, JRDC or Joint Patent Committee. “Collaboration Committees” means any combination of the foregoing.

1.17 “Collaboration Product” means a Program Antibody that has been selected by the Joint Steering Committee and SPRI as a lead or backup development candidate for further development under the Collaboration.

1.18 “Collaboration Target” means any Proposed Target that has been selected for Research and Development in accordance with Section 2.2 hereof.

1.19 “Combination Product” has the meaning specified in Section 1.58 hereof.

1.20 “Commercially Reasonable and Diligent Efforts” means the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with either (a) the efforts such Party devotes to products or research and development projects of similar scientific and commercial potential, or (b) if such Party does not have and has not had any such products or projects, the efforts a peer company in the biopharmaceutical industry would devote, in accordance with industry standards and practices, to products or research and development projects of similar scientific and commercial potential, and subject in any event to any Pre-existing Obligations of such Party properly disclosed to the other Party in accordance herewith. For the avoidance of doubt, matters or events beyond the reasonable control of a Party, such as delays or actions taken by a Regulatory Authority, that result in delays in an R&D Program shall not constitute a lack of diligence hereunder.

1.21 “Confidential Information” means any information and data received by a Party (the “Receiving Party”) from the other Party or its Affiliates (the “Disclosing Party”) in connection with this Agreement or the Mutual Confidentiality Agreement (For Common Interest Privileged Discussions) effective as of March 6, 2006 between the Parties (including, without limitation, all information disclosed by the Parties under Article 2 hereof and any research, testing, clinical, regulatory, marketing or other scientific or business information, plans, or data pertaining to any Collaboration Product of the Disclosing Party). Notwithstanding the foregoing, Confidential Information shall not include any part of such information or data:

(a) which is or becomes public knowledge (through no fault of the Receiving Party); or

(b) which is made available to the Receiving Party by an independent third Party not under an obligation of confidentiality with the Disclosing Party (and such lawful right can be demonstrated by the Receiving Party’s written records); or

(c) which is already rightfully in the Receiving Party's possession at the time of receipt from the Disclosing Party (and such prior possession can be demonstrated by the Receiving Party's written records); or

(d) which is independently developed by an employee of the Receiving Party and/or its affiliates without the aid, application or use of confidential information disclosed by the Disclosing Party (and such independent development can be demonstrated by the Receiving Party's written records).

[\*]

1.22 "Contract Quarters" has the meaning specified in Section 1.23 hereof.

1.23 "Contract Year" means, with respect to a particular Collaboration Target, (a) with respect to the first Contract Year, the period beginning on the date such Collaboration Target is accepted into the Collaboration (or, in the case of the first Collaboration Target, the Effective Date) and ending on December 31 of the calendar year in which such acceptance takes place (or, in the case of the first Collaboration Target, December 31, 2006) (such period, the "First Contract Year"), and (b) with respect to each subsequent Contract Year, the twelve (12) month period beginning on the day following the end of the First Contract Year and each succeeding twelve (12) month period thereafter. Each Contract Year (other than the First and last Contract Years, as applicable) shall be divided into four (4) "Contract Quarters" comprised of successive three (3) month periods. In the First Contract Year, the first Contract Quarter shall begin on the first day of the First Contract Year and shall end on the last day of the calendar quarter in which the relevant Collaboration Target is accepted into the Collaboration (or, in the case of the first Collaboration Target, June 30, 2006).

1.24 "Control" or "Controlled" means, with respect to any (a) material, document, item of information, method, data or other Know-How or (b) Patent Right or other intellectual property right, the possession (whether by ownership or license, other than by a license granted pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access, ownership, a license and/or a sublicense as provided herein under such item or right without violating the terms of any agreement or other arrangement with any Third Party as of the time such Party would first be required hereunder to grant the other Party such access, ownership, license or sublicense.

1.25 "Cover," "Covered" or "Covering" means, with respect to a Patent Right, that, but for rights granted to a person or entity under such Patent Right, the practice by such person or entity of an invention claimed in such Patent Right would infringe a Valid Claim included in such Patent Right, or in the case of a Patent Right that is a patent application, would infringe a pending claim in such patent application if it were to issue as a patent.

1.26 "Disclosing Party" has the meaning specified in Section 1.21 hereof.

1.27 "Effective Date" means the date specified in the initial paragraph of this Agreement.

1.28 "EMEA" means the European Medicines Agency, or any successor thereto.

1.29 "Escrow Agent" means an independent Third Party consultant hired by XOMA with whom XOMA has deposited a list of Excluded Targets, which XOMA may update from time to time, and who shall notify SPRI which, if any, Proposed Targets are Excluded Targets.

1.30 "Event of Default" means an event described in Section 13.3 hereof.

1.31 [\*]

1.32 “Excluded Target” means a Target that XOMA has elected, in its sole discretion, to exclude from consideration for inclusion in the Collaboration and is identified on the list of Excluded Targets deposited with the Escrow Agent prior to such Target being designated as a Proposed Target by SPRI.

1.33 “FDA” means the United States Food and Drug Administration, or any successor thereto.

1.34 “FDC Act” means the United States Food, Drug and Cosmetic Act (or any successor thereto), as amended, and the rules and regulations promulgated thereunder.

1.35 “Field” means the diagnosis, prevention, control and treatment of any human disease or condition excluding, until the expiration of the Chiron Exclusivity Period, Cancer. Upon expiration of the Chiron Exclusivity Period, Cancer shall immediately be included within the Field.

1.36 “First Commercial Sale” means the first sale for use or consumption by the general public of a Collaboration Product in a country after Regulatory Approval has been obtained in such country. For the avoidance of doubt, First Commercial Sale shall not include the sale of any Collaboration Product for use in clinical trials or for compassionate use prior to Regulatory Approval.

1.37 “First Contract Year” has the meaning specified in Section 1.23 hereof.

1.38 “FTE” means a full-time equivalent person-year [\*] of scientific, medical, technical, regulatory or managerial work on or directly related to R&D Plan activities or Manufacturing Plan activities, as applicable, calculated on a calendar monthly fractional effort basis for each individual engaged in such activities. The fraction of an FTE attributable to an individual’s scientific, medical, technical, regulatory or managerial work on or directly related to such activities in any given calendar month shall be determined as follows: (a) the numerator of such fraction shall equal the actual hours worked by such individual on or directly related to R&D Plan activities or Manufacturing Plan activities, as applicable (which number of hours shall be adjusted on a pro-rata basis in the case of exempt employees, to the extent necessary, such that the individual in question is not in any case allocating more of his or her time in such calendar month than there are total “monthly working hours” in such month to (i) R&D Plan activities and Manufacturing Plan activities, (ii) working activities other than R&D Plan activities and Manufacturing Plan activities (e.g., work on other projects, administrative duties, and other working activities not allocable to the Collaboration) and (iii) weekday holidays, vacation, medical leave and other paid-time-off, collectively), and (b) the denominator of such fraction shall be [\*] hours. The numerator shall exclude paid-time-off and administrative and other non-allocable activities. For purposes of the foregoing, “monthly working hours” for a given calendar month shall be equal to (x) the total number of weekdays (including weekday holidays) in such calendar month multiplied by (y) [\*] hours.

1.39 “FTE Costs” means the amounts determined by multiplying (a) the number of FTEs allocated by a Party during the relevant time period, subject to any limitations set forth in the applicable R&D Plan or Manufacturing Plan and associated budget(s) or otherwise established by the Joint Steering Committee, by (b) the applicable FTE Rates.

1.40 “FTE Rate” means, for each functional area, the rate set forth below corresponding to such functional area, to be adjusted annually (beginning in January of 2007) for inflation using the latest available U.S. Producer Price Index for finished goods, less food and energy (WPUSOP3500) as published by the Bureau of Labor Statistics as a simple percentage. In addition, the Joint Steering Committee shall discuss and approve, as needed, further adjustments to FTE Rates every [\*] on a prospective basis

beginning in January of [\*]. In the event the Joint Steering Committee is unable to reach consensus on any adjustment pursuant to the immediately preceding sentence, then SPRI shall have the deciding vote with respect thereto but shall, in reaching its decision, give due consideration to the FTE rates reflected in XOMA's then most recent comparable agreements of similar scope and financial terms with Third Parties. The FTE Rate is intended to embody costs (i) directly attributable to such Party's supervisory functions, service functions, occupancy costs, and its payroll, information systems, or purchasing functions, all of which are in direct support of the development, manufacture, use and/or sale of an applicable Collaboration Product, and (ii) allocated to departments based on space occupied or headcount or other activity-based methods; but shall not include any costs attributable to general corporate activities including but not limited to executive management, investor relations, human resources, business development, legal affairs, finance and employee costs associated with stock option plans and other equity incentive plans as permitted by applicable accounting rules. For the avoidance of doubt, the services of administrative employees and support services necessary for the conduct of the Collaboration are considered part of general and administrative services overhead and, as such, the costs for such services have been included in the calculation of the fully burdened FTE Rates listed herein. [\*] Establishment of annual FTE Rates for functional areas not set forth in the table below shall be the responsibility of the JRDC. Such rates will be used to determine the R&D Plan and related budget for the applicable annual period.

Functional Area	Annual FTE Rate
Pre-Clinical	\$ [*]
Clinical	\$ [*]
Regulatory	\$ [*]
Pilot Plant (Process Development)	\$ [*]
Quality	\$ [*]
Technical Development (Cell Line Work and Assay Development)	\$ [*]
Project Management	\$ [*]

1.41 "GAAP" means United States generally accepted accounting principles, as they exist from time to time, consistently applied.

1.42 "Human Engineering™ Technology" means the Human Engineering™ technology Controlled by XOMA, as more fully described in Schedule 1.42.

1.43 "IND" means an Investigational New Drug application filed with the U.S. Food and Drug Administration or a similar application for the clinical testing of a Collaboration Product in human subjects filed with a foreign Regulatory Authority.

1.44 "Indemnitee" has the meaning specified in Section 12.4 hereof.

1.45 "Indemnitor" has the meaning specified in Section 12.4 hereof.

1.46 "Initial Royalty Period" means, for each Collaboration Product the period commencing with the First Commercial Sale thereof and continuing on a country-by-country basis until [\*].

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1.47 “Joint Patent Committee” has the meaning specified in Section 3.1.3 hereof.

1.48 “Joint Project Team” has the meaning specified in Section 3.1.2 hereof.

1.49 “Joint Steering Committee” has the meaning specified in Section 3.1.1 hereof.

1.50 “JRDC” has the meaning specified in Section 3.1.2.

1.51 “Know-How” means any and all know-how, trade secrets, data, processes, techniques, procedures, compositions, materials, devices, methods, formulas, protocols, and research, pre-clinical and clinical data and information, including any and all chemical, biochemical, toxicological, and scientific research information, whether in written, electronic, graphic or video form or any other form or format. Know-How shall not include Patent Rights.

1.52 “Laws” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.53 “LIBOR” has the meaning specified in Section 7.12 hereof.

1.54 “Manufacturing” or “Manufacture” means all activities set forth in the applicable Manufacturing Plan associated with the production, processing, formulating, filling, finishing and packaging of Collaboration Products in the Field, including pilot plant process development; pilot plant stability testing; manufacturing process development; manufacturing process and assay validation; manufacturing scale-up; preclinical, clinical and commercial manufacture; and analytical development, quality assurance and quality control activities directly related to any of the preceding activities.

1.55 “Manufacturing Costs” means, with respect to the Manufacture of a Collaboration Product as set forth in the applicable Manufacturing Plan, the [\*] internal costs of XOMA, which costs shall be determined based on FTE Costs or Batch Price, and the [\*] costs billed to XOMA by Third Parties, in each case consistent with and directly related to the budget set forth in the applicable Manufacturing Plan incurred in pilot plant process development; manufacturing process development; manufacturing process improvement; manufacturing scale-up; the development of manufacturing standard operating procedures, batch records, and quality assurance and quality control methods and procedures; and the time of manufacturing personnel for preparing, submitting, reviewing or developing data or information for the purpose of a drug master file or for submission to a Regulatory Authority.

1.56 “Manufacturing Plan” has the meaning specified in Section 5.1.1 hereof.

1.57 “Master Cell Bank” means an aliquot of a single pool of cells which generally has been prepared from the selected cell clone under defined conditions, dispensed into multiple containers and stored under defined conditions. The single pool of cells will be generated from a cell line having agreed upon characteristics, including [\*], established prior to the initiation of preparation of such Master Cell Bank pursuant to the relevant R&D Program, or as subsequently agreed to by the Joint Steering Committee, based on relevant cGMP and GLP standards for [\*].

1.58 “Net Sales” means, with respect to each country of the world, the gross amount invoiced by SPRI, or its Affiliates or sublicensees, on sales of a Collaboration Product to a Third Party end user, and exclusive of intercompany transfers or sales, less the actually granted or incurred reasonable and customary deductions from such gross amounts including: (i) normal and customary trade, cash and quantity discounts, allowances and credits; (ii) credits or allowances for damaged goods, returns or rejections and

retroactive price reductions; (iii) sales or similar taxes (including duties or other governmental charges levied on, absorbed or otherwise imposed including without limitation value added taxes or other governmental charges otherwise measured by the billing amount, when included in billing); (iv) freight, postage, shipping, customs duties and insurance charges; (v) charge back payments and rebates (or equivalents thereof) granted to managed health care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to trade customers, including but not limited to, wholesalers and chain and pharmacy buying groups; and (vi) commissions paid to Third Parties other than sales personnel and sales representatives or sales agents.

In the event the Collaboration Product is sold as part of a Combination Product (as defined below), the Net Sales from the Combination Product, for the purposes of determining royalty payments, will be determined by [\*].

In the event that the average sale price of the Collaboration Product can be determined but the average sale price of the other active compounds or active ingredients cannot be determined, Net Sales for purposes of determining royalty payments will be calculated by [\*]. If the average sale price of the other active compounds or active ingredients can be determined but the average price of the Collaboration Product cannot be determined, Net Sales for purposes of determining royalty payments will be calculated by [\*].

In the event that the average sales price of both the Collaboration Product and the other active compounds or active ingredients in the Combination Product cannot be determined, the Net Sales of the Collaboration Product shall be negotiated in good faith by the Parties [\*].

As used above, the term "Combination Product" means any Collaboration Product sold in conjunction with any other active component(s) (whether packaged together or in the same therapeutic formulation).

Free samples of Collaboration Product and the disposition of Collaboration Product for, or the use of Collaboration Product in, pre-clinical or clinical (Phase 1 – 3) trials or other market-focused (Phase 4) trials in which Collaboration Product is provided to patients without any payment shall not result in any Net Sales.

1.59 "Patent Prosecution" has the meaning specified in Section 9.2.1 hereof.

1.60 "Patent Rights" means all existing patents and patent applications and all patent applications hereafter filed and patents hereafter issued, including, without limitation, any continuations, continuations-in-part, divisionals, provisionals or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

1.61 "Phage Display License Agreements" means the license agreements listed in Schedule 1.61.

1.62 "Phase 1 Trial" means a human clinical trial in any country that is intended to initially evaluate the safety and/or pharmacological effect of a Collaboration Product in subjects as more fully described in 21 C.F.R. 312.21(a), or its foreign equivalent. For purposes of this Agreement, "commencement of a Phase 1 Trial" for a Collaboration Product means the first introduction of such Collaboration Product into a human patient in a Phase 1 Trial.

1.63 “Phase 2 Trial” means a human clinical trial in any country that is intended to initially evaluate the effectiveness of a Collaboration Product for a particular indication or indications in patients with the disease or indication under study as more fully described in 21 C.F.R. 312.21(b), or its foreign equivalent. For purposes of this Agreement, “commencement of a Phase 2 Trial” for a Collaboration Product means the first introduction of such Collaboration Product into a human patient in a Phase 2 Trial.

1.64 “Phase 3 Trial” means a pivotal human clinical trial, generally undertaken after proof of concept has been demonstrated (whether by trend, biomarker or otherwise), in numbers of patients anticipated to be adequately powered, in any country, the results of which could be used to establish safety and efficacy of a Collaboration Product as a basis for a BLA as more fully described in 21 C.F.R. 312.21(c) or its foreign equivalent. For purposes of this Agreement, “commencement of a Phase 3 Trial” for a Collaboration Product means the first introduction of such Collaboration Product into a human patient in a Phase 3 Trial. In the event of a Phase 2/3 trial, initiation of Phase 3 shall be deemed to have occurred upon a decision by SPRI to continue enrollment for the pivotal portion of such trial.

1.65 “Plan” means an R&D Plan or Manufacturing Plan, as the case may be.

1.66 “Pre-existing Obligations” means the obligations of SPRI or XOMA, as the case may be, existing under agreements in effect prior to the Effective Date with respect to SPRI Background Technology or XOMA Background Technology, in each case as disclosed to the other Party in writing (a) prior to the execution of this Agreement, (b) if related to a Proposed Target, in accordance with Section 2.2, and/or (c) if related to a Program Antibody, at the time such Program Antibody is first disclosed to the JRDC or otherwise promptly upon a Party’s realization that such obligation is relevant to the activities to be carried out in the course of the Collaboration, as applicable.

1.67 “Program Antibody” means an Antibody Product that (a) is first identified or discovered by XOMA in the course of the Collaboration, (b) (i) is Controlled by SPRI, (ii) either is in SPRI’s or any of its Affiliates’ possession as of the Effective Date or is discovered or acquired by SPRI or any of its Affiliates during the Program Term but outside the conduct of the Collaboration, and (iii) is designated a Program Antibody by the Joint Steering Committee, or (c) the Parties agree to acquire from a Third Party, and, in the case of clauses (a), (b) and (c), selectively binds to and acts through a Collaboration Target; *provided, however*, that in no event shall an Antibody Product that is subject to one or more Pre-existing Obligations become a Program Antibody unless such designation is affirmatively agreed to by the Joint Steering Committee after disclosure of the nature of such Pre-existing Obligation(s) by the applicable Party, such agreement not to be unreasonably withheld or delayed.

1.68 “Program Director” has the meaning specified in Section 3.2 hereof.

1.69 “Program Materials” means (a) any Program Antibodies and (b) any materials other than Program Antibodies Controlled by a Party or jointly by the Parties that are first identified or discovered in the conduct of the Collaboration and during the applicable Program Term.

1.70 “Program Patent Rights” means any Patent Rights Controlled by a Party or jointly by the Parties that Cover any Program Technology first invented, discovered, made, conceived, reduced to practice or otherwise licensed or acquired, or Program Materials first identified or discovered, during the applicable Program Term.

1.71 “Program Technology” means any and all Know-How and inventions Controlled by a Party or jointly by the Parties that are first invented, discovered, made, conceived, reduced to practice or otherwise licensed or acquired in the conduct of the Collaboration and during the applicable Program

Term; *provided* that Know-How or inventions that constitute an improvement to the Human Engineering™ Technology (including any Know-How or inventions otherwise meeting this definition and constituting an improvement thereto) shall not be included in Program Technology. For clarity, Program Technology excludes Program Materials.

1.72 “Program Term” has the meaning specified in Section 2.1.2 hereof.

1.73 “Proposed Targets” has the meaning specified in Section 2.2.2 hereof.

1.74 “R&D Costs” means costs and expenses that are incurred after the Effective Date by either Party in performing Research and Development activities consistent with and directly related to an applicable R&D Plan and associated budget, including:

(a) the costs of internal scientific, medical, technical, and/or managerial personnel engaged in such efforts, which costs shall be determined based on FTE Costs, unless another basis is otherwise agreed upon by the Parties in writing; and

(b) all [\*] costs and expenses incurred, including payments to investigators, contract research organizations, and consultants, for preclinical studies, pharmacodynamic or pharmacokinetic studies, molecular biology, toxicology studies, data management, statistical design, programming and analysis, clinical studies, clinical trial management, document preparation and review, subject recruitment and reimbursement, insurance, contract negotiation and travel;

(c) fees and costs incurred in connection with the preparation, filing and submission of INDs, BLAs and other regulatory filings with Regulatory Authorities (including pharmacoeconomic studies and any other clinical studies reasonably necessary for Regulatory Approval by relevant Regulatory Authorities to sell such Collaboration Product in each country);

(d) Collaboration related costs incurred under any Third Party licenses entered into prior to the Effective Date and disclosed to the other Party prior to the Effective Date or in accordance with Section 2.8;

(e) the [\*] costs and expenses of clinical supplies, lab supplies, animals and other direct charges for such efforts as set forth in the R&D Plan, including: (i) costs and expenses incurred to purchase and/or package comparator or combination drugs or devices; and (ii) costs and expenses of disposal of clinical samples;

(f) the [\*] costs of capital equipment incurred for Collaboration projects [\*]; and

(g) any other costs included in the budget for such R&D Plan.

1.75 “R&D Plan” means the plan relating to a particular Collaboration Target for each Contract Year prepared, developed and approved in accordance with Section 2.2.5 or Section 4.2.1, as applicable. An outline of the tasks to be considered for inclusion in each R&D Plan is set forth in Schedule 1.75.

1.76 “R&D Program” means the Research and Development activities relating to a particular Collaboration Target and to be conducted in accordance with an applicable R&D Plan.

1.77 “Receiving Party” has the meaning specified in Section 1.23 hereof.

1.78 “Regulatory Approval” means any and all approvals (including any applicable governmental price and reimbursement approvals), licenses, registrations, or authorizations of any federal, national, multinational, state, provincial or local regulatory agency, department bureau or other governmental entity that are necessary for the manufacture, use, storage, import, transport, promotion, marketing and sale of a Collaboration Product in the Field in a country or group of countries.

1.79 “Regulatory Authority” means any governmental authority in a country or region that regulates the manufacture or sale of pharmaceutical products, including the FDA and the EMEA, and any successors thereto.

1.80 “Representatives” has the meaning specified in Section 3.8.2.2 hereof.

1.81 “Research and Development” means the conduct of activities relating to the discovery of Antibodies for Collaboration Targets, the identification, characterization, selection, optimization and research of Program Antibodies and Collaboration Products and the conduct of all tests, clinical and other studies and other activities (including test method development, toxicology studies, statistical analysis and report writing, preclinical and other testing, packaging and regulatory affairs, product approval and registration activities) set forth in, or required to obtain the information set forth in, applicable R&D Plan(s). Research and Development may include without limitation (a) the discovery of Program Antibodies that selectively bind to and act through Collaboration Targets, (b) the development of assays for Program Antibodies to, *inter alia*, confirm the activity of such Program Antibodies or Collaboration Target, (c) the Human Engineering™ of non-human Antibodies that selectively bind to and act through such Collaboration Target, and (d) the performance of affinity maturation on such Program Antibodies, in each case with the objective of identifying Program Antibodies that meet the criteria for designation as Collaboration Products.

1.82 “Specifications” means, with respect to any Collaboration Product, the applicable written specifications for such Collaboration Product in effect at a particular time including, but not limited to, specifications provided in any Regulatory Approval for such Collaboration Product.

1.83 “SPRI Background Technology” means any and all Know-How and Patent Rights Controlled by SPRI as of the Effective Date or that comes to be Controlled by SPRI during the Program Term (other than the Program Technology) and, in particular, any such Patent Rights and Know-How Covering any Collaboration Target, Program Antibody or Collaboration Product, for purposes of conducting Research and Development or Manufacturing activities in connection with the Collaboration. For the avoidance of doubt, the Parties acknowledge that, to the extent any SPRI Background Technology is covered by a license or other agreement with a Third Party, such SPRI Background Technology shall, for all purposes of this Agreement, be subject to the limitations, restrictions and financial obligations established in such Third Party license or agreement, with SPRI being responsible for the payment of all payments due thereunder.

1.84 “Target” means a gene and the products encoded by such gene, including, without limitation, (a) any partial or full-length DNA sequence from such gene (including any mutant or polymorphic forms thereof), (b) any RNA sequence (including any post-transcriptionally modified variants thereof) encoded by any such gene, (c) any peptide, polypeptide or protein (including any post-translationally modified variants thereof) encoded by any such gene, (d) any derivatives or fragments of any of the foregoing, and/or (e) any species variants or homologs of any of the foregoing. Each Target shall be identified by the full-length cDNA sequence of the gene and/or the amino acid sequence of the encoded protein or, in the event the gene has more than one splice variant form, by the full-length cDNA sequence of at least one splice variant form of such gene and/or the amino acid sequence of the encoded protein (with all such splice variants being included within the definition of Target).

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1.85 “Territory” means all of the countries of the world.

1.86 “Upfront Fee” has the meaning specified in Section 7.1 hereof.

1.87 “Third Party” means any person or entity other than SPRI, XOMA and their respective Affiliates.

1.88 “Valid Claim” means a claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

1.89 [\*]

1.90 “XOMA Background Technology” means any and all Know-How and Patent Rights Controlled by XOMA as of the Effective Date, or acquired or developed by XOMA during and in connection with the Collaboration (other than the Program Technology), that are [\*] for (a) research related to Collaboration Target(s) or (b) Research and Development, Manufacture or commercialization of Program Antibody(ies) or Collaboration Product(s). For the avoidance of doubt, the Parties acknowledge that, to the extent any XOMA Background Technology is covered by a license or other agreement with a Third Party, such XOMA Background Technology shall, for all purposes of this Agreement, be subject to the limitations, restrictions and financial obligations established in such Third Party license or agreement, with SPRI being responsible for the payment of all Collaboration- related payments due thereunder. XOMA Background Technology excludes the Human Engineering™ Technology.

## ARTICLE 2

### COLLABORATION OVERVIEW

#### 2.1 General.

2.1.1 Objectives. The Parties intend to carry out a program in which SPRI and XOMA will collaborate to identify and characterize Program Antibodies and to carry out the Research and Development and Manufacturing of Antibody Products that act through Collaboration Targets for use in the Field (the “Collaboration”), consistent with the objectives set forth in the applicable Plan(s). It is intended that the Collaboration will be conducted as a unified collaborative effort with activities by the Parties carried out primarily at each Party’s respective facilities, and this intent shall be reflected in the applicable Plan(s).

2.1.2 Program Term. Each R&D Program shall have its own term, which shall commence on the date the R&D Program is initiated and shall continue until SPRI assumes full responsibility for the relevant Collaboration Product(s) (each, a “Program Term”). In no event shall XOMA be obligated, without its prior approval, to carry out activities beyond those listed in Section 4.1 and Schedule 1.75 as activities which it is anticipated XOMA may conduct.

#### 2.1.3 Certain Restrictions.

2.1.3.1 Once a Proposed Target is disclosed to and accepted by XOMA as a Collaboration Target (as provided in Section 2.2), neither Party will conduct work on its own, or will work with any Third Party (except as provided in Section 2.4.3), on any preclinical research program to identify antibodies directed to such Collaboration Target for

so long as SPRI is funding XOMA's activities with respect to such Collaboration Target under the Collaboration. For purposes hereof, "funding XOMA's activities with respect to such Collaboration Target under the Collaboration" does not include Manufacturing related activities (or required or requested regulatory or similar follow-up due to XOMA having conducted prior activities pursuant to this Agreement) beyond those activities enumerated in Schedule 1.75. After SPRI has stopped such funding, either Party may work on such Collaboration Target on its own or with a Third Party under the following conditions, *provided* that such work does not use any Confidential Information of the other Party, Program Materials or Program Technology except as otherwise permitted hereby:

(a) for a period of [\*], neither Party will conduct an internal preclinical antibody research program (except SPRI may continue the program(s) initiated in collaboration with XOMA) with respect to such Collaboration Target nor solicit any Third Party to sponsor such a program; thereafter, either Party may conduct its own preclinical antibody research program with respect to such Collaboration Target and/or solicit one or more Third Parties to sponsor such a program; or

(b) following [\*], in the event that either Party receives an unsolicited request from a Third Party to initiate a preclinical antibody research program with respect to such Collaboration Target, it will be free to do so.

The foregoing provisions of this Section 2.1.3.1 shall not apply [\*].

2.1.3.2 SPRI agrees that, during the Chiron Exclusivity Period, it will not conduct any research or development in the field of Cancer with respect to any Antibodies or Antibody Products provided by XOMA, including Program Antibodies. Notwithstanding the foregoing, SPRI may use models of its own choosing to demonstrate the therapeutic activity for an Antibody or Antibody Product that will not be used in the field of Cancer during the Chiron Exclusivity Period. [\*]

## 2.2 Selection of Collaboration Targets

2.2.1 Initial Target. SPRI has designated [\*] as the initial Target, and XOMA has accepted such Target into the Collaboration, thereby making it a Collaboration Target and the subject of the first R&D Program. In addition, the Parties acknowledge that [\*] additional Proposed Targets have been disclosed to the Escrow Agent and have cleared XOMA's conflict clearance procedure, but have not been designated by SPRI for inclusion in the Collaboration pursuant to Section 2.2.2 and therefore are not yet Collaboration Targets.

2.2.2 Proposal of Additional Targets. As used herein, "Proposed Targets" means Targets identified and validated by SPRI as having potential application in the Field and which are to be considered as candidates for Collaboration Targets. During the period [\*], SPRI may request XOMA's consent (which consent shall not be unreasonably withheld) to submit additional Proposed Targets to the Escrow Agent, for consideration as proposed Collaboration Targets, but shall have no obligation to submit any particular Target for consideration as a Proposed Target.

2.2.3 Exclusion of Targets from Consideration. Upon receipt of XOMA's written consent as provided in Section 2.2.2, SPRI shall submit the identity of the Proposed Target to the Escrow Agent in confidence for comparison against XOMA's list of Excluded Targets, which

XOMA may update from time to time. In the event such Proposed Target matches any Excluded Target on such list, the Escrow Agent shall promptly so notify each Party in writing. In the event the Proposed Target does not match any Excluded Target, the Escrow Agent shall promptly so notify each Party in writing and SPRI shall disclose the identity of the Proposed Target to XOMA. For the avoidance of doubt, the Escrow Agent shall not disclose the identity of the Proposed Target to XOMA. All fees and expenses of the Escrow Agent related to the performance of services under this Agreement shall be borne by SPRI.

2.2.4 Disclosure of Additional Information. In the event the Escrow Agent notifies the Parties that a Proposed Target does not match any Excluded Target, SPRI shall promptly disclose to XOMA [\*].

2.2.5 Designation of Collaboration Targets. Within [\*] following the submission by SPRI to XOMA of the information required pursuant to Section 2.2.4(a) – (c), XOMA shall give SPRI written notice of its rejection of or its intention, subject to mutual agreement between the Parties on an initial R&D Plan as provided below, to accept such Proposed Target as a Collaboration Target. If XOMA indicates that it intends to accept the Proposed Target as a Collaboration Target, then within [\*] of such indication of intent to accept, the Parties shall prepare and agree (or conclude that they cannot agree) on an initial R&D Plan for such Collaboration Target. If such initial R&D Plan is mutually agreed within such period, then such Proposed Target shall become a Collaboration Target. XOMA may elect to reject such Proposed Target in the event that [\*]. In the event XOMA rejects such Proposed Target or the Parties cannot agree on an initial R&D Plan, then such Proposed Target shall not become a Collaboration Target. In the event XOMA accepts such Proposed Target as a Collaboration Target, then the Parties shall proceed with the Research and Development of Antibody Products directed to such Collaboration Target in accordance with the applicable Plans. In the event that XOMA rejects a Proposed Target or the Parties cannot agree on an initial R&D Plan under this Section 2.2.5, XOMA shall not initiate an internal preclinical antibody research program directed to such rejected Target, directly or indirectly, or solicit any Third Party to sponsor such a program, for a period of [\*] after the date of rejection under the following conditions: [\*].

2.3 [\*]

#### 2.4 Conduct of Collaboration.

2.4.1 Efforts. Each Party shall use Commercially Reasonable and Diligent Efforts to conduct the activities of the Collaboration that are assigned to it in the then-applicable Plan(s), and each shall devote sufficient resources to carry out such respective activities.

2.4.2 Resources. Over the course of the Collaboration, tasks will be allocated between the Parties in the best interest of the Collaboration. The Parties agree to commit to the Collaboration the personnel necessary to meet their respective responsibilities set forth in each Plan.

2.4.3 Subcontractors. As necessary and in furtherance of the Collaboration, either Party may enter into Research and Development-related agreements or subcontracts in accordance with this Section 2.4.3; *provided that* [\*].

2.4.4 Reports. Each Party shall submit written quarterly reports to the Joint Steering Committee, as may be required by the then-current Plan(s), detailing its activities under the Collaboration.

2.5 Collaboration Records. In order to protect the Parties' Patent Rights and Know-How under U.S. law in respect of any inventions conceived or reduced to practice during or as a result of the Collaboration, each Party agrees to maintain a policy or procedures for its employees to record and maintain all data and information developed during the Collaboration in such a manner as to enable the Parties to use such records to establish the earliest date of invention and/or diligence to reduction to practice. At a minimum, the policy or procedures shall require such individuals to record all inventions generated by them in standard laboratory notebooks or other suitable means that are dated and corroborated by non-inventors on a regular, contemporaneous basis.

2.6 Disclosure of Collaboration Results. Subject to restrictions imposed by a Party's confidentiality obligations to any Third Party with respect to SPRI Background Technology or XOMA Background Technology, each Party will disclose to the JRDC and to the Joint Patent Committee all Program Technology and Program Materials that are discovered, invented or made by such Party in the course of the Collaboration and that are useful in or relate to the Collaboration, including without limitation information regarding Collaboration Targets, Program Antibodies and Collaboration Products and uses thereof and the results of all Research and Development studies. Such Program Technology and Program Materials will be promptly disclosed to the JRDC and to the Joint Patent Committee, with meaningful discoveries or advances being communicated as promptly as practicable after such information is obtained or its significance is appreciated. [\*] Any information disclosed pursuant to this Section 2.6 may be used by the other Party solely for the purposes of the Collaboration or as otherwise expressly permitted in this Agreement.

2.7 Material Transfer. In order to facilitate the Collaboration, either Party may provide to the other Party certain Program Materials Controlled by the supplying Party for use by the other Party in furtherance of the Collaboration. All such Program Materials shall be considered the Confidential Information of both Parties and shall be subject to the restrictions in Article 10. Except as otherwise provided under this Agreement or in accordance with the applicable Plan(s), all such Program Materials delivered to the other Party shall remain the sole property of the supplying Party, shall be used only in furtherance of the Collaboration and solely under the control of the other Party and its Affiliates, shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party and shall not be used in research or testing involving human subjects, in each case except as may be provided in the applicable R&D Plan. The Program Materials supplied under this Section 2.7 must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known. THE PROGRAM MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

2.8 [\*]

### ARTICLE 3

#### COLLABORATION MANAGEMENT

##### 3.1 Collaboration Committees.

3.1.1 Joint Steering Committee. As soon as practicable after the Effective Date, XOMA and SPRI shall establish a Joint Steering Committee (the "Joint Steering Committee") comprised of three (3) representatives from each of XOMA and SPRI, each of whom shall have experience and seniority sufficient to enable him or her to make decisions on behalf of the Party

he or she represents within the scope of the responsibilities of the Joint Steering Committee as provided herein.

3.1.2 Joint Research and Development Committee. As soon as practicable after the Effective Date, XOMA and SPRI shall establish a Joint Research and Development Committee (the “JRDC”) comprised of three (3) representatives from each of XOMA and SPRI, each of whom shall have experience and seniority sufficient to enable him or her to make decisions on behalf of the Party he or she represents within the scope of the responsibilities of the JRDC as provided herein. From time to time during the Program Term, the JRDC may establish one or more Joint Project Teams (each, a “Joint Project Team”) to implement various aspects of any R&D Plan. Such teams shall be governed in the same manner and subject to the relevant requirements as set forth herein for the JRDC.

3.1.3 Joint Patent Committee. As soon as practicable after the Effective Date, XOMA and SPRI shall establish a Joint Patent Committee (the “Joint Patent Committee”) comprised of an equal number of representatives designated by each of XOMA and SPRI, each of whom shall have experience and seniority sufficient to enable him or her to make decisions on behalf of the Party he or she represents within the scope of the responsibilities of the Joint Patent Committee as provided herein.

3.2 Program Directors. Each Party shall appoint one of its designees on the Joint Steering Committee and/or the JRDC to serve as a program director (each, a “Program Director”) with responsibility for overseeing the day-to-day activities of the Parties with respect to the Collaboration and for being the primary point of contact between the Parties with respect to the Collaboration.

3.3 Replacement of Collaboration Committee Representatives and Program Directors. Each Party shall be free to replace its representative members of any Collaboration Committee and its Program Director with new appointees who have authority to act on behalf of such Party, on notice to the other Party.

3.4 Responsibilities of Joint Steering Committee. The Joint Steering Committee shall be responsible for overseeing and directing the Parties’ interaction and performance of their respective obligations under this Agreement. The respective members of the Joint Steering Committee shall be responsible for obtaining all necessary approvals from the managements of their respective companies for the decisions they will be making as members of the Joint Steering Committee. Without limiting the generality of the foregoing, its duties shall include:

- (a) preparing such procedures as may be necessary for the operation of the Joint Steering Committee, JRDC and Joint Patent Committee, and other committees the Joint Steering Committee decides to establish to assure the efficient operation of the Collaboration;
- (b) approving strategy for the overall Research and Development and Manufacturing of Collaboration Products in the Field in the Territory and for all other activities conducted by the Parties hereunder;
- (c) reviewing and approving the annual R&D Plans proposed by the JRDC and approving the budget therefor and any modifications thereto as recommended by the JRDC;
- (d) reviewing and approving the Manufacturing Plans proposed by the applicable Party and approving the budget therefor and any modifications thereto as recommended by such Party;

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- (e) overseeing the implementation of the Plans and allocation of resources and other activities in support of the Collaboration;
  - (f) establishing criteria for selection of Collaboration Products;
  - (g) selecting Collaboration Products, including a lead Program Antibody and one or more backup Program Antibodies for each Collaboration Target;
  - (h) facilitating the transfer of technology between the Parties through the JRDC;
  - (i) upon the recommendation of the JRDC, making decisions with respect to (i) the preclinical and clinical Development of Collaboration Products, and (ii) the in-licensing of applicable technology;
  - (j) evaluating the performance of the JRDC and Joint Patent Committee, and on a quarterly basis at a minimum, evaluating the progress of the R&D Program(s) against the applicable R&D Plan(s), including their respective timelines;
  - (k) resolving matters within the responsibilities of the JRDC and Joint Patent Committee as to which the members of such Collaboration Committee are unable to reach a consensus, and dissolving each such Collaboration Committee when its duties under the Collaboration are complete; and
  - (l) addressing issues and resolving differences that may arise between the Parties.

3.5 Responsibilities of JRDC. The JRDC shall be responsible for preparing for approval by the Joint Steering Committee and implementing the applicable annual R&D Plan, allocation of resources and other activities in support of the Collaboration, with the objective of expeditiously identifying Program Antibodies meeting the criteria for designation as Collaboration Products. Without limiting the generality of the foregoing, its duties shall include;

- (a) establishing criteria for the selection of Program Antibodies;
- (b) selecting Program Antibodies for characterization and optimization in the conduct of the Collaboration;
- (c) monitoring, reviewing and reporting on the progress of the Collaboration;
- (d) considering modifications to the applicable R&D Plan budget(s) as may be necessary or appropriate and, to the extent agreed upon by the JRDC, recommending that the Joint Steering Committee approve such modifications;
- (e) proposing and overseeing the Research and Development strategy of Collaboration Products;
- (f) overseeing the filing of INDs with the FDA pursuant to Section 4.3.1;
- (g) establishing advisory committees comprised of scientific, medical and/or other appropriate experts not affiliated with either Party to advise the JRDC on matters related to the Research and Development of Collaboration Products;

(h) with advice from the Joint Patent Committee, evaluating the need for licenses from Third Parties, and determining their utility in the Collaboration (if any), and making the appropriate recommendation(s) to the Joint Steering Committee;

(i) providing all appropriate information regarding the progress of the R&D Plan(s) to the Joint Steering Committee in advance of each quarterly Joint Steering Committee meeting; and

(j) performing such other activities as are contemplated by the terms of this Agreement.

The JRDC shall report its activities and make proposals to the Joint Steering Committee at least once each Contract Quarter, but more frequently as appropriate.

**3.6 Responsibilities of Joint Patent Committee.** The Joint Patent Committee shall be responsible for forming and implementing the intellectual property strategy of the Collaboration, with the objective of maximizing the patent and other protections for Program Antibodies and Collaboration Products afforded by applicable intellectual property Laws. The Joint Patent Committee shall report its activities and make proposals to the Joint Steering Committee at least once each Contract Quarter, but more frequently as appropriate.

**3.7 Meetings of Collaboration Committees.** As applicable, the Joint Steering Committee and the JRDC shall meet at least once every Contract Quarter, and more frequently as the Parties deem appropriate, on such dates and at such times as the Parties shall agree, on [\*] written notice to the other Party unless such notice is waived by the Parties. The other Collaboration Committees shall meet at a frequency to be mutually agreed by the Parties when such committees are created. The first meeting of the Joint Steering Committee shall take place as soon as [\*], but no later than [\*], after the Effective Date. Each Collaboration Committee may convene or be polled or consulted from time to time by means of telecommunications, videoconferences or correspondence, as deemed necessary or appropriate by the Parties. To the extent that meetings are held in person, they shall alternate between the offices of the Parties unless the Parties otherwise agree.

### **3.8 Decisions.**

**3.8.1 Quorum; Voting.** A quorum for a meeting of a Collaboration Committee shall require the presence of at least one SPRI member (or designee) and at least one XOMA member (or designee) in person or by telephone. All decisions made or actions taken by a Collaboration Committee shall be made unanimously by its members, with the SPRI members cumulatively having one vote and the XOMA members cumulatively having one vote.

#### **3.8.2 Dispute Resolution.**

3.8.2.1 In the event that unanimity cannot be reached by either the JRDC or the Joint Patent Committee with respect to a matter that is a subject of their respective decision-making authority, then the matter shall be referred for further review and resolution to the Joint Steering Committee. In the event that unanimity cannot be reached by the Joint Steering Committee with respect to a matter that is a subject of its decision-making authority, then SPRI shall have the deciding vote with respect to such matter, except as otherwise provided in this Section 3.8.2.

3.8.2.2 In the event that unanimity cannot be reached by the Joint Steering Committee with respect to a matter that is a subject of its decision-making authority [ \* ], the matter shall be referred for further review and resolution to the Chief Executive Officer of XOMA, or such other similar position designated by XOMA from time to time, and the President of SPRI, or such other similar position designated by SPRI from time to time (the “Representatives”). The Representatives shall use reasonable efforts to resolve the matter within [ \* ] after the matter is referred to them.

3.8.2.3 Any dispute over (i) the interpretation of the meaning of any term or condition of this Agreement or (ii) [ \* ] may be referred by either Party to a Third Party arbitrator or arbitrators, in accordance with the following procedures, whose decision shall be non-binding. The Parties shall attempt to mutually agree upon a single independent Third Party arbitrator (who shall be a professional with appropriate experience in the subject matter at issue in such dispute) within [ \* ] of providing written notice of an election to pursue arbitration hereunder. If the Parties are unable to mutually agree upon one such person, then each Party shall appoint one independent Third Party professional with appropriate experience in the subject matter at issue in such disagreement within [ \* ] after the date of the arbitration notice and such person(s) shall select a single independent Third Party arbitrator, who shall be a professional with appropriate experience in the subject matter at issue in such disagreement. Each Party shall present all relevant information supporting its position on the matter in dispute and all other information as such Party reasonably desires regarding such disagreement. Within [ \* ] after the date of the arbitration notice, the arbitrator shall provide written notice to the Parties regarding his or her determination regarding such disagreement. If the Parties cannot resolve any such matter within [ \* ] following the arbitrator’s provision of written notice to the Parties regarding his or her determination regarding such disagreement, the Parties shall be free to pursue all available recourse both at law and in equity with respect to the applicable matter(s).

3.8.2.4 Notwithstanding anything herein to the contrary, SPRI shall not have the deciding vote if: [ \* ].

3.9 Minutes. As soon as reasonably practicable after each Collaboration Committee meeting, a member of such Collaboration Committee designated by the Party hosting such meeting shall prepare and distribute draft minutes of the meeting (which shall provide a summary of the discussions at the meeting and a list of any actions, decisions or determinations approved by such Collaboration Committee) and shall revise such draft to reflect any comments thereon received from other members of such Collaboration Committee. Minutes in final form shall be circulated to all members of such Collaboration Committee sufficiently in advance of the next meeting to allow review and approval prior to the next meeting of such Collaboration Committee. Final minutes (including the actions, decisions or determinations included therein) shall be approved no later than the date of the next such meeting.

#### **ARTICLE 4**

##### **RESEARCH AND DEVELOPMENT PROGRAMS**

4.1 General. The Research and Development of Antibodies for Collaboration Targets, Program Antibodies (including their identification, characterization, selection and optimization) and Collaboration Products will be pursued jointly by the Parties under the direction of the JRDC in accordance with annual R&D Plans. Each Party shall use Commercially Reasonable and Diligent Efforts to conduct those

Collaboration activities for which it has responsibility. It is anticipated that key activities to be conducted by XOMA may include the following: [\*].

#### 4.2 R&D Plans.

4.2.1 The JRDC shall be responsible for preparation of, and the Joint Steering Committee shall be responsible for approval of, the R&D Plan for each Collaboration Target for every Contract Year (other than the First Contract Year) during the applicable Program Term at least [\*] prior to the commencement of such Contract Year. The R&D Plan relating to the first Collaboration Target for the First Contract Year shall be prepared by the Parties and approved by the JRDC within [\*] after the Effective Date. The first R&D Plan relating to any other Collaboration Target shall be prepared and agreed to in accordance with Section 2.2.5. Prior to the approval of any R&D Plan (or as soon as reasonably practicable following any change or proposed change to an approved R&D Plan that would affect XOMA's proposal regarding discovery and/or optimization technologies), XOMA shall identify to SPRI in writing the discovery and/or optimization technology or technologies that XOMA proposes to use to discover and/or optimize Antibodies in accordance with such R&D Plan (or change or proposed change thereto). In addition, XOMA's in-house patent counsel shall discuss with SPRI's designated intellectual property counsel XOMA's counsel's then current knowledge about any Third Party patent issues related to such technology, including but not limited to any Third Party patent or patent application that contains claims which, if granted or issued, are or would be infringed by XOMA's use of such technology or which could provide a basis for an allegation of infringement by either Party in operating under the terms of this Agreement. [\*] In the first Contract Year in which the Parties designate a Collaboration Product, the JRDC shall revise the initial R&D Plan for such Collaboration Product to include the preclinical Research and Development activities for such Collaboration Product [\*]. The responsibility of the JRDC for preparing annual R&D Plans shall terminate upon the completion of all Research and Development activities under all R&D Plans.

4.2.2 Each annual R&D Plan shall be in writing and shall set forth with reasonable specificity the Research and Development objectives, priorities, activities, milestones, budgets, personnel requirements, other resources and allocations of responsibilities between the Parties for the period covered by such annual R&D Plan in a manner consistent with the terms of this Agreement. The R&D Plans shall cover all aspects of Research and Development (including without limitation the discovery of Antibodies for Collaboration Targets and the identification, characterization, selection and optimization of Program Antibodies prior to their designation as Collaboration Products) and shall include, with reasonable specificity, the Research and Development activities to be performed by each Party and the Research and Development activities, if any, to be performed by subcontractors. The JRDC may agree on modifications, and recommend that the Joint Steering Committee approve such modifications, to the provisions of any R&D Plan at any time.

4.2.3 [\*]

#### 4.3 Regulatory Matters.

4.3.1 Regulatory Responsibility. The preparation, filing, prosecution and maintenance of INDs and other regulatory documents required to be filed with any Regulatory Authority with regard to each Collaboration Product will be in the name of SPRI. With respect to each Collaboration Product, SPRI shall oversee, monitor and coordinate all regulatory actions, communications and filings with and submissions to Regulatory Authorities, including filings and submissions of supplements and amendments thereto, with respect to each Collaboration Product, shall

give XOMA a reasonable opportunity for prior review of and comment on all such substantive communications, filings and submissions and shall incorporate those of such comments as can reasonably be incorporated into such communications, filings and submissions. Ownership and control of all establishment licenses and other Regulatory Approvals shall be, to the extent possible, in the name of SPRI, or as otherwise agreed by the Joint Steering Committee.

4.3.2 Regulatory Meetings and Correspondence. SPRI shall be responsible for interfacing, corresponding and meeting with Regulatory Authorities with respect to such Collaboration Product, and XOMA will promptly refer any contacts or questions from Regulatory Authorities to SPRI. XOMA will be entitled to attend all meetings and, if reasonably practicable, telephone conferences with Regulatory Authorities.

4.3.3 Reporting Adverse Drug Reactions. After the Effective Date and prior to the first IND filing for a Collaboration Product, the Parties will develop and mutually agree upon safety data exchange procedures governing the collection, investigation, reporting, and exchange of information concerning Adverse Drug Reactions, product quality and product complaints involving Adverse Drug Reactions, sufficient to permit each Party to comply with its legal obligations, [\*]. The safety data exchange procedures will be promptly updated if required by changes in the Law or by agreement between the Parties. SPRI will be responsible for reporting all Adverse Drug Reactions to the appropriate Regulatory Authorities in the applicable country(ies) or region(s) in accordance with applicable Laws.

4.3.4 DMF Reference Right. XOMA hereby grants SPRI a right of reference to any Drug Master File or similar filing that XOMA may make relating to [\*] for any Collaboration Product and upon request shall provide a letter of access to such filing allowing regulatory review of such filing by the FDA in conjunction with SPRI's submissions to the FDA with respect to such Collaboration Product.

## ARTICLE 5

### MANUFACTURING AND SUPPLY

#### 5.1 Designation of XOMA as Manufacturing Party.

5.1.1 Generally. XOMA shall have the first right to Manufacture and supply (itself or through one or more Third Parties) all quantities of each Collaboration Product necessary for Research and Development through the [\*] of such Collaboration Product. XOMA shall be responsible for implementing all aspects of Manufacturing under the direction and oversight of the Joint Steering Committee, as set forth in Section 3.4, and in accordance with a manufacturing plan proposed by XOMA for the applicable Collaboration Product(s) in the Field in the Territory and subject to review and approval by the Joint Steering Committee. Such manufacturing plan shall describe the specific Manufacturing activities to be undertaken by XOMA, shall include a general description of the personnel and other resources of XOMA to be used in the implementation thereof and shall set forth a unanimously agreed budget for such activities (each, as may be modified or amended and approved from time to time in accordance with this Agreement, a "Manufacturing Plan"). [\*]

5.1.2 [\*]

## 5.2 Supply.

5.2.1 Product Supply. XOMA shall use Commercially Reasonable and Diligent Efforts to supply (subject to Section 5.1) all requirements of Collaboration Product consistent with the Plan(s) [\*] for such Collaboration Product.

5.2.2 Certain Covenants. XOMA covenants that, during the term of this Agreement, it will (a) use Commercially Reasonable and Diligent Efforts to avoid shortfalls of supply based on the forecasts provided to it in the Manufacturing Plan(s), shall promptly notify SPRI in the event it becomes aware of any probable shortfall and shall use Commercially Reasonable and Diligent Efforts to remedy any shortfall of supply as soon as practicable; (b) be responsible for manufacturing, filling, packaging and warehousing of the Collaboration Product in conformity with applicable cGMP Guidelines and the Specifications, and in accordance, in all material respects, with all other applicable Laws; (c) maintain or cause to be maintained all records necessary and appropriate to demonstrate compliance with applicable cGMP Guidelines; and (d) grant SPRI the right, on reasonable advance notice and during normal business hours during the term of this Agreement, to have its personnel or representatives with quality control or quality assurance responsibilities inspect and audit the facilities and operations of XOMA directly related to the manufacture and supply of the Collaboration Product in order to confirm compliance with the covenants contained in this Section 5.2.2; *provided* that the foregoing inspection and audit right of SPRI shall be limited to [\*] such visit per calendar year and [\*] such personnel or representatives per visit, [\*].

5.3 Manufacturing Technology Transfer. Unless the Parties otherwise agree in writing during the applicable Program Term, as soon as reasonably practicable following XOMA providing to SPRI [\*], XOMA shall, at SPRI's expense, make a complete Manufacturing technology transfer to SPRI, an Affiliate or a Third Party designee, of all Program Materials, Program Technology and all other information and materials necessary for SPRI to Manufacture the Collaboration Product on its own using the developed process. The Third Party designee shall be subject to XOMA's prior approval, which shall not be unreasonably withheld. XOMA shall provide reasonable assistance to SPRI, at SPRI's expense, to enable SPRI to begin Manufacturing the Collaboration Product [\*].

## ARTICLE 6

### GRANTS OF RIGHTS; COVENANTS

#### 6.1 Grants of Licenses.

6.1.1 By XOMA. Subject to the terms of this Agreement and any applicable Pre-existing Obligations, during the term of this Agreement, XOMA hereby grants to SPRI, in the Field and within the Territory:

(a) an exclusive right and license, with the right to sublicense, under XOMA's interests in any Program Patent Rights and Program Technology relating to a Program Antibody, to make, have made, use, sell and import such Program Antibody;

(b) an exclusive right and license, without the right to sublicense except as provided in clause (c), under XOMA's interests in any Program Patent Rights directed to one or more Antibodies binding to and reactive with the same Target as a Program Antibody (including compositions containing, methods of using and methods of making such Antibodies), to make, have made, use, sell and import such related Antibody(ies); *provided*,

that any such related Antibodies that are not Collaboration Products shall be subject to (i) [\*] royalty due XOMA [\*] for the term of [\*], and (ii) milestone payments equal to [\*] payable upon achievement of each event set forth in Section 7.3 achieved subsequent to SPRI's initiation of a program with respect to such related Antibody, [\*];

(c) SPRI may sublicense the rights granted in this clause (b) but only in conjunction with a sublicense under clause (a) above of rights to a Program Antibody;

(d) a non-exclusive right and license, with the right to sublicense, under the XOMA Background Technology to make, have made, use, sell and import Program Antibodies;

(e) a non-exclusive right and license, with the right to sublicense, under any Patent Rights and Know-How Controlled by XOMA Covering any control antibodies provided by XOMA for the sole purpose of using such control antibodies to evaluate the Program Antibodies; and

(f) an exclusive right and license, with the right to sublicense, under any Program Patent Rights or other Patent Rights and Know-How Controlled by XOMA Covering each antibody-producing cell line created by XOMA that expresses a Program Antibody provided by XOMA, for the sole purpose of using such cell line to produce the applicable Program Antibody.

For the avoidance of doubt, the above license grants do not include the Human Engineering™ Technology, although to the extent XOMA uses the Human Engineering™ Technology in the Collaboration, patent claims arising out of XOMA's activities in connection with the Collaboration directed to Human Engineered™ Program Antibodies are included in the license grant set forth in clause (a) above.

6.1.2 By SPRI. Subject to the terms of this Agreement and any applicable Pre-existing Obligations, during the Program Term, SPRI hereby grants to XOMA, in the Field and within the Territory, a non-exclusive right and license, without any right to sublicense (except as set forth below), under the SPRI Background Technology, to conduct activities in connection with the Collaboration. Such right and license shall include the right to grant sublicenses to Affiliates of XOMA and to Third Parties hired by XOMA to conduct work on the Collaboration and that are approved by, and under terms and conditions that are approved by, the Joint Steering Committee. Any such sublicense shall be set forth in a written agreement containing confidentiality, non-use and ownership of intellectual property provisions consistent with and no less restrictive than those contained herein; shall be subject and subordinate to the terms and conditions of this Agreement; and a copy of such sublicense agreement shall be submitted to the Joint Steering Committee for approval prior to execution. XOMA shall provide SPRI with a copy of each sublicense agreement promptly after executing the same; *provided, however*, that subject to the exceptions set forth in Section 1.21, each such sublicense agreement shall be Confidential Information of XOMA.

6.2 No Grant of Other Technology or Patent Rights. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party hereto, as a result of this Agreement, obtain any ownership interest in or other right to any technology, know-how, patents, patent applications, gene or genomic sequence data or information, products, or biological materials of the other Party, including items owned, controlled or developed by, or licensed to, the other Party, or transferred by the other Party to said Party, at any time pursuant to this Agreement.

**ARTICLE 7**  
**FINANCIAL TERMS**

7.1 Upfront Fee. For each Proposed Target that becomes a Collaboration Target, SPRI shall pay XOMA a non-refundable fee in cash of [\*] (each, an Upfront Fee) within [\*] of acceptance by XOMA of such Proposed Target for Research and Development in accordance with Section 2.2.5 hereof. The Parties acknowledge that, because the first Target has been accepted into the Collaboration, the first Upfront Fee is due within [\*] of execution of this Agreement by the Parties.

7.2 Annual Maintenance Fee. For each R&D Program then in effect, SPRI shall pay XOMA a non-refundable fee in cash of [\*] (each, an Annual Maintenance Fee) on the second anniversary of the Effective Date and on each anniversary of the Effective Date thereafter [\*].

7.3 Milestones. For each R&D Program (in the case of the first milestone event set forth below) or for each Program Antibody (in the case of each of the remaining milestone events set forth below), SPRI shall pay XOMA the following milestone payments upon the occurrence of each of the following events:

Event	Payment Amount
1. Delivery to SPRI of at least one (1) Program Antibody that meets the success criteria established at the initiation of the related R&D Program	\$ [*]
2. Successful establishment of Master Cell Bank (i.e., successfully passes FDA Points to Consider and ICH guidelines for cell bank testing)	\$ [*]
3. First patient dosed in first indication	\$ [*]
4. First patient dosed in a Phase 2 Trial in first indication	\$ [*]
5. First patient dosed in a Phase 3 Trial in first indication	\$ [*]
6. First patient dosed in a Phase 3 Trial in second indication or for purposes of label expansion	\$ [*]
7. Submission of BLA or equivalent in first indication	\$ [*]

Event	Payment Amount
8. Submission of BLA or equivalent in second indication or for purposes of label expansion	\$ [*]
9. First to occur of Regulatory Approval in the United States or Regulatory Approval and pricing approval outside the United States in first indication	\$ [*]
10. First to occur of Regulatory Approval in the United States or Regulatory Approval and pricing approval outside the United States in second indication or of label expansion	\$ [*]

[\*]

7.4 Royalty. For each Collaboration Product, SPRI shall pay XOMA a royalty of [\*] of Net Sales of such Collaboration Product during the Initial Royalty Period. After the Initial Royalty Period with respect to a particular Collaboration Product has ended, and for a period of time of up to [\*] thereafter, a [\*] royalty of [\*] will apply in each country where the royalty referred to in the immediately preceding sentence has been paid, *provided* that (a) the full period during which a royalty shall be payable in such country shall not exceed [\*], and (b) [\*]. Upon expiration of such period, SPRI shall be deemed to have a fully paid-up license to such Collaboration Product and the related Program Materials, including any cell line producing such Collaboration Product.

#### 7.5 Reporting and Payment

7.5.1 Milestones. During the term of this Agreement, SPRI shall within [\*] after the achievement of any milestone event referred to in Section 7.3, furnish to XOMA a written notice indicating the milestone achieved and, if applicable, the relevant indication, label expansion and/or Regulatory Authority.

7.5.2 Royalties. During the term of this Agreement following the First Commercial Sale of any Collaboration Product, SPRI shall (a) as soon as [\*] after the end of each Contract Quarter but in any event within [\*] thereof, furnish to XOMA a written quarterly royalty report of, on a Collaboration Product-by-Collaboration Product basis:

- (i) the gross sales and Net Sales of Collaboration Products sold by SPRI, its sublicensees and their respective Affiliates during the reporting period and the calculation of Net Sales from such gross sales;
- (ii) the royalties payable in United States dollars which shall have accrued hereunder in respect of such Net Sales;
- (iii) the dates of the First Commercial Sales of Collaboration Products in any country during the reporting period; and

(iv) the exchange rates used in determining the amount of United States dollars payable hereunder.

Royalties payable on sales in countries other than the United States shall be calculated in accordance with the standard exchange rate conversion practices used by SPRI for financial accounting purposes. If no royalty or payment is due for any royalty period hereunder, SPRI shall so report. SPRI shall keep, and shall require its sublicensees to keep (all in accordance with GAAP), complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable hereunder to be determined. SPRI shall include in each agreement with each applicable sublicensee a provision requiring such sublicensee to make reports to SPRI, to keep and maintain records of sales made pursuant to such agreement and to grant access to such records by XOMA's independent certified public accountant to the same extent required of SPRI under this Agreement.

7.5.3 Payment Terms. Milestone payments for each milestone event shall be due as soon as practicable, but in any event within [\*], following the time of SPRI's report under Section 7.5.1 for such milestone event shall be due. Royalty payments for each Contract Quarter shall be due simultaneously with SPRI's royalty report under Section 7.5.2 for such Contract Quarter.

#### 7.6 Costs and Expenses.

7.6.1 FTEs. SPRI shall be responsible for all of its own R&D Costs and Manufacturing Costs, if any, and shall pay XOMA [\*] of XOMA's R&D Costs and [\*] of XOMA's Manufacturing Costs (excluding in each case the costs of Third Party goods and services, which are addressed in Section 7.6.2 below, and Batch production costs, which are addressed in Section 7.7 below), calculated on a functional area-by-functional area basis based on FTE Rates.

7.6.2 Third Party Costs. Charges for Third Party goods and services and other financial obligations to Third Parties incurred or undertaken consistent with and directly related to any Plan shall be the responsibility of SPRI. XOMA will separately charge SPRI for XOMA's [\*] costs, which may include, but are not limited to, extraordinary raw materials (e.g., purification resins), project required capital purchases (e.g., dedicated purification columns), outside testing, and reasonable Collaboration-specific travel expenses.

7.6.3 Committee Expenses. SPRI shall be responsible for all travel and related costs for its representatives, and, to the extent not paid pursuant to Section 7.6.1, shall reimburse XOMA, pursuant to Section 7.14, for all reasonable travel and related costs for XOMA's representatives whose FTE costs are not otherwise reimbursed by SPRI, to attend meetings of, and otherwise participate on, any Collaboration Committee.

7.6.4 Advances. SPRI will make advance payments to XOMA in quarterly increments with the funds being drawn down on a monthly basis according to work actually done, plus any other associated direct costs and expenses due XOMA and incurred in each such month. XOMA shall provide reasonably detailed invoices, including supporting documentation for disbursements, to SPRI for each monthly payment. The advance payment for a particular quarter will be adjusted for any credits or unpaid balance from the preceding quarter, plus the projected costs for such quarter.

7.7 Batch Prices. For each Batch Manufactured by XOMA in accordance with a Manufacturing Plan, SPRI shall pay XOMA the Batch Price. XOMA will separately charge SPRI for [\*] costs, which may include, but are not limited to, extraordinary raw materials (e.g., purification resins), project

required capital purchases (e.g., dedicated purification columns), outside testing, and reasonable Collaboration-specific travel expenses.

7.8 Records. The Parties shall each keep accurate books and accounts of record in connection with the R&D Programs and the Manufacture of Collaboration Products in a manner consistent with GAAP and in sufficient detail to permit accurate determination of all figures necessary for verification of R&D Costs, Manufacturing Costs and Net Sales hereunder.

7.9 Audits. Upon the written request of a Party, the other Party shall permit an independent certified public accountant selected by the requesting Party and acceptable to the other Party, which acceptance shall not be unreasonably withheld or delayed, to have access, at reasonable times and during normal business hours, to such records of such other Party as may be reasonably necessary to verify the accuracy of an SPRI payment report or XOMA charges and invoices submitted to SPRI hereunder, *provided* that such records shall be limited to the immediately preceding [\*] period. In the event of an SPRI audit of XOMA charges and invoices, SPRI may use its internal finance or audit personnel to conduct the audit in lieu of the certified public accountant under the same conditions set forth in this Section 7.9 and any negative audit findings by such internal personnel may be confirmed by a certified public accountant if so requested by XOMA. Each Party shall use commercially reasonable efforts to schedule all such verifications within [\*] after the requesting Party makes its written request. All such verifications shall be conducted not more than [\*] in, or with respect to, each Contract Year. The report of the requesting Party's independent certified public accountant or internal personnel shall be made available to both Parties. Subject to the other Party's rights under Section 14.8, in the event the requesting Party's independent certified public accountant or internal personnel concludes that additional amounts were owed to the requesting Party for such period, the additional amounts shall be paid by the other Party within [\*] of the date the requesting Party delivers to the other Party such written report so concluding, unless such report contains manifest error. In the event the requesting Party's independent certified public accountant or internal personnel concludes that there was an overpayment to such Party during such period, the overpayment shall be repaid by the requesting Party within [\*] of the date the requesting Party received such written report so concluding, unless such report contains manifest error. The fees charged by such independent certified public accountant shall be paid by the requesting Party unless such audit discloses a payment discrepancy of more than [\*] of the amount due under this Agreement for the period in question, in which case the Party responsible for a payment discrepancy that is detrimental to the other Party will bear the full cost of such audit. Each Party agrees that all information subject to review under this Section 7.9, or under any agreement with a sublicensee of SPRI, is confidential and that the Party receiving such information shall cause its independent certified public accountant or internal personnel to retain all such information in confidence. The requesting Party's independent certified public accountant or internal personnel shall only report to the requesting Party as to the computation of royalties or charges and invoices payable under this Agreement, as applicable, and shall not disclose to the requesting Party any other information of the other Party or any sublicensee of SPRI.

7.10 Withholding Taxes. In the event that any royalties or other payments due to a Party are subject to withholding tax required by Law to be paid to the taxing authority of any foreign country, the amount of such tax may be withheld from the applicable royalties or other payment due such Party. The Party owing such payment shall promptly pay such tax on behalf of the Party to which such payment is owed and shall furnish the Party to which such payment is owed with a certificate of withholding tax so deducted for such Party's avoidance of duplicate taxation in United States. Except as permitted in accordance with Section 1.58, the Party owing such payment may not deduct any other withholding or any other governmental charges from the payments agreed upon under this Agreement, except to the extent same are paid on behalf of, or for the benefit of, the Party to which such payment is owed. The Party owing

such payment shall maintain official receipts of payment of any such withholding taxes and shall forward such receipts to the Party to which such payment is owed.

7.11 Blocked Currency. If by Law conversion into United States dollars or transfer of funds of a convertible currency to the United States is restricted or forbidden, the Party owing such payment shall give the Party to which such payment is owed prompt written notice and shall make such payment due under this Article 7 through such means or methods as are lawful in such country as the Party to which such payment is owed may reasonably designate. Failing the designation by the Party to which such payment is owed of such lawful means or methods within [\*] after such written notice is given to such Party, the Party owing such payment shall deposit such royalty payment in local currency to the credit of the Party to which such payment is owed in a recognized banking institution designated by such Party, or if none is designated by such Party within the [\*] period described above, in a recognized banking institution selected by the Party owing such payment and identified in a written notice to other Party, and such deposit shall fulfill all obligations of the Party owing such payment to the other Party with respect to such payment.

7.12 Interest on Late Payments. Any failure by SPRI to make a payment within [\*] after the date when due shall obligate SPRI to pay interest, the interest period commencing on the due date and ending on the payment date. The applicable interest rate shall be [\*]. For clarity, it is understood that the calculation of Net Sales will require an ongoing reconciliation process, and no interest shall be payable under this Section 7.12 with respect to any adjustments that are made from the initial report of Net Sales, as applicable, for a particular Contract Quarter so long as the calculation of Net Sales that was reflected in the royalty statement for such calendar quarter was made in good faith.

7.13 Manner of Payment. Except as provided in Section 7.11, payments to be made by one Party to the other under this Agreement shall be payable in United States dollars and shall be paid by wire transfer in immediately available funds to such bank account as is designated in writing by such Party from time to time. Attached hereto as Schedule 7.13 is such bank account information for payments to be made to XOMA hereunder, until such time as XOMA designates a different bank account as provided herein.

7.14 Reimbursement for Travel Expenses. Reimbursement for any travel related expenses under this Agreement shall be subject to SPRI's internal travel reimbursement policy and guidelines, a copy of which is attached hereto as Schedule 7.14.

## ARTICLE 8

### PRODUCT DEVELOPMENT DILIGENCE

8.1 SPRI Obligations. SPRI shall use Commercially Reasonable and Diligent Efforts to actively Develop and seek Regulatory Approval for at least one Program Antibody selectively binding to and acting through each applicable Collaboration Target and use Commercially Reasonable and Diligent Efforts to market and sell the related Collaboration Product.

8.2 XOMA Obligations. With respect to each Collaboration Target for which XOMA completes Research and Development activities set forth in any R&D Plans, XOMA shall deliver to SPRI copies of all such data, information, registrations and applications therefore, or, where appropriate, otherwise provide SPRI with reasonable access, directly or indirectly, to such data, information, registrations or applications (e.g., by way of a letter of access to a Drug Master File or similar filing), in each case as [\*] to enable SPRI to pursue the development and commercialization of such Collaboration Product(s).

**8.3 Termination of an R&D Program or a Collaboration Product License** With respect to each Collaboration Target for which SPRI fails to timely satisfy its diligence obligations under Section 8.1 above, or the Research and Development of which SPRI otherwise abandons, subject to the provisions of Section 8.4, at the option of XOMA,

(a) the corresponding R&D Program shall terminate, the licenses granted under Section 6.1.1 by XOMA to SPRI with respect to the applicable Collaboration Product(s) shall terminate, except for the license granted in Section 6.1.1(b) which shall be converted to a co-exclusive license between SPRI and XOMA, and (for the avoidance of doubt) the provisions of Section 2.1.3 with respect to such Collaboration Target shall terminate for XOMA but shall remain in effect for SPRI;

(b) SPRI shall be deemed to have granted to XOMA

(i) an exclusive right and license, with the right to sublicense, under SPRI's interests in any Program Patent Rights and Program Technology relating to any Program Antibodies to such Collaboration Target, to make, have made, use, sell and import such Antibodies; and

(ii) a co-exclusive (with SPRI) right and license, with the right to sublicense, under any other of SPRI's interests in Program Patent Rights, to make, have made, use, sell and import Antibodies to such Collaboration Target;

(c) SPRI shall transfer to XOMA ownership of all cell lines, including Master Cell Banks, that produce Collaboration Products to such Collaboration Target as to which ownership was previously transferred to SPRI pursuant to Section 5.3; and

(d) without limiting the foregoing, SPRI shall (i) deliver to XOMA copies of all such data, information, registrations and applications therefore (or, where appropriate, otherwise provide XOMA with reasonable access, directly or indirectly, to such data, information, registrations or applications (e.g., by way of a letter of access to a Drug Master File or similar filing)) as are existing, and (ii) grant such other licenses and/or sublicenses as are available under any Patent Rights Controlled by SPRI as of the date of such termination and used or contemplated to be used by SPRI in the course of the Collaboration (as demonstrated by the Parties' written records or otherwise as reasonably agreed by the Parties at the time of such termination), subject to XOMA being responsible for any Third Party payments for such licenses or sublicenses, where each of (i) or (ii) is reasonably necessary to enable XOMA to pursue the development and commercialization of such Collaboration Product(s).

If the termination or abandonment is prior to IND filing for the relevant Collaboration Product, XOMA may continue any R&D Program with respect to such Collaboration Target or the development or commercialization of a related Collaboration Product free of charge, provided that if SPRI is not developing an Antibody binding to and reactive with the same Target, then XOMA shall pay to SPRI a royalty on the Net Sales of any products so licensed in an amount equal to [\*] the royalty SPRI would have been required to pay XOMA hereunder, and for the term of a Valid Claim of any Program Patent Rights Covering such product, had such product been a Collaboration Product. If the termination or abandonment is after IND filing for the relevant Collaboration Product, XOMA's option with respect to clauses (b), (c) and (d) of this Section 8.3 shall be subject to XOMA paying to SPRI, with respect to any such R&D Program or Collaboration Product as to which such option is exercised, (i) a royalty on Net Sales of any products so licensed in an amount equal to [\*] the royalty that SPRI would have been required to pay XOMA hereunder, and for the term of a Valid Claim of any Program Patent Rights Covering such products,

had such product been a Collaboration Product and (ii) milestone payments in amounts equal to [\*] the payments that SPRI would have been required to pay XOMA hereunder had such product been a Collaboration Product.

**8.4 Conditions for Termination of an R&D Program or a Collaboration Product License** Notwithstanding the provisions of Section 8.3 above, SPRI's exclusive rights under Section 6.1.1 shall not terminate as set forth above and SPRI shall not be required to deliver such copies or provide such access unless (a) XOMA gives to SPRI [\*] prior written notice of XOMA's intent to terminate such licenses, stating the reasons and justification for such termination and recommending steps which SPRI should take to satisfy its diligence obligations hereunder, and (b) SPRI (or its sublicensee) has not used Commercially Reasonable and Diligent Efforts during such [\*] period to pursue the research and/or development of, and/or to obtain Regulatory Approvals for, a Collaboration Product with respect to such Collaboration Target and/or the active outlicensing of such a Collaboration Product. In the event that SPRI disagrees with a termination notice under this Section or Section 8.3, the provisions of Section 14.8 shall apply.

**8.5 Mutual Termination of an R&D Program for Futility**. An R&D Program may be terminated by the mutual written agreement of the Parties for reasons of futility, such as the publication of blocking Third Party Patent Rights or technical failure. In such an event,

(a) the licenses granted under Section 6.1 with respect to all Collaboration Products as to which such termination relates shall terminate and (for the avoidance of doubt) the provisions of Section 2.1.3 with respect to the Collaboration Target that is the subject of such R&D Program shall terminate;

(b) each Party shall be deemed to have granted to the other Party non-exclusive licenses under such Party's interests in any Program Patent Rights, Program Materials and Program Technology with respect to Antibodies to such Collaboration Target and such licenses shall be limited to each Party's internal research use (as used in Sections 8.5(b) and 8.5(c), "internal research" shall mean any activities conducted internally by a Party or by a Third Party contractor for the sole benefit of a Party for a program prior to the filing of an IND); and

(c) SPRI shall be deemed to have granted to XOMA a non-exclusive right and license to all cell lines, including Master Cell Banks, that produce Collaboration Products to such Collaboration Target as to which ownership was previously transferred to SPRI pursuant to Section 5.3 and both Parties shall be limited in their use of such cell lines to internal research.

## ARTICLE 9

### INTELLECTUAL PROPERTY

#### 9.1 Ownership of Intellectual Property.

9.1.1 Ownership of Background Technologies. Subject to the rights and licenses granted under this Agreement, XOMA (and its licensors, as applicable) shall own and retain all rights to the XOMA Background Technology and SPRI (and its licensors, as applicable) shall own and retain all rights to the SPRI Background Technology.

9.1.2 Ownership of Program Technology.

9.1.2.1 Inventorship. Inventorship for patentable inventions and discoveries conceived or reduced to practice in the course of the performance of activities pursuant to this Agreement shall be determined in accordance with U.S. patent laws. In the event of a dispute regarding inventorship, the matter shall be referred to the Joint Patent Committee, and if the Joint Patent Committee is unable to resolve such inventorship dispute, then either Party may present the matter to a court of competent jurisdiction for resolution as provided in Section 9.6.

9.1.2.2 Ownership of Program Materials and Technology. Subject to the rights and licenses granted under this Agreement, title to all Program Materials and Program Technology, including, without limitation, all Program Patent Rights therein, shall be based upon the inventorship for such Program Materials and Program Technology. Subject to the rights and licenses granted under this Agreement, (a) SPRI shall own Program Materials and Program Technology invented solely by employees, agents, consultants or contractors of SPRI or a SPRI Affiliate; (b) XOMA shall own Program Materials and Program Technology invented solely by employees, agents, consultants or contractors of XOMA or a XOMA Affiliate; and (c) SPRI and XOMA shall jointly own Program Materials and Program Technology invented jointly by employees, agents, consultants or contractors of both SPRI and XOMA or Affiliates of SPRI and XOMA.

9.1.3 Certain Rights With Respect to Program Materials and Technology.

9.1.3.1 Subject to the terms of this Agreement and any applicable Pre-existing Obligations, SPRI hereby grants to XOMA, within the Territory, a non-exclusive, [\*] right and license, with the right to sublicense, under SPRI's interest in the Program Materials and the Program Technology, including without limitation any Program Patent Rights Controlled by SPRI, that are related to antibody discovery, optimization or evaluation or general cell line development or protein expression methodology, for purposes of discovering, creating, researching, developing, manufacturing and commercializing antibodies and antibody products and related activities with respect thereto, including without limitation the conduct of activities in connection with the Collaboration and any product or use that, but for the license grant in this Section 9.1.3.1 would infringe any Program Patent Rights Controlled by SPRI.

9.1.3.2 Subject to the exclusive licenses granted to SPRI hereunder and any applicable Pre-existing Obligations, XOMA shall have the right to exploit or to grant licenses under the Program Technology and Program Patent Rights jointly owned by the Parties as provided in Section 9.1.2.2, without the prior approval of any Collaboration Committee or the approval of, or accounting or other financial obligations to, SPRI. To the extent any Laws governing any portion of the Program Technology require the consent of the other joint owner(s) of such portion of the Program Technology in order for a Party to exploit or grant licenses to such portion of the Program Technology, each Party hereby grants such consent to the other Party for the exploitation of and/or grant of licenses to such portion of the Program Technology.

9.2 Prosecution and Maintenance of Program Patent Rights

9.2.1 Primary Prosecution Rights. SPRI shall have responsibility for Patent Prosecution (as defined below) of Program Patent Rights Covering inventions within the Program Materials

and the Program Technology that in accordance herewith (a) are solely owned by SPRI, (b) are jointly owned by SPRI and XOMA or (c) are solely owned by XOMA and which contain Antibody Related Claims (as defined below). XOMA shall have the right to participate therein and be represented by counsel of its choice. XOMA shall have responsibility for Patent Prosecution of Program Patent Rights Covering inventions within the Program Materials and the Program Technology that in accordance herewith are solely owned by XOMA and which do not contain Antibody Related Claims. The Party carrying out such responsibility shall bear all Patent Prosecution expenses, including attorneys' fees, incurred by such Party, or by the other Party at the request of the prosecuting Party, in the performance of Patent Prosecution. As used herein, "Patent Prosecution" means, with respect to particular Program Patent Rights, (i) preparing, filing and prosecuting patent applications (including, but not limited to, provisional, reissue, continuing, continuation, continuation-in-part, divisional, and substitute applications and any foreign counterparts thereof) for such Program Patent Rights; (ii) maintaining such Program Patent Rights; and (iii) managing any interference or opposition or similar proceedings relating to the foregoing. As used herein, "Antibody Related Claims" means those claims included in the Program Patent Rights which are directed to [\*].

9.2.2 Secondary Prosecution Rights. If SPRI elects not to, or fails after reasonable notice from XOMA to use Commercially Reasonable and Diligent Efforts to, pursue Patent Prosecution with respect to an invention within the Program Materials and Program Technology for which it has Patent Prosecution responsibility, then XOMA shall have the right to assume Patent Prosecution for such invention. In the case where SPRI makes such an election, it shall notify XOMA in writing of such election at least [\*] prior to the next date for action to preserve such Program Patent Rights. If XOMA elects to continue such Patent Prosecution, it may do so at its own expense. In such case, SPRI will provide XOMA with such assistance and execute such documents as are necessary to continue or permit such Patent Prosecution by XOMA.

### 9.3 Enforcement of the Program Patent Rights

9.3.1 Notifications. Each Party shall provide to the other Party copies of (a) any written notices it receives from any Third Party regarding any patent nullity action, declaratory judgment action, alleged invalidity, unenforceability, infringement or non-infringement with respect to Program Patent Rights or alleged misappropriation of intellectual property with respect to Program Technology, Program Materials or Collaboration Products, and (b) any written allegations it receives from a Third Party that the manufacture, use, sale, offer for sale or import of Program Technology, Program Materials or any Collaboration Product infringes the intellectual property rights of such Third Party, in each case promptly following receipt thereof.

#### 9.3.2 Infringement Proceedings Against Third Parties

9.3.2.1 SPRI shall have the first right, but not the obligation, to institute and direct legal proceedings against any Third Party believed to be infringing the Program Patent Rights that (a) are Controlled in whole by SPRI, (b) are Controlled jointly by SPRI and XOMA or (c) are Controlled in whole by XOMA and which contain Antibody Related Claims. XOMA shall have the sole right, but not the obligation, to institute and direct legal proceedings against any Third Party believed to be infringing the Program Patent Rights that are Controlled in whole by XOMA and which do not contain Antibody Related Claims. Each Party will bear its own costs, including attorneys' fees, relating to such legal proceedings; *provided* that the Party directing such legal proceedings shall bear the other Party's out-of-pocket expenses, including attorneys' fees, incurred in complying

with requests for cooperation made by the directing Party. Any recovery in connection with such suit or proceeding will first be applied to reimburse the Parties for their out-of-pocket expenses, including attorneys' fees. All recoveries resulting from such legal proceedings that are in excess of the Parties' costs of bringing or participating in such action, including attorneys' fees, shall be for the account of the Party directing such proceedings.

9.3.2.2 If SPRI elects not to exercise, or fails after reasonable notice from XOMA to use Commercially Reasonable and Diligent Efforts in the exercise of, its right to institute and direct legal proceedings based on the jointly owned Program Patent Rights or XOMA solely owned Program Patent Rights that do not contain Antibody Related Claims as set forth in Section 9.3.2.1, then XOMA shall have the right to institute and direct such legal proceedings. In the case where SPRI makes such an election, it shall notify XOMA in writing of such election at least [\*] prior to the last available date for instituting any such legal proceeding. If XOMA elects to institute and direct such legal proceedings, it may do so at its own expense. In such case, SPRI will provide XOMA with such assistance and execute such documents as are necessary to continue or permit such legal proceedings by XOMA.

9.3.2.3 In the event that either Party takes action under this Section 9.3.2, the other Party shall cooperate to the extent reasonably necessary at the sole expense of the acting Party. Upon the reasonable request of such acting Party, the other Party shall join the suit and shall be represented in any such legal proceedings using counsel of its own choice. The non-acting Party shall have the right to participate and be represented in any such legal proceedings by counsel of its own choice. Neither Party shall settle any claim or proceeding relating to Program Patent Rights Controlled in whole or in part by the other Party or licensed under this Agreement to the other Party without the prior written consent of such other Party, which consent shall not be unreasonably withheld or delayed.

9.4 Infringement Proceedings by Third Parties. In the event that a Party receives written notice that it or any of its Affiliates have been individually named as a defendant in a legal proceeding by a Third Party alleging infringement or misappropriation of a Third Party patent or other intellectual property right as a result of the manufacture, use, sale, offer for sale or import of the Program Technology, the Program Materials or a Collaboration Product, such Party shall promptly notify the other Party in writing. Such written notice shall include a copy of any summons or complaint (or the equivalent thereof) received regarding the foregoing. In addition to its obligations under Section 12.1, SPRI agrees to defend, indemnify and hold XOMA, its Affiliates and their respective employees and agents harmless from all claims, losses, damages or expenses (including reasonable attorneys' fees and costs of litigation) based on, arising out of or in connection with (a) SPRI's activities, decisions or determinations (or failures to act, decide or determine) in the course of the Collaboration under this Agreement and/or (b) XOMA's activities in the course of the Collaboration under this Agreement with respect to Collaboration Targets or Antibodies to Collaboration Targets (including assays and reagents related thereto) or as otherwise explicitly stated in any approved R&D Plan or any approved modification thereof. SPRI's obligations under this Section 9.4 shall be subject to the limitations set forth in Section 12.3, and any claim for indemnification under this Section 9.4 shall be subject to the procedural requirements of Section 12.4.

9.5 Cooperation. Each Party hereby agrees:

(a) to cooperate in the Patent Prosecution of any inventions within the Program Materials or Program Technology that in accordance herewith are jointly owned by the Parties in order to segregate the claims so as to implement the terms of Section 9.2;

(b) to take all reasonable additional actions and execute such agreements, instruments and documents as may be reasonably required to perfect the other Party's ownership interest of the Program Materials and the Program Technology in accordance with the intent of this Agreement;

(c) to provide the other Party with copies of drafts of all material filings with or other submissions to the U.S. Patent and Trademark Office or its foreign counterparts relating to Patent Prosecution, or the court or other tribunal relating to any infringement claims against Third Parties under the Program Patent Rights or the defense of infringement or misappropriation claims by Third Parties relating to the Program Technology, the Program Materials or a Collaboration Product, in each case reasonably prior to the filing or submission thereof, and to give due consideration to the comments and suggestions of the other Party in relation thereto;

(d) to provide the other Party with copies of all material filings with or other submissions to the U.S. Patent and Trademark Office or its foreign counterparts relating to Patent Prosecution or the court or other tribunal relating to any infringement claims against Third Parties under the Program Patent Rights or the defense of infringement or misappropriation claims by Third Parties relating to the Program Technology, the Program Materials or a Collaboration Product;

(e) to keep the other Party apprised of material developments in any discussions or negotiations with Third Parties concerning the licensing of any intellectual property in connection with the Collaboration or the settlement of any dispute relating thereto, and as reasonably requested by the other Party to provide (for review and comment) copies of drafts of any license, settlement or other agreement relating thereto, as well as copies of the final versions of any such agreements;

(f) to cooperate, as reasonably necessary, with the other Party in gaining patent term extensions, supplemental protection certificates or their equivalents wherever applicable to any Program Patent Rights;

(g) to endeavor in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the Patent Prosecution of the other Party's patent applications related to inventions within the Program Materials and Program Technology; and

(h) to make its employees, Affiliates, agents, independent contractors and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives and, in any case, at the directing or acting Party's expense as provided in this Article 9) to the extent reasonably necessary by the other Party in connection with Patent Prosecution, the pursuit of infringement claims against Third Parties relating to the Program Patent Rights or the defense of infringement or misappropriation claims by Third Parties relating to the Program Technology, the Program Materials or a Collaboration Product.

9.6 Disputes Regarding Intellectual Property. Without limiting or otherwise restricting the Parties' respective rights and obligations expressly set forth in the other provisions of this Article 9, the Parties agree that any dispute between them over the ownership, validity, enforceability or infringement

of any Patent Rights related to the Collaboration and Controlled by either Party that cannot be resolved between them after following the procedures of Section 14.8 shall be presented only to a court of competent jurisdiction for resolution.

## ARTICLE 10 CONFIDENTIALITY

### 10.1 Nondisclosure Obligations.

10.1.1 General. Except as otherwise provided in this Article 10, during the term of this Agreement and for a period of [\*] thereafter, or longer if required by any agreement with a Third Party relating to such Confidential Information, each Receiving Party shall maintain the Confidential Information of each Disclosing Party in confidence and use it only for purposes specifically authorized under this Agreement. Upon the expiration or termination of this Agreement, each Party shall promptly inform the other Party in writing if any Confidential Information the other Party received from such Party hereunder is covered by such a Third Party agreement with such Party and if the term of confidentiality for such Confidential Information will extend beyond such [\*] period.

10.1.2 Limitations. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement and subject to advance written notification to the Disclosing Party: (a) a Party may disclose Confidential Information it is otherwise obligated not to disclose under this Section 10.1, to its Affiliates, sublicensees, consultants, outside contractors and clinical investigators, on a strict need-to-know basis for the purposes contemplated by this Agreement and on condition that such entities or persons agree to keep the Confidential Information confidential for the same time periods and to the same extent as such Party is required to keep the Confidential Information confidential hereunder; and (b) a Party or its sublicensees may disclose, using appropriate measures to preserve confidentiality, such Confidential Information to government or other regulatory authorities to the extent that such disclosure is reasonably necessary to obtain authorizations to conduct clinical trials of, and to commercially market, Collaboration Products pursuant to this Agreement. Furthermore, a Receiving Party may request permission from the Disclosing Party to disclose such Confidential Information to the extent that such disclosure is reasonably necessary to obtain patents which such Receiving Party is permitted to obtain hereunder, which permission shall not be unreasonably withheld or delayed.

10.1.3 Required Disclosure. A Receiving Party may disclose Confidential Information pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demand issued by a court or governmental agency or as otherwise required by Law; *provided, however*, that the Receiving Party shall notify the Disclosing Party promptly upon receipt thereof, giving (where practicable) the Disclosing Party sufficient advance notice to permit it to oppose, limit or seek confidential treatment for such disclosure; and *provided, further*, that the Receiving Party shall furnish only that portion of the Confidential Information which it is advised by counsel is legally required whether or not a protective order or other similar order is obtained by the Disclosing Party.

10.2 Injunctive Relief. The Parties hereto understand and agree that remedies at law may be inadequate to protect against any breach of any of the provisions of this Article 10 by either Party or their employees, agents, officers or directors or any other person acting in concert with it or on its behalf. Accordingly, each Party shall be entitled to the granting of injunctive relief by a court of competent jurisdiction against any action that constitutes any such breach of this Article 10.

### 10.3 Publication.

10.3.1 SPRI may publish or present data and/or results relating to a Collaboration Product, subject to the prior review of the proposed disclosure by XOMA, solely for the purposes of determining (a) whether the proposed disclosure contains the Confidential Information of XOMA or (b) whether the information contained in the proposed disclosure should be the subject of a patent application to be filed by XOMA prior to such disclosure. SPRI shall provide XOMA with the opportunity to review any proposed abstract, manuscript or presentation by delivering a copy thereof to XOMA no less than [\*] before its intended submission for publication or presentation. XOMA shall have [\*] from its receipt of any such abstract, manuscript or presentation in which to notify SPRI in writing of any specific objections to the disclosure, based on either the need to seek patent protection or concern regarding the specific disclosure of the Confidential Information of XOMA, and XOMA shall so notify SPRI within such time period. In the event XOMA objects to the disclosure for a reason identified above, the SPRI agrees not to submit the publication or abstract or make the presentation containing the objected-to information until XOMA is given a reasonable additional period of time (not to exceed an additional [\*]) to seek patent protection for any material in the disclosure which XOMA believes is patentable (subject, in all events, to Section 10.2) or, in the case of Confidential Information, to allow the SPRI to delete any Confidential Information of XOMA from the proposed disclosure. The SPRI agrees to delete from the proposed disclosure any Confidential Information of XOMA upon request.

10.3.2 Notwithstanding anything herein to the contrary, the Parties agree that XOMA may use “blinded” data (so long as such use does not jeopardize the patentability of any invention claimed by a patent or patent application filed by SPRI) for purposes of demonstrating, presenting or otherwise promoting its technologies, expertise, capabilities and/or applications of any thereof. With respect to the immediately preceding sentence, XOMA shall submit such blinded data to SPRI for approval at least [\*] prior to disclosure, such approval not to be unreasonably withheld. The blinded data shall not reveal the identity of SPRI, any Collaboration Target or any Program Antibody.

10.3.3 In any manuscript, publication or presentation relating to the Collaboration, SPRI will acknowledge the contributions of XOMA (including, where appropriate, co-authorship), giving equal prominence in such manuscript, publication or presentation to the name of the other Party.

10.4 Publicity. The terms and conditions of this Agreement are Confidential Information hereunder and, except as expressly set forth herein, SPRI and XOMA each agree not to disclose any terms or conditions of this Agreement to any Third Party without first obtaining the written approval of the other Party prior to such disclosure. The Parties hereby agree to the release of a press release in the form attached hereto as Schedule 10.4 upon full execution of this Agreement and the terms that are expressly described in such press release shall be deemed to be in the public domain. The Parties may thereafter from time to time (a) mutually agree on revisions to material to be used as a routine reference, which revisions shall be submitted by one Party for the review and approval of the other Party at least [\*] prior to the anticipated use or disclosure of the revised material, such approval not to be unreasonably withheld or delayed, and (b) disclose any such agreed revised information without consulting the other Party. The terms of this Agreement shall be treated as the Confidential Information of SPRI and XOMA, and, except to the extent required by applicable law, shall not be disclosed except as otherwise provided herein without the written permission of XOMA or SPRI. If either Party desires to release a separate announcement relating to this Agreement, it shall first allow the other Party [\*] to approve in writing such proposed announcement; *provided* that such approval shall not be unreasonably withheld or delayed. Nothing herein

shall be deemed to prohibit, restrict or limit any disclosure that is consistent in all material respects with prior disclosures.

## ARTICLE 11

### REPRESENTATIONS AND WARRANTIES

11.1 Representations, Warranties and Covenants of SPRI. SPRI represents and warrants to and covenants with XOMA that:

11.1.1 SPRI is a corporation duly organized, validly existing and in corporate good standing under the laws of New Jersey;

11.1.2 SPRI has the corporate and legal right, authority and power to enter into this Agreement, and to extend the rights and licenses granted to XOMA in this Agreement;

11.1.3 SPRI has taken all necessary action to authorize the execution, delivery and performance of this Agreement;

11.1.4 upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of SPRI, enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting Parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

11.1.5 the performance of SPRI's obligations under this Agreement will not conflict with its charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a Party or violate any court or administrative order by which it is bound; and

11.1.6 neither it nor any of its employees or consultants working on the Collaboration have been debarred pursuant to the FDC Act or are currently excluded, debarred, suspended or otherwise ineligible to participate in Federal health care program and SPRI shall promptly notify XOMA of any change in this warranty and representation.

11.2 Representations, Warranties and Covenants of XOMA. XOMA represents and warrants to and covenants with SPRI that:

11.2.1 XOMA is a limited liability company duly organized, validly existing and in good standing under the laws of Delaware;

11.2.2 XOMA has the corporate and full legal right, authority and power to enter into this Agreement, and to extend the rights and licenses granted to SPRI in this Agreement;

11.2.3 XOMA has taken all necessary corporate action to authorize the execution, delivery and performance of this Agreement;

11.2.4 upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of XOMA enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting Parties' rights generally and except as enforceability

may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

11.2.5 the performance of its obligations under this Agreement will not conflict with XOMA's charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a Party [\*] or violate any court or administrative order by which it is bound;

11.2.6 neither it nor any of its employees or consultants working on the Collaboration have been debarred pursuant to the FDC Act or are currently excluded, debarred, suspended or otherwise ineligible to participate in Federal health care program and XOMA shall promptly notify SPRI of any change in this warranty and representation;

11.2.7 [\*].

11.3 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY PRODUCT, PATENT RIGHTS, GOODS, SERVICES, MATERIALS OR ANY OTHER SUBJECT MATTER OF THIS AGREEMENT, AND EACH PARTY HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

11.4 Limited Liability. EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT, NEITHER SPRI NOR XOMA WILL BE LIABLE WITH RESPECT TO ANY MATTER ARISING UNDER THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY PUNITIVE, EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOST PROFITS.

## ARTICLE 12

### INDEMNITY

12.1 SPRI Indemnity Obligations. SPRI agrees to defend, indemnify and hold XOMA, its Affiliates and their respective employees and agents harmless from all claims, losses, damages or expenses (including reasonable attorneys' fees and costs of litigation) arising as a result of: (a) actual or asserted violations of any applicable law or regulation by SPRI, its sublicensees and their respective Affiliates by virtue of which any Collaboration Products manufactured, distributed or sold by SPRI, its sublicensees or their respective Affiliates hereunder shall be alleged or determined to be adulterated, misbranded, mislabeled or otherwise not in compliance with any applicable law or regulation; (b) claims for bodily injury, death or property damage attributable to the manufacture, distribution, sale or use of any Collaboration Products by SPRI, its sublicensees or their respective Affiliates; (c) a recall of a Collaboration Product manufactured, distributed or sold by SPRI, its sublicensees or their respective Affiliates ordered by a governmental agency or required by a confirmed Collaboration Product failure as reasonably determined by the Parties hereto; or (d) SPRI's breach of any of its representations, warranties or covenants hereunder.

12.2 XOMA Indemnity Obligations. XOMA agrees to defend, indemnify and hold SPRI, its Affiliates and their respective employees and agents harmless from all claims, losses, damages or expenses (including reasonable attorneys' fees and costs of litigation) arising as a result of: (a) actual or asserted violations of any applicable law or regulation by XOMA, its sublicensees and their respective Affiliates by virtue of which any Collaboration Products manufactured, distributed or sold by XOMA, its sublicensees or their respective Affiliates hereunder shall be alleged or determined to be adulterated, misbranded, mislabeled or otherwise not in compliance with any applicable law or regulation; (b) claims for

bodily injury, death or property damage attributable to the manufacture, distribution, sale or use of any Collaboration Products by XOMA, its sublicensees or their respective Affiliates; (c) a recall of a Collaboration Product manufactured, distributed or sold by XOMA, its sublicensees or their respective Affiliates hereunder ordered by a governmental agency or required by a confirmed Collaboration Product failure as reasonably determined by the Parties hereto; or (d) XOMA's breach of any of its representations, warranties or covenants hereunder.

12.3 Limitation on Indemnity Obligations. Neither Party, its Affiliates or their respective employees and agents shall be entitled to the indemnities set forth in Sections 12.1 or 12.2, respectively, to the comparative extent the claim, loss, damage or expense for which indemnification is sought was caused by a negligent, reckless or intentional act or omission by such Party, its directors, officers, employees or authorized agents.

12.4 Procedure. If a Party or any of its Affiliates or their respective employees or agents (collectively, the "Indemnitee") intends to claim indemnification under this Article 12, the Indemnitee shall promptly notify the other Party (the "Indemnitor") of any loss, claim, damage, liability or action in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall assume the defense thereof with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; *provided, however,* that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other Party represented by such counsel in such proceedings. The Indemnitor shall have the right to settle or compromise any claims for which it is providing indemnification under this Article 12, *provided* that the consent of the Indemnitee (which shall not be unreasonably withheld or delayed) shall be required in the event any such settlement or compromise would adversely affect the interests of the Indemnitee. The indemnity agreement in this Article 12 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to the Indemnitor's ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 12 resulting from such failure, but the omission so to deliver notice to the Indemnitor will not relieve it of any liability that it may have to any Indemnitee otherwise than under this Article 12. The Indemnitee under this Article 12, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by this indemnification.

12.5 Insurance. Each Party shall maintain appropriate product liability insurance (and/or self-insurance) with respect to Research and Development and Manufacture of Collaboration Products by such Party in such amount as such Party customarily maintains with respect to sales of its other products. Each Party shall maintain such insurance for so long as it continues to manufacture or sell Collaboration Products, and thereafter for so long as such Party customarily maintains insurance with respect to sales of its other products.

### ARTICLE 13

#### EXPIRATION AND TERMINATION

13.1 Term of Agreement. The term of this Agreement shall commence on the Effective Date and shall continue until the latest of (a) the expiration or termination of the last to expire of any Valid Claim or pending claim within the Program Patent Rights or other Patent Rights Covering the manufacture, use or sale of any Collaboration Product with respect to which SPRI would have a payment obligation

to XOMA hereunder, (b) the expiration of the royalty term provided for in Section 7.4, and (c) the cessation of all Research and Development activities with respect to all Program Antibodies, Collaboration Targets and/or Collaboration Products, as applicable, pursuant to the terms hereof.

13.2 SPRI Unilateral Right to Terminate. SPRI shall have the unilateral right to terminate this Agreement for any reason and at any time following the date that is [\*] after the Effective Date by providing XOMA with [\*] advance written notice of such termination. Following receipt of such notice, (a) XOMA shall cease all Collaboration activities as soon as reasonably practicable and use Commercially Reasonable and Diligent Efforts to minimize Collaboration costs, and (b) SPRI shall continue to pay during such notice period the full amount contemplated in the respective R&D Plan with respect to work to be conducted by XOMA based on XOMA's fully funded FTE rates, as well as during and after such notice period all committed, non-cancellable Third Party Collaboration costs incurred by XOMA for work set forth in the respective R&D Plan, provided that in the event that XOMA elects to pursue on its own a Collaboration Product that is the subject of a terminated R&D Plan, then SPRI shall not be obliged to make any such payments to XOMA after such [\*] period has expired.

13.3 Events of Default. An "Event of Default" by either Party shall have occurred upon (a) the occurrence of a material breach of this Agreement if such Party fails to remedy such breach within [\*] after written notice thereof by the non-breaching Party (["\*"] in the event of a Party's failure to make a payment required hereunder) or, if remediation of such breach (other than a payment breach) within [\*] is not practicable, if such Party fails to commence and diligently pursue such remediation during such [\*] period, or (b) the commencement of any proceeding in or for bankruptcy, insolvency, dissolution or winding up by or against such Party that is not dismissed or otherwise disposed of within [\*] thereafter.

13.4 Effect of an Event of Default. In the event of an Event of Default, the non-defaulting Party shall have the right, at its option exercisable in its sole discretion, in addition to any other rights or remedies available to it at law or in equity and subject to the limitations set forth in Sections 3.8, 11.4 and 14.8 hereof, to (a) if the Event of Default directly relates to less than all Collaboration Targets, Program Antibodies and Collaboration Products, by written notice to the other Party, deem that such Party has abandoned work on the Collaboration Target(s), Program Antibodies and/or Collaboration Product(s) to which such Event of Default directly relates, or (b) if the Event of Default directly relates to all Collaboration Targets, Program Antibodies and Collaboration Products, by written notice to the other Party, deem that such Party has terminated this Agreement in its entirety.

13.5 XOMA's Rights After Unilateral Termination by SPRI or Termination for an Event of Default by SPRI. In the event SPRI terminates this Agreement pursuant to Section 13.2 or this Agreement is terminated pursuant to Section 13.4 for an Event of Default by SPRI, all R&D Programs as to which such termination relates shall terminate, the licenses granted under Section 6.1.1 by XOMA to SPRI with respect to all Collaboration Products as to which such termination relates shall terminate, except for the license granted in Section 6.1.1(b) which shall be converted to a co-exclusive license between SPRI and XOMA and shall become fully-sublicensable, and (for the avoidance of doubt) the provisions of Section 2.1.3 as to all Collaboration Targets as to which such termination relates shall terminate for XOMA but shall remain in effect for SPRI. At the option of XOMA, XOMA shall be free to continue any R&D Program as to which such termination relates or development or commercialization of a Collaboration Product as to which such termination relates on its own, in which event, notwithstanding anything herein to the contrary:

- (a) the licenses granted to XOMA herein shall remain in effect with respect thereto;

(b) SPRI shall be deemed to have granted to XOMA

(i) an exclusive right and license, with the right to sublicense, under SPRI's interests in any Program Patent Rights and Program Technology relating to any Program Antibodies or Collaboration Products, to make, have made, use, sell and import such Antibodies or products; and

(ii) a co-exclusive (with SPRI) right and license, with the right to sublicense, under any other of SPRI's interests in Program Patent Rights, to make, have made, use, sell and import Antibodies;

(c) SPRI shall transfer to XOMA all Program Materials and Program Technology requested by XOMA, including but not limited to ownership of all cell lines, including Master Cell Banks, that produce, as applicable, Collaboration Products to such Collaboration Target or such Collaboration Product and as to which ownership was previously transferred to SPRI pursuant to Section 5.3; and

(d) without limiting the foregoing, SPRI shall (i) deliver to XOMA copies of all such data, information, registrations and applications therefore (or, where appropriate, otherwise provide XOMA with reasonable access, directly or indirectly, to such data, information, registrations or applications (e.g., by way of a letter of access to a Drug Master File or similar filing)) as are existing, and (ii) grant such other licenses and/or sublicenses as are available under any Patent Rights Controlled by SPRI as of the date of such termination, subject to XOMA being responsible for any Third Party payments for such licenses or sublicenses, where each of (i) or (ii) is reasonably necessary to enable XOMA to pursue the development and commercialization of such Collaboration Product(s).

XOMA's option in the preceding sentence shall be subject to XOMA paying to SPRI the consideration provided for in the last paragraph of Section 8.3, if any, with respect to any such R&D Program or Collaboration Product as to which such option is exercised. For the avoidance of doubt, SPRI's license in Section 6.1.1(b), converted to co-exclusive as provided above, shall continue to be subject to its continuing payment obligations under Section 6.1.1(b).

13.6 SPRI's Rights After Termination for an Event of Default by XOMA In the event this Agreement is terminated pursuant to Section 13.4 for an Event of Default by XOMA, all R&D Programs as to which such termination relates shall terminate, the licenses granted under Section 6.1.2 by SPRI to XOMA with respect to all Collaboration Products as to which such termination relates shall terminate and (for the avoidance of doubt) the provisions of Section 2.1.3 as to all Collaboration Targets as to which such termination relates shall terminate for SPRI but shall remain in effect for XOMA. At the option of SPRI, SPRI shall be free to continue any R&D Program as to which such termination relates or development or commercialization of a Collaboration Product as to which such termination relates on its own, in which event, notwithstanding anything herein to the contrary:

(a) the licenses granted to SPRI herein shall remain in effect with respect thereto;

(b) XOMA shall transfer to SPRI all Program Materials and Program Technology requested by SPRI, including but not limited to ownership of all cell lines, including Master Cell Banks, that produce, as applicable, Collaboration Products to such Collaboration Target or such Collaboration Product and as to which ownership has not previously been transferred to SPRI pursuant to Section 5.3; and

(c) without limiting the foregoing, XOMA shall (i) deliver to SPRI copies of all such data, information, registrations and applications therefore (or, where appropriate, otherwise provide SPRI with reasonable access, directly or indirectly, to such data, information, registrations or applications (e.g., by way of a letter of access to a Drug Master File or similar filing)) as are existing, and (ii) grant such other licenses and/or sublicenses as are available under any Patent Rights Controlled by XOMA as of the date of such termination, subject to SPRI being responsible for any Third Party payments for such licenses or sublicenses, where each of (i) or (ii) is reasonably necessary to enable SPRI to pursue the development and commercialization of such Collaboration Product(s).

SPRI's option in the preceding sentence shall be subject to SPRI paying to XOMA, with respect to any such R&D Program or Collaboration Product as to which such option is exercised, (i) a royalty on Net Sales of any products so licensed in an amount equal to [\*] the royalty that SPRI would have been required to pay XOMA hereunder, and for the term of a Valid Claim of any Program Patent Rights Covering such products, had such product been a Collaboration Product and (ii) milestone payments in amounts equal to [\*] the payments that SPRI would have been required to pay XOMA hereunder had such product been a Collaboration Product.

13.7 Effect of Expiration or Termination of Agreement. The expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. In no way limiting the generality of the foregoing, the provisions of Articles 1, 10 - 12 and 14, and Sections 2.1.3, 2.2.5, 4.3.1, 7.3 - 7.5, 7.8 - 7.13, 8.3, 8.5, 9.1 and 13.4 - 13.7, hereof shall survive the expiration or termination of this Agreement.

#### ARTICLE 14

#### MISCELLANEOUS

14.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any obligation under this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including but not limited to fire, floods, embargoes, war, acts of war (whether war is declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority; *provided, however*, that the Party so affected shall use reasonable commercial efforts to avoid or remove such causes of nonperformance, and shall continue performance hereunder with reasonable dispatch whenever such causes are removed. Either Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of force majeure. The Parties shall mutually seek a resolution of the delay or the failure to perform as noted above.

14.2 Assignment. This Agreement may not be assigned or otherwise transferred, in whole or in part, by either Party without the consent of the other Party; *provided, however*, that either SPRI or XOMA may, without such consent, assign its rights and obligations under this Agreement (i) to any Affiliate, or (ii) in connection with a merger, consolidation or sale of such portion of a Party's assets that includes rights under this Agreement to an unrelated Third Party; *provided, further*, that such Party's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction and shall not be transferred separate from all or substantially all of its other business assets, including those business assets that are the subject of this Agreement. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement, unless the Parties otherwise agree.

14.3 Bankruptcy. All rights and licenses granted under this Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title XI of the United States Code (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101(56) of the Bankruptcy Code. The Parties agree that the licensing Party under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code in the event of a bankruptcy by the other Party. The Parties further agree that in the event of the commencement of a bankruptcy proceeding by or against one Party under the Bankruptcy Code, the other Party shall be entitled to complete access to any such intellectual property pertaining to the rights granted in the licenses hereunder of the Party by or against whom a bankruptcy proceeding has been commenced and all embodiments of such intellectual property.

14.4 Severability. Each Party hereby agrees that it does not intend to violate any public policy, Law, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions in lieu of such invalid provisions. In case such valid provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

14.5 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by telephone, personal delivery or courier) or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon receipt by the addressee.

If to SPRI: Schering-Plough Research Institute  
2015 Galloping Hill Road  
Kenilworth, New Jersey 07033  
Attention: Discovery Collaborations & Technology  
Telephone: 908-740-3290  
Facsimile: 908-740-7164

with a copy to: Schering-Plough Corporation  
2000 Galloping Hill Road  
K-6-1 (1800)  
Kenilworth, New Jersey 07033  
Attention: Staff Vice President, Research Contracting  
Telephone: 908-298-4249  
Facsimile: 908-298-5388

If to XOMA: XOMA (US) LLC  
2910 Seventh Street  
Berkeley, California 94710  
Attention: Legal Department  
Telephone: (510) 204-7200  
Facsimile: (510) 649-7571

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with a copy to: XOMA (US) LLC  
2910 Seventh Street  
Berkeley, California 94710  
Attention: Vice President, Business Development  
Telephone: (510) 204-7200  
Facsimile: (510) 649-7571

14.6 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without reference to the conflicts of law principles thereof.

14.7 Forum Selection; Consent to Jurisdiction. Any litigation based hereon, or arising out of, under, or in connection with this Agreement, shall be brought and maintained exclusively in the state or federal courts located within New York County, the State of New York. The Parties hereby expressly and irrevocably submit to the jurisdiction of the courts located within New York County, the State of New York for the limited purpose of any such litigation as set forth above. The Parties further irrevocably consent to the service of process by registered mail, postage prepaid, or by personal service. The Parties hereby expressly and irrevocably waive, to the fullest extent permitted by law, any objection which it may now or hereafter have to the laying of venue of any such litigation brought in any such court referred to above and any claim that any such litigation has been brought in an inconvenient forum.

14.8 Dispute Resolution. Except for those matters that are to be resolved by the Joint Steering Committee and the JRDC as set forth in Section 3.8 herein acting in good faith, the Parties hereby agree that they will first attempt in good faith to resolve any controversy or claim arising out of or relating to this Agreement promptly by negotiations. If a controversy or claim should arise hereunder the manner of resolution of which is not addressed in Section 3.8, the matter shall be referred to the Representatives. If the matter has not been resolved within [\*] of the first meeting of the Representatives (which period may be extended by mutual agreement) concerning such matter, the Parties shall be free to pursue all available recourse both at law and in equity.

14.9 Entire Agreement. This Agreement, together with the exhibits and appendices hereto and any confidentiality agreement(s) executed in contemplation of this Agreement, contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties hereto.

14.10 Headings. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

14.11 No Partnership. It is expressly agreed that the relationship between SPRI and XOMA shall not constitute a partnership, joint venture or agency. Neither SPRI nor XOMA shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party to do so.

14.12 Exports. The Parties acknowledge that the export of technical data, materials or products is subject to the exporting Party receiving any necessary export licenses and that the Parties cannot be responsible for any delays attributable to export controls which are beyond the reasonable control of either Party. SPRI and XOMA agree not to export or re-export, directly or indirectly, any information, technical data, the direct product of such data, samples or equipment received or generated under this Agreement in violation of any applicable export control laws or governmental regulations. SPRI and

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XOMA agree to obtain similar covenants from their licensees, sublicensees, or corporate partners, as the case may be, and contractors with respect to the subject matter of this Section 14.12.

14.13 Waiver. The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

14.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties have caused their duly authorized officers to execute and deliver this Agreement as of the Effective Date.

**SCHERING CORPORATION, acting through its  
Schering-Plough Research Institute division**

By: /s/ Robert Bertolini  
Name: Robert Bertolini  
Title: Chief Financial Officer

**XOMA (US) LLC**

By: /s/ John L. Castello  
Name: John L. Castello  
Title: Chairman of the Board, President and  
Chief Executive Officer

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**Schedule 1.42**

[\*]

**Schedule 1.61**

[\*]

**Schedule 1.75**

[\*]

**Schedule 7.13**

[\*]

**Schedule 7.14**

[\*]





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**SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

**ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

The purpose of this acquisition is to seek to advance the development of a mixture of three monoclonal antibodies (mAbs) as a therapeutic against Botulinum neurotoxin serotype A, which is a Category A threat agent.

**ARTICLE B.2. ESTIMATED COST PLUS FIXED FEE**

- a. The estimated cost of this contract is \$15,347,397.
- b. The fixed fee for this contract is \$920,844. 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 the contract. Payment of fixed fee shall not be made in less than monthly increments.
- c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee is \$16,268,241.
- d. Total funds currently available for payment and allotted to this contract are \$16,268,241, of which \$15,347,397 represents the estimated costs, and of which \$920,844 represents the fixed fee. For further provisions on funding see the LIMITATION OF COSTS clause referenced in Part II, ARTICLE I.1.,
- e. It is estimated that the amount currently allotted will cover performance of the contract through July 27, 2009.

**ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

**a. Items Unallowable Unless Otherwise Provided**

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, 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 paragraph b.(2) below); (6) Consultant costs;
- (7) Subcontracts;
- (8) Overtime;
- (9) Patient care costs;
- (10) Light Refreshment and Meal Expenditures

Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the project officer, with a copy to the contracting officer, at least six (6) weeks in advance of the event. The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshment and/or meal costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held somewhere other than a government facility, provide an explanation of why the event is not being held at a government facility.

Refer to NIH Manual Chapter 1160-1, Entertainment, for more information on NIH's policy on the use of appropriated funds for light refreshments and meals.

**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 \$27,399 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) 31.205-46.

**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. Indirect Costs**

- (1) Overhead and General and Administrative (G&A) Ceiling

A current negotiated indirect rate agreement is not in place at the time of the award. The proposed overhead rate – see Section J, Attachment 6 — and G&A rate of 32.2% will be ceiling for the purpose of funding until a negotiated rate agreement with NIH is in effect. Once a negotiated Overhead and G&A rates agreement is in place, Overhead and G&A costs will be adjusted and reimbursed accordingly.
- (2) The Government is not obligated to pay any additional amount should the final indirect cost rates exceed the attached ceiling rates. In the event that the final indirect cost rates are less than these negotiated ceiling rates, the Government's obligation shall be reduced to conform to the lower rate.

Any costs over and above this cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement.

**b. Subcontracts**

- (1) Consent is provided to enter into a Cost-plus-fixed-fee type subcontract with SRI International, 333 Ravenswood Avenue, Menlo Park, CA 94025, in an amount not to exceed \$882,722.

The period of performance of this subcontract shall be from the date of contract award until July 27, 2009. Within 30 calendar days after receipt of written consent from the Contracting Officer, a copy of the final executed subcontract shall be provided to the Contracting Officer.
- (2) Consent is provided to enter into a Cost Reimbursement type subcontract with the University of California, San Francisco, Office of Research Administrator, 3333 California Street, Suite 315, San Francisco, CA 94118, in an amount not to exceed \$956,891.

The period of performance of this subcontract shall be from the date of contract award until July 27, 2009. Within 30 calendar days after receipt of written consent from the Contracting Officer, a copy of the final executed subcontract shall be provided to the Contracting Officer

**c. Consultants**

Consultant fees to be paid to the following individuals:

<u>Name</u>	<u>Rate</u>	<u>Number of Days/Hours</u>	<u>Travel Cost</u>	<u>Total Cost Not to Exceed</u>
Barbara Matthews – BioDirect	\$ 2,200/day	18 days	\$ 3,000	\$ 42,600
Stephen Zale	\$ 2,000/day	2 days		\$ 4,000
John Carpenter	\$ 400/hour	150 hours		\$ 60,000

**d. Confidential Treatment of Sensitive Information**

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

**e. Contract Number Designation**

On all correspondence submitted under this contract, the contractor agrees to clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. HHSN266200600008C  
ADB Contract No. N01-AI-60008

**SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

**ARTICLE C.1. STATEMENT OF WORK**

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, SECTION J, ATTACHMENT 1, dated July 28, 2006, attached hereto and made a part of this contract.

**ARTICLE C.2. REPORTING REQUIREMENTS**

All reports required herein shall be submitted in paper copy and electronic format.

As part of the work to be performed under this RFP, the Contractor shall prepare and deliver the following reports throughout the period of performance. For all reports the Contractor shall submit two (2) paper copies and two (2) electronic copies, comprising one (1) original paper and one (1) electronic copy to the NIAID Contracting Officer and one (1) paper copy and one(1) electronic copy to the NIAID Project Officer.

A. **Technical Reports**

**1. Monthly Progress Report**

On the due date specified in the contract the Contractor shall submit a Monthly Progress Report. A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted. The Monthly Progress Report shall include:

- a) Cover page that lists the contract number and title, the period of performance being reported, the contractor's name, address, telephone number, fax number and email address and the date of submission;
- b) SECTION I: INTRODUCTION - describes the purpose and scope of the contract effort;
- c) SECTION II: PROGRESS
  - i) SECTION II Part A: OVERALL PROGRESS - A description of overall progress on the contract to date;
  - ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE 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. evaluating and managing subcontractors performance);
  - iii) SECTION II Part C: TECHNICAL PROGRESS – For each activity document the results of work completed and cost incurred during the reporting period, in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain any significant 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 corrective action; differences between planned and actual progress, why the differences have occurred and what correction actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;
  - iv) SECTION II Part D: - PROPOSED WORK - A summary of work proposed for the next reporting period; and
  - v) Preprints and reprints of papers and abstracts shall be submitted with the Monthly Report.

**2. DRAFT Annual Progress Report**

The Contractor shall provide the Project Officer with two (2) copies of the Annual Progress Report in **draft** form twenty-eight (28) calendar days prior to the delivery date for the final version of the report. The Project Officer will review the draft report and provide the Contractor with comments within fourteen (14) calendar days after receipt. The Annual Progress Report shall be corrected by the Contractor, if necessary.

**3. Annual Progress Report**

On the due date specified in the contract the Contractor shall submit an Annual Progress Report. An Annual Progress Report will not be required for the period when the Final Report is due. Each Annual Report shall include:

- a) A Cover page that lists the contract number and title, the period of performance being reported, the contractor's name, address, telephone number, fax number and email address and the date of submission;
- b) SECTION I: EXECUTIVE SUMMARY – A brief overview of the work completed, and the major accomplishments achieved during the current reporting period;
- c) SECTION II: PROGRESS
  - i) SECTION II Part A: OVERALL PROGRESS - A description of overall progress on the contract to date;
  - ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE 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. evaluating and managing subcontractors performance);

- iii) **SECTION II Part C: TECHNICAL PROGRESS** – For each activity document the results of work completed and cost incurred during the reporting period, in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain any significant 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 corrective action; differences between planned and actual progress, why the differences have occurred and what correction actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;
- iv) **SECTION II Part D: - PROPOSED WORK** - A summary of work proposed for the next reporting period;
- v) Preprints and reprints of papers and abstracts shall be submitted with the Monthly Progress Report; and
- vi) A summary of any inventions developed during the course of the contract.

#### **4. Draft Final Report**

The Contractor shall provide the Project Officer with two (2) copies of the Final Report in draft form twenty-eight (28) calendar days prior to the delivery date for the final version of the Final Report. The Project Officer will review the Draft Final Report and provide the Contractor with comments within fourteen (14) calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary.

#### **5. Final Report**

The Final Report shall be submitted on expiration date of the contract. An Annual Progress Report shall not be required for the period when the Final Report is due. The Final Report shall document and summarize the results of the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall include:

- a) a cover page to include the contract number, contract title, performance period, Contractor's name and address, telephone number, fax number, email address and submission date;
- b) **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.
- c) **SECTION II: RESULTS** – A detailed description of the work-performed, the results obtained, and the impact of the results and the scientific or public health community, including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance, and a summary of all inventions.

#### **6. Invention Report Requirement**

All reports and documentation required by FAR Clause 52.227-13 including: the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of 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(a)(2)(ii)) shall be submitted on the expiration date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES, of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the following address:

Contracting Officer, Office of Acquisitions  
National Institutes of Health, DHHS  
National Institute of Allergy and Infectious Diseases  
Room 3214, MSC 7612  
6700B Rockledge Drive  
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 Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

**7. Summary of Salient Results**

The Contractor shall submit, with the Final Report, a Summary of Salient results achieved during the performance of the contract.

**8. Milestone Report**

The contractor shall submit a Milestone Report as specified in the contract after the completion of each Milestone unless otherwise agreed by the Principal Investigator and the Project Officer. Milestone Reports may be appended to Monthly Progress Reports if approved by the NIAID Project Officer. The Milestone Report shall include:

- a) a Cover page that lists the contract number and title, the milestone being reported, the period of performance being reported, the contractor's name, address, telephone number, fax number and email address and the date of submission;
- b) SECTION I: INTRODUCTION – A brief overview of the purpose and scope of the contract effort and the specific milestone that is covered in the report; and
- c) SECTION II: PROGRESS
  - i) SECTION II Part A: OVERALL PROGRESS - A description of overall progress on the contract to date and the milestone specifically;
  - ii) SECTION II Part B: TECHNICAL PROGRESS – For the milestone document the results of work completed, a summary of data that supports the completion of the milestone and an analysis of the results. The report shall be in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data. The report shall include a description of problems encountered, corrective actions implemented; differences between planned and actual progress and why the differences occurred, conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

**B. Technical Reports Delivery Schedule**

Satisfactory performance of the contract is defined as satisfactorily performing the Statement of Work and delivering the following items.

Item	Type of Deliverable	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
1.	Monthly Progress Report	The 15 <sup>th</sup> of the month following the first full month of contract award.	1 Original and 1 electronic to CO 2 Paper copies and 1 electronic to PO	Monthly, due on or before the 15 <sup>th</sup> of each month. A Monthly Progress Report will not be due when an Annual Progress Report or Final report is due.
2.	Draft Annual Progress Report	28 days before the anniversary date of contract	See Above	Annually, submitted 28 days before the anniversary date. An Annual Progress Report is not due when a Final Report is due.
3.	Annual Progress Report	Anniversary date of contract	See Above	Annually, on the anniversary date of the contract.
4.	Draft Final Report	28 days before the expiration date of the contract.	See Above	Twenty eight (28) days prior to the final due date.
5.	Final Report	On the expiration date of the contract.	See Above	On the expiration date of the contract.
6.	Invention Report	On the expiration date of the contract.	See Above	Submit along with the Final Report.
7.	Summary of Salient Results	On the expiration date of the contract.	See Above	Submit along with the Final Report.
8.	Milestone Report	See A.8. above		

**C. Other Reports/Deliverables**

The following are also considered deliverable under this contract: Assay Development Reports, Process Development Reports, Validation Protocols, Validation Reports, testing protocols, Technology Transfer Reports for assays and processes developed and/or improved under the contract, interim and final GLP, cGMP and GCP audit reports, SOPs, Batch Production Records, Master Production Records, Certificate of Analysis for cGMP products, CMC section for FDA submission, copies of FDA correspondence, and regulatory documentation required by the FDA.

All physical materials produced under the contract, including reagents, test article/product, and samples from nonclinical safety studies. The Contractor shall package and ship according to all applicable federal guidelines for packaging and shipping hazardous material or cGMP product.

**Bulk Drug Substance:** All remaining Bulk Drug Substance not used to produce final drug product shall be delivered to NIAID as directed by the NIAID Project Officer.

**Final Drug Product:** In addition, to each type of final drug product required to complete the IND-enabling studies to be performed as part of this statement of work, the Contractor shall deliver, at a minimum, to NIAID as directed by the NIAID Project Officer:

- One thousand (1000) vials of formulated mixture of three monoclonal antibodies, vialled and labeled with a Certificate of Analysis; and
- Five hundred (500) vials of each of three single monoclonal antibodies, formulated, vialled and labeled with a Certificate of Analysis.

**D. Copies of reports shall be sent to the following addresses:**

Liem T. Nguyen, Contracting Officer  
 Office of Acquisitions, DEA, NIAD, NIH, DHHS  
 6700 B Rockledge Dr., Room 3214  
 Bethesda, MD 20817

and

Katherine A. Taylor, Ph.D.,  
 Project Officer, DMID, NIAID, NIH, DHHS  
 6610 Rockledge Dr., Room 5123  
 Bethesda, MD 20892

**ARTICLE C.3. INVENTION REPORTING REQUIREMENT**

All reports and documentation required by FAR Clause 52.227-13 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(a)(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 ARTICLE F.1. DELIVERIES of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the following address:

Contracting Officer  
National Institutes of Health  
National Institute of Allergy and Infectious Diseases  
Office of Acquisition  
6700B Rockledge Drive, 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.

**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: DMID, NIAID, NIH, DHHS, 6610 Rockledge Drive, Bethesda, MD, 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 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984).  
FAR Clause 52.246-8, Inspection Of Research And Development—Cost Reimbursement (May 2001).

**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 Article C.1. 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 SECTION C, ARTICLE C.2. 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:

<u>Item No.</u>	<u>Type of Report</u>	<u>No. of Copies</u>	<u>Addresses/Distribution</u>	<u>Due Date</u>
<b>PROGRESS REPORTS</b>				
1.	Monthly Technical Progress Report	3 paper 2 electronic	CO: Original hardcopy and one (1) electronic copy; PO: Two (2) paper copies and one (1) electronic	The 15 <sup>th</sup> of each month following the first full month of contract award. The monthly report will not be required on months when an Annual Technical Report is due.
2.	Draft Annual Progress Report	See above	Same as CO and PO above	Annually, submitted twenty eight (28) days before the anniversary date.
3.	Annual Progress Report	See above	Same as CO and PO above	Annually, on the anniversary date of the contract. An Annual Progress Report is not due when a Final Report is due.
4.	Draft Final Report	See above	Same as CO and PO above	Twenty eight (28) calendar days prior to completion date of the contract
5.	Final Report	See above	Same as CO and PO above	On the expiration date of the contract.
6.	Invention Report	See above	Same as CO and PO above	Submit along with the Final Report.
7.	Summary of Salient Results	See above	Same as CO and PO above	Submit along with the Final Report.
8.	Milestone Report	See paragraph A.8. above	Same as CO and PO above.	
<b>Other Reports/ Deliverables</b>				
9.	See paragraph C. Other Reports/Deliverables above	Same as above	Same as PO above	As directed by the NIAID PO

- b. The above items shall be addressed and delivered to:

<u>Addressee</u>	<u>Deliverable Item No.</u>	<u>Quantity</u>
Liem T. Nguyen, Contracting Officer 6700B Rockledge Drive Rm 3214 Rockledge Drive Bethesda, MD 20892	1. through 8.	Original paper and one (1) electronic
Kathy M. Taylor, Ph.D. Project Officer 6610 Rockledge Drive, Room 5123 Bethesda, MD 20892	1. through 9.	Two (2) paper copies and one (1) electronic
EITRB, Office of Biodefense Research Affairs, NIH	6.	Original paper and one (1) electronic

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

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. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

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 A. Taylor, Ph.D.  
OBRA, DMID, NIAID, NIH, DHHS  
6610 Rockledge Drive, Room 5123  
Bethesda, MD 20892  
Phone: 301-451-5068  
Email: [ktaylor@niaid.nih.gov](mailto:ktaylor@niaid.nih.gov)

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 any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.

The Government may unilaterally change its Project Officer designation.

**ARTICLE G.2. KEY PERSONNEL**

Pursuant to HHSAR Clause 352.270-5, Key Personnel, incorporated in Section I of this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

<u>Name</u>	<u>Title</u>
Milan T. Tomic, Ph.D.	Principal Investigator

Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate

**ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST**

- 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 instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a “proper” payment request pursuant to FAR 32.9.
- These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.
- (1) Invoices/financing requests shall be submitted as follows:
    - (a) To be considered a “proper” invoice in accordance with FAR 32.9, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:  
Contract No. HHSN266200600008C  
ADB Contract No. N01-AI-60008
    - (b) An original and two copies to the following designated billing office:  
Contracting Officer  
Office of Acquisitions, DEA  
National Institute of Allergy and Infectious Diseases, NIH, DHHS  
Room 3214, MSC 7612  
6700B Rockledge Drive  
BETHESDA MD 20892-7612
  - (2) Inquiries regarding payment of invoices should be directed to the designated billing office, 301-451-3687.
- b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified 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 applicable Public Law Number for the applicable Fiscal Year as stated in SECTION H of the above referenced contract.”
- c. Cost and Personnel Reporting, and Variances from the Negotiated Budget
- (1) The contractor agrees to provide a detailed breakdown on invoices of the following cost categories:
    - (a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed
    - (b) Bonus
    - (c) Fringe Benefits (cite rate, base and amount)
    - (d) Facility Costs (cite rate, base and amount)
    - (e) Materials & Supplies - Include detailed breakdown when total amount is over \$1,000

- (f) Travel (Domestic and Foreign) - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel
- (g) Workshops and Advisory Committee Meeting Expenses
- (h) Consultant Fees (Honoraria and Instructor Fees) - Identify individuals and amounts
- (i) Freight & Postage
- (j) CRS Allocated (cite base, rate and amount)
- (k) Glassware allocated (cite base, rate and amount)
- (l) Subcontracts - Attach subcontractor invoice(s)
- (m) Equipment - Cite authorization and amount.
- (n) G&A (cite rate, base and amount)
- (o) Total Cost
- (p) Fixed Fee
- (q) Total CPPF

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

- (2) The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the 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 BLVD 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 evaluations will be prepared bi-annually to coincide with the anniversary date of the contract.

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 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.2. 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.3. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

- a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used 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.

b.	Public Law and Section No.	Fiscal Year	Period Covered
	P.L. 109-149, Title V-General Provisions Section 509	2006	10/1/2005-9/30/2006

**ARTICLE H.4. NEEDLE EXCHANGE**

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

<b>Public Law and Section No.</b>	<b>Fiscal Year</b>	<b>Period Covered</b>
P.L. 109-149, Title V-General Provisions Section 505	2006	10/1/2005-9/30/2006

**ARTICLE H.5. 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.6. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES**

All contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

<http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/>

**ARTICLE H.7. INFORMATION SECURITY**

The Statement of Work (SOW) requires the contractor to develop or access Federal automated information systems; therefore, the contractor shall comply with the "DHHS Information Security Program Policy" (<http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgram.doc>) as set forth below. The contractor shall include this provision in any subcontract awarded under this contract.

a. Information Type

**Administrative, Management and Support Information:**

**Mission Based Information:**

b. Security Categories and Levels

\*\*\*\* (NOTE: The resultant contract will include the Security Categories and Levels, however for the purposes of this RFP, the Security Categories and Levels are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) \*\*\*\*

Confidentiality	Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity	Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability	Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
<b>Overall</b>	<b>Level:</b>	<input checked="" type="checkbox"/> <b>Low</b>	<input type="checkbox"/> <b>Moderate</b>	<input type="checkbox"/> <b>High</b>

c. Position Sensitivity Designations

- (1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract:
- Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).
  - Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).
  - 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).

- (2) The contractor shall submit a deliverable, by name, position and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of staffing changes shall be submitted within fifteen (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, ARoster 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 Investigation required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the ANIAID Information Technology Security Policies, Background Investigation Process@ website: <http://ais.nci.nih.gov>.

(NOTE: The website listed at <http://ais.nci.nih.gov> provides information about IT Security Policies and the background investigation process. NCI points of contact do not apply to this acquisition. Contact your NIAID contract specialist for applicable contact information.)

Contractor employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.

- (3) Contractor employees shall comply with the DHHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor 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 in paragraph c.(2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the preappointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor employee to work under the contract.

d. Systems Security Plan

The contractor shall protect Federal automated information systems that are developed or accessed by the contractor. System security shall be accomplished in accordance with the contractor's System Security Plan dated (upon award). The plan must:

- (1) Include a detailed plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The contractor shall use the **NIH Systems Security Plan Template** (detailed) at <http://irm.cit.nih.gov/security/secplantemp.doc> or **NIH Systems Security Plan Outline** (outline only) at [http://irm.cit.nih.gov/nihsecurity/Security\\_Plan\\_Outline.doc](http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc).

Include an acknowledgment of its understanding of the security requirements.

Provide similar information for any proposed subcontractor developing or accessing an AIS.

e. Rules of Behavior

The contractor shall comply with the **NIH Information Technology General Rules of Behavior** at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Information Security Training

Each contractor employee shall complete the NIH Computer Security Awareness Training (<http://irtsectraining.nih.gov/>) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of this contract.

The contractor shall maintain a listing by name and title of each individual working under this contract that has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing.

Contractor staff shall complete the following additional training prior to performing any work under this contract:

g. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the **A**Employee Separation Checklist@, attached and made a part of this contract, when a contractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request

h. Commitment to Protect Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor shall not release, publish, or disclose sensitive Department 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 sensitive 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 employee who may have access to sensitive Department information under this contract shall complete 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.

i. References

1. DHHS Information Security Program Policy: <http://www.hhs.gov/ohr/manual/pssh.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIST Special Publication 800-16, Information Technology Security Training Requirements: <http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>  
Appendix A-D: <http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf>
4. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: <http://csrc.nist.gov/publications/nistpubs/index.html>
5. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories,

Volume I: <http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf>

6. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: <http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf>
7. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: <http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf>
8. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>
9. Roster of Employees Requiring Suitability Investigations: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>
10. NIAID Information Technology Security Policies, Background Investigation Process: <http://ais.nci.nih.gov/>
11. NIH Systems Security Plan Template (detailed): <http://irm.cit.nih.gov/security/secplantemp.doc>
12. NIH Systems Security Plan Outline (outline only): [http://irm.cit.nih.gov/nihsecurity/Security\\_Plan\\_Outline.doc](http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc)
13. NIH Information Technology General Rules of Behavior: <http://irm.cit.nih.gov/security/nihitrob.html>
14. Commitment To Protect Non-Public Information - Contractor Agreement: <http://irm.cit.nih.gov/security/Nondisclosure.pdf>

#### ARTICLE H.8. SALARY RATE LIMITATION LEGISLATION PROVISIONS

- a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. 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 per year 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>Public Law No.</b>	<b>Fiscal Year</b>	<b>Dollar Amount of Salary Limitation</b>
P.L. 109-149, Public Health & Social Services Emergency Fund	FY 06	Executive Level I

- c. Payment of direct salaries is limited to the Executive Level I\* rate which was in effect on the date(s) the expense was incurred.

*For the period 10/1/05 - 12/31/05, the Executive Level I rate is \$180,100. Effective January 1, 2006, the Executive Level I rate increased to \$183,500 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:*

**FOR FY-06 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2006:**

<http://www.opm.gov/oca/06tables/html/ex.asp>

*(Note: This site shows the FY-06 rates. For previous years, click on “salaries and wages” and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates.)*

#### ARTICLE H.9. PUBLICATION AND PUBLICITY

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. HHSN266200600008C/N01-AI-60008.”

**ARTICLE H.10. PRESS RELEASES**

- a. Pursuant to Public Law(s) cited in paragraph b., below, 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.

<b>Public Law and Section No.</b>	<b>Fiscal Year</b>	<b>Period Covered</b>
P.L. 109-149, Title V-General Provisions Section 506	2006	10/1/2005-9/30/2006

**ARTICLE H.11. 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](mailto: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.12. ANTI-LOBBYING**

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

<b>c.</b>	<b>Public Law and Section No.</b>	<b>Fiscal Year</b>	<b>Period Covered</b>
	for a., above: P.L. 109-149, Title V-General Provisions Section 503a.	FY-06	10/1/2005-9/30/2006
	for b., above: P.L. 109-149, Title V-General Provisions Section 503b.	FY-06	10/1/2005-9/30/2006

**ARTICLE H.13. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR**

NIAID may collaborate with an outside investigator who has proprietary rights to compounds which may be assigned under this contract. This collaborator will be identified by the Project Officer (PO) at the time of assignment and in this case, the following option regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NIAID and "Collaborator" in writing of any inventions, discoveries or innovations

made by the contractor's principal investigator or any other employees or agents of the contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Agent (hereinafter "Contractor Inventions").

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (2) a time-limited first option to negotiate an exclusive world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Contractor Inventions on terms to be negotiated in good faith by Collaborator and Contractor. Collaborator shall notify Contractor, in writing, of its interest in obtaining an exclusive license to any Contractor Invention within six (6) months of Collaborator's receipt of notice of such Contractor Invention(s). In the event that Collaborator fails to so notify Contractor or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Contractor Invention, and Contractor will be free to dispose of its interests in such Contractor Invention in accordance with its own policies. If Contractor and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter, Contractor shall not offer to license the Contractor Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Contractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 U.S.C. 201(e),\* arising out of any unauthorized use of the Collaborator's Study Agent shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Contractor will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all right, title and interest in an to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Contractor may also be conducting other more basic research using Study Agent under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

\*35 U.S.C. (e): The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d)(FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

#### **Protection of Proprietary Data**

Data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the and the Collaborator. The Contractor retains the right to publish research results subject to the terms of this contract.

#### **ARTICLE H.14. 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.*

##### **a. Sharing of Model Organisms for Biomedical Research**

The plan for sharing model organisms submitted by the contractor is acceptable. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

#### ARTICLE H.15. SHARING RESEARCH DATA

The data sharing plan submitted by the contractor is acceptable. 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 expedite the translation of research results into knowledge, products, and procedures to improve human 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.16. 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](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)), as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to *foreign institutions* that possess, use, and/or transfer Select Agents under this contract, before using NIH funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to the NIAID, NIH 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 at:

([http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf))

are in place and will be administered on behalf of all Select Agent work sponsored 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. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 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](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)). The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

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](http://www.aphis.usda.gov/programs/ag_selectagent/index.html); and [http://www.aphis.usda.gov/programs/ag\\_selectagent/ag\\_bioterr\\_forms.html](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](http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm)

**ARTICLE H.17. 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.18. 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.19. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH**

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine (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-05-022.html>.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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/far/>.

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

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	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	Jun 2003	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	Oct 2003	Central Contractor Registration
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
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
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
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	Oct 1997	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	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
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
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
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	Dec 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	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 \$500,000)
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	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor- Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	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:

<b>HHSAR CLAUSE NO.</b>	<b>DATE</b>	<b>TITLE</b>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[ End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 10/2004].

**ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES**

ARTICLE I.1. of this SECTION is hereby modified as follows:

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

**ARTICLE I.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 **52.219-25, Small Disadvantage Business Participation Program – Disadvantaged Status and Reporting** (October 1999).
- (2) FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).
- (3) FAR Clause **52.227-14, Rights in Data - General** (June 1987).
- (4) **Alternate II** (June 1987), FAR Clause **52.227-14, Rights in Data—General** (June 1987). Additional purposes for which the limited rights data may be used are:
- (5) **Alternate III** (June 1987), FAR Clause **52.227-14, Rights in Data—General** (June 1987).  
Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows:
- (6) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
- (7) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
- (8) FAR Clause **52.242-4, Certification of Final Indirect Cost** (January 1997).
- (9) FAR Clause **52.246-23, Limitation of Liability** (February 1997). AND/OR
- (10) FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997).
- (11) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
- (12) FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (April 2003).

- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:
- (1) HHSAR Clause **352.223-70, Safety and Health** (January 2001). [This clause is provided in full text in Section J - Attachments.]
  - (2) HHSAR Clause **352.224-70, Confidentiality of Information** (April 1984 - including revisions mandated by the 1/3/2005 Federal Register notice which was effective March 2005).
  - (3) HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).
  - (4) HHSAR Clause **352.270-9, Care of Live Vertebrate Animals** (March 2005).
- 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) (OMB Bulletin 81-16).

**ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT**

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

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.nlr.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 20210, 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.

PART III

**SECTION J - LIST OF ATTACHMENTS**

The following documents are attached and incorporated in this contract:

1. Statement of Work, 7/28/2006, 4 pages.
2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (5/97), 5 pages.
3. Safety and Health, HHSAR Clause 352.223-70, (1/01), 1 page.
4. Procurement of Certain Equipment, NIH(RC)-7, 4/1/84.
5. Commitment To Protect Non-Public Information.  
Available on the web at the following address: <http://irm.cit.nih.gov/security/Nondisclosure.pdf>.
6. XOMA Proposed Indirect Rates

PART IV

**SECTION K - REPRESENTATIONS AND CERTIFICATIONS**

The following documents are incorporated by reference in this contract:

1. Representations and Certifications, dated March 17, 2006.

**END of the SCHEDULE  
(CONTRACT)**

STATEMENT OF WORK

**DEVELOPMENT OF A FINAL DRUG PRODUCT FOR A MIXTURE OF MONOCLONAL ANTIBODIES FOR  
TYPE A BOTULINUM NEUROTOXINS  
RFP NIH-NIAID-DMID-06-38**

**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. Through this contract NIAID is seeking to advance the development of a mixture of three monoclonal antibodies (mAbs) as a therapeutic against botulinum neurotoxin serotype A, which is a Category A threat agent. The three mAbs were discovered by Dr. James Marks at the University of California San Francisco (UCSF). The mixture of the three mAbs has demonstrated neutralizing activity for botulinum neurotoxin subtypes A1 and A2 in a small laboratory animal model. The NIAID is currently funding XOMA to manufacture by current Good Manufacturing Process (cGMP) bulk drug substance of the three mAbs. To this end, XOMA negotiated a non-exclusive agreement with UCSF to access the three mAbs. XOMA recloned the three mAbs into proprietary commercial production cell lines and named the mAbs NX01, NX02 and NX11. Master Cell Banks and Master Working Cell Banks were produced by XOMA and small amounts of each mAb have been produced for use in development of analytical assays, clone selection, and verification of neutralizing activity in a small animal model. XOMA is developing a manufacturing process for each of the mAbs and will manufacture and deliver at least 7.0 grams of each as a cGMP bulk drug substance.

**OVERALL PURPOSE AND SCOPE**

Through this contract with XOMA the NIAID will support activities to complete the development of NX01, NX02 and NX11 mAbs from three separate cGMP bulk drug substances to three formulated, finished, vialled and labeled as single mAbs final drug products, and finally to one formulated mixture of the three mAbs finished, vialled and labeled as a final drug product. The final drug product should be suitable for clinical evaluation by sterile intravenous infusion. Using the Master Working Cell Banks that the Contractor produced under contract N01AI50004, the Contractor shall manufacture additional cGMP mAb bulk drug substance as directed by the NIAID Project Officer to complete the development of the final drug products, and to perform IND-enabling studies and a Phase 1 clinical trial. The Contractor shall perform viral clearance validations for a minimum of three viruses for the final production process of the mAbs. The Contractor shall formulate, finish, vial, and label the final drug product as three single mAb formulations and a mixture of the three mAbs. The optimal ratio of the three antibodies in the mixture shall be determined by the Contractor from potency, pharmacokinetic and stability studies. A single vial of the mixture shall contain an equal or greater number of neutralizing units for botulinum serotype A1, as the licensed equine anti-toxin product, unless otherwise directed through discussions with the FDA. The neutralizing units for botulinum serotype A2 shall be agreed upon through discussion with the FDA and NIAID Project Officer. The final drug product shall be formulated for maximum stability when stored at -20 C or 4 C, as determined in accelerated stability studies. The Contractor shall plan and implement a long-term stability program for all of the final drug product and the remaining bulk drug product.

The Contractor shall develop and either qualify or validate (depending on regulatory requirements) assays to support: a) nonclinical and clinical pharmacokinetic studies; b) nonclinical toxicity and safety studies; and c) formulation, lot release, and stability studies. In addition, the Contractor shall perform nonclinical IND-enabling studies to assess toxicity, safety, and pharmacokinetics. The Contractor shall participate with NIAID in meetings with the FDA and preparation of the IND application. The Contractor shall be responsible for performing studies and activities in compliance with Good Laboratory Practice (GLP: as defined in the U.S. Code of Federal Regulations – 21CFR§58) and current Good Manufacturing Practice guidelines (cGMP: as defined in the U.S. Code of Federal Regulations – 21CFR§211), including data management and quality control systems.

The Contractor is expected to use knowledge, reagents, materials, and bulk drug substance produced under contract N01-AI-50004 to most efficiently perform the activities outlined in this Statement of Work and as agreed upon with the NIAID Project Officer and Contracting Officer. The NIAID is aware that this Statement of Work requires facilities with select agent approval and biosafety level 2 facilities, experience and trained personnel. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. The Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

#### 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 provide the following:

- 1) Manufacture additional cGMP mAb bulk drug substance as requested by the NIAID Project Officer as follows:**
    - a) estimate and justify the total amount of GMP bulk drug substance that will be required to complete the studies included in the Statement of Work for this contract;
    - b) manufacture cGMP bulk drug substance as requested by the NIAID Project Officer;
    - c) Aliquot and store cGMP bulk drug substance under cGMP conditions as agreed upon with the NIAID Project Officer;
    - d) develop and implement a stability program for the bulk drug substance; and
    - e) ship the cGMP bulk drug substance as requested by the NIAID Project Officer.
  - 2) Perform viral clearance validations for three viral types for the final production process**
  - 3) Produce fully formulated final drug products from the cGMP mAb bulk drug substances as follows:**
    - a) formulate each of the three mAbs individually for optimal potency, safety, and stability;
    - b) finish, vial, and label the single mAbs as final drug product as requested by the NIAID Project Officer;
    - c) formulate a mixture of the three mAbs for optimal potency, safety, and stability;
    - d) finish, vial and label the mAb mixture bulk drug product as requested by the NIAID Project Officer;
    - e) store the final drug products under cGMP conditions;
    - f) develop and implement a stability program for the final drug products;
    - g) ship the final drug product as requested by the NIAID Project Officer;
    - h) provide a final formulation and product characterization report to the NIAID Project Officer; and
    - i) provide all data and analysis for the CMC section of the IND application to the NIAID Project Officer.
  - 4) Develop and qualify and/or validate assays, depending on regulatory requirements, for IND-enabling studies or a Phase 1 clinical trial, to support:**
    - a) nonclinical and clinical pharmacokinetic studies: Assays shall include at least one assay capable of differentiating the three mAbs and one assay capable of assessing neutralizing activity in the plasma of laboratory animals and humans. The assays are required to support pharmacokinetic studies in laboratory animals and humans involving doses that range from 0.02 mg antibody/kg to 2.0 mg antibody/kg;
    - b) nonclinical toxicity and safety studies; and
    - c) formulation, lot release, and stability studies as required for bulk drug substances and final drug products.
- 4.1.** For each assay the Contractor shall:
- a) develop the assay, qualify and/or validate the assay, and provide critical reagents;
  - b) submit a final assay qualification and/or validation report; and
  - c) submit a technology transfer package at the request of the NIAID Project Officer.

**5) Perform nonclinical IND-enabling studies to assess toxicology, safety and pharmacokinetics of the mAbs as follows:**

- a) develop a plan for the performance of all IND-enabling nonclinical toxicology, safety and pharmacokinetic studies;
- b) perform nonclinical toxicology, safety and pharmacokinetic safety studies with formulated cGMP product according to GLP guidelines;
- c) provide a final report to the NIAID Project Officer; and
- d) provide all data and analysis as requested by the NIAID Project Officer for submission in the IND application.

**6) Perform regulatory compliance and data management as follows:**

- a) provide data management and quality control systems/procedures, including data transmission, storage, and retrieval;
- b) provide for the statistical design and analysis of data resulting from the research undertaken;
- c) provide raw data or specific analyses of data generated with contract funding to the NIAID Project Officer;
- d) ensure strict adherence to FDA regulations and guidance, including requirements for the conduct of animal studies and assays under GLP and the production of bulk drug product and final drug products under cGMP;
- e) arrange for independent audits as needed or as requested by the NIAID 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 NIAID Project Office and the NIAID 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. Such audits may also be conducted prior to contract award; and
- f) participate with NIAID in meetings with the FDA regarding the IND application and approval for the product.

**7) Technical, Management, and Administrative Team**

The Contractor shall provide all expertise needed for the performance of the Statement of Work, including research, manufacturing, regulatory, statistical, management and administrative activities. The team must include strong scientific leadership as well as significant experience and expertise in the management, design and execution of a product development program focused on manufacturing, formulation and nonclinical IND-enabling studies. The Principal Investigator (PI) shall be responsible for all aspects of project performance and communication with the NIAID Project Officer and the NIAID Contracting Officer. In addition, the Contractor shall provide Project Manager(s) who are responsible for the day-to-day monitoring and tracking of progress and timelines, the coordination of project activities and costs incurred. The Contractor shall provide and implement a plan that addresses how the activities of the prior Fixed-Price contract shall be accounted for separately and apart from the activities of this cost reimbursement contract.

**8) Project Management**

The Contractor shall provide for:

- b) the overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;
- c) effective communication with the NIAID Project Officer and the NIAID Contracting Officer;
- d) a PI with responsibility for overall project management and communication, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors;

- e) Project Manager(s) with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities and costs incurred;
- f) administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors; and
- g) The organization of a bi-annual one day meeting to include the PI, key personnel, key subcontractor personnel, consultants, the NIAID Project Officer, the NIAID Contracting Officer and up to 2 other key NIAID staff. One meeting to be held in Bethesda and one meeting to held at the Contractor's site.

The Contractor shall prepare and provide all reports and other deliverables listed in the "Reporting Requirements and Other Deliverables" section of this solicitation.

**9) Facilities, Equipment and Other Resources**

The Contractor shall provide the equipment, facilities, and other resources required to perform all parts of the Statement Work in compliance with all Federal and NIH regulations, either in their own facilities or through subcontractor(s). This shall include the performance of in vitro and in vivo IND-enabling studies under GLP, production of mAbs under cGMP, the humane care and use of vertebrate animals, and receiving, storing, and handling dangerous biological agents, including Select agents under biosafety levels required for working with the biological agents under study. A copy of the current interim CDC/NIH DRAFT guidelines in the Biosafety in Microbiology and Biomedical Laboratories, 4<sup>th</sup> edition is available at: <http://www.cdc.gov/od/ohs/biosfty/bmb14toc.htm>.

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

**General:** The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

**Format:** Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal— Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

**Number of Copies:** As indicated in the Invoice Submission Clause in the contract.

**Frequency:** Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise 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 amount and month(s) in which such costs were incurred shall be cited.

**Contractor's Fiscal Year:** Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

**Currency:** All NIH contracts are expressed in United States dollars. When payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States 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 so identified and reference the Contracting Officer's Authorization (COA) Number. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

**Invoice/Financing Request Identification:** Each invoice/financing 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 is 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 this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.
- (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 explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

- (a) **Designated Billing Office Name and Address**— Enter the designated billing office and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

- (b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request.
- (c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.
- (d) **Contract Number, ADB Number and Date**— Insert both the contract number and the ADB number (which appears in the upper left hand corner of the face page of the contract), and the effective date of the contract.
- (e) **Payee's Name and Address**— Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.
- (f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.
- (g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.
- (h) **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.
- (i) **Incurred Cost — Current C** Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.
- (j) **Incurred Cost — Cumulative C** Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.
- (k) **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 Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.
- (2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.
- (3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of \$1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach the NIH Form entitled, "Report of Government Owned, Contractor Held Property," in accordance with the following instructions:  
List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):
- The item number for the specific piece of equipment listed in the Property Schedule.
  - The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule.
  - An asterisk (\*) shall precede the item if the equipment is below the approval level.
- (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's Advance Understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being 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.
- (l) **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.
- (m) **Indirect Costs—Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.
- (n) **Fixed-Fee Earned** — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.
- (o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.
- (p) **Adjustments** — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.
- (q) **Grand Totals**

**The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing 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 doing contract negotiations 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—Incurred Cost-Current** - Enter the costs, which were incurred during the current period.

**Column E—Incurred Cost-Cumulative** - Enter the cumulative cost 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 during contract negotiations 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) Billing Office Name and Address  
 NATIONAL INSTITUTES OF HEALTH  
 National Cancer Institute, OA  
 EPS, Room  
 6120 EXECUTIVE BLVD MSC  
 Bethesda, MD 20892-
- (b) Invoice/Financing Request No. \_\_\_\_\_  
 (c) Date Invoice Prepared \_\_\_\_\_
- (d) Contract No. \_\_\_\_\_  
 ADB No. \_\_\_\_\_  
 Effective Date \_\_\_\_\_
- (e) Payee's Name and Address  
 ABC CORPORATION  
 100 Main Street  
 Anywhere, USA zip code
- (f) Total Estimated Cost \_\_\_\_\_
- (g) Total Fixed Fee \_\_\_\_\_

Attn: Name, Title, & Phone Number of Official to Whom  
 Payment is Sent

- (h) This invoice/financing request represents reimbursable costs for the period from \_\_\_\_\_ to \_\_\_\_\_

Expenditure Category A*	Cumulative Percentage of Effort/Hrs.		Incurred Cost		Cost at Completion F	Contract Amount G	Variance H
	Negotiated B	Actual C	(i) Current D	(j) Cumulative E			
(k) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property (attach HHS-565)							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(l) Cost of Money							
(m) Overhead G&A							
(n) Fixed Fee							
(o) Total Amount Claimed							
(p) Adjustments							
(q) Grand Totals							

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

(Name of Official)

(Title)

\* Attach details as specified in the contract

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

- (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).
- (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 officer, 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 promptly 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 operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

PROCUREMENT OF CERTAIN EQUIPMENT

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 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)  
OMB Bulletin 81-16

ATTACHMENT 4



**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, John L. Castello, 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 officers 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 function):
  - 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: August 9, 2006

/s/ JOHN L. CASTELLO

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**John L. Castello**  
**Chairman of the Board, President and**  
**Chief Executive Officer**

**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, J. David Boyle II, 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 officers 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 function):
  - 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: August 9, 2006

/s/ J. DAVID BOYLE II  
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**J. David Boyle II**  
**Vice President, Finance and Chief Financial Officer**

**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 June 30, 2006, 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: August 9, 2006

/s/ JOHN L. CASTELLO

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**John L. Castello**  
**Chairman of the Board, President and**  
**Chief Executive 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.

**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 June 30, 2006, 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: August 9, 2006

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/s/ J. DAVID BOYLE II

**J. David Boyle II**  
**Vice President, Finance and Chief Financial 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.

# News Release



Paul Goodson  
Sr. Director, Investor Relations  
Tel: (510) 204-7270

## XOMA Reports Second Quarter 2006 Results

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**Berkeley, CA – August 9, 2006** – XOMA Ltd. (NASDAQ: XOMA), a leader in the discovery and development of antibody therapeutics for cancer and immunological disorders, today announced its results for the second quarter ended June 30, 2006.

### *Second Quarter Results*

XOMA recorded total revenues for the second quarter of \$7.5 million, an increase of \$2.3 million over the second quarter of 2005. Growth in revenues was due primarily to higher contract development and manufacturing revenues and growth in royalties from Genentech, Inc.'s ("Genentech", NYSE: DNA) RAPTIVA®.

The operating loss for the second quarter was \$9.0 million in 2006 compared with \$8.1 million in the 2005 quarter, reflecting the higher revenue in 2006, offset primarily by higher research and development expenses and contract service costs. The net loss for the second quarter of 2006 was \$5.9 million or (\$0.06) per share, compared with a net loss of \$8.6 million or (\$0.10) per share for the quarter ended June 30, 2005. Net non-cash credits related to convertible debt derivative accounting and debt conversions were \$4.1 million in the second quarter of 2006, which contributed to the reduction in net loss. A more detailed discussion of XOMA's second quarter financials is provided below, in XOMA's most recent 10-Q filing, and in a question and answer format on XOMA's website at <http://www.xoma.com/wt/page/investors>.

### *Recent Highlights*

- XOMA and Schering Corporation (NYSE: SGP) through its Schering-Plough Research Institute division ("Schering-Plough"), formed a collaboration for the development of therapeutic antibodies in which XOMA will receive up-front payments, funded R&D, milestones, and royalties. Based on currently anticipated development plans and costs, XOMA estimates that the aggregate amount of up-front, R&D funding and milestone payments under the collaboration could amount to between \$25 million and \$75 million.
- Taligen Therapeutics, Inc. ("Taligen") and XOMA completed a letter agreement for XOMA to develop processes, scale up, and manufacture quantities of Taligen's antibody product to support pre-clinical studies and entry into clinical trials.
- XOMA launched a new line of business based on its Human Engineering™ technology with the announcement of its agreement with AVEO Pharmaceuticals, Inc. ("AVEO") to humanize AV-299, an antibody being developed against a cancer target. Previously, XOMA had used Human Engineering™ only for its

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own and for partnered development programs. XOMA will receive up-front payments, milestones and royalties from AVEO.

- Genentech's LUCENTIS™ (ranibizumab injection) was approved by the Food and Drug Administration ("FDA") and sales began at the end of the quarter. XOMA will receive a royalty from Genentech on sales of LUCENTIS™.
- NEUPREX® clinical development progressed with the initiation of a trial for patients with severe burns and the clearance by FDA of the Investigational New Drug ("IND") application for a trial in hematopoietic stem cell transplant ("HSCT").
- During the second quarter, \$2.9 million of XOMA's 6.5% convertible notes were voluntarily converted to equity by the holders. The total face value of XOMA's outstanding convertible debt was \$56.6 million at June 30, 2006, on which date XOMA held \$34.9 million in cash, cash equivalents, and marketable securities.
- On July 14, 2006, the European Medicines Agency's ("EMA") Committee for Orphan Medicinal Products recommended to the European Commission that opebacan (NEUPREX®) be granted orphan medicinal product designation. XOMA is evaluating the possibility of submitting a marketing authorization application in Europe for NEUPREX® for meningococemia under the EMA's exceptional circumstances approval mechanism.
- On July 28, 2006, XOMA was awarded a \$16.3 million contract with the National Institute of Allergy and Infectious Diseases ("NIAID"), which follows NIAID's \$15.0 million contract award to XOMA in 2005 for antibody development work against botulinum neurotoxin.

"During the second quarter, we continued to make progress on multiple fronts to move products forward in XOMA's pipeline while reducing our financial and development risk," said John L. Castello, chairman of the board, president, and chief executive officer of XOMA. "In addition to advancing products toward approval, our corporate focus continues to be on securing new licensees for our technologies, forming new drug discovery collaborations and completing new contracts for antibody development and manufacturing. Because revenues from collaborations, licenses and manufacturing agreements occur only after agreements are completed and not in any designated quarter, XOMA's financial results may not show a smooth progression toward our goals."

### ***Financial Discussion***

#### ***Revenues***

Total revenues for the second quarter of 2006 were \$7.5 million, compared with \$5.2 million during the second quarter of 2005. Revenues for the first half of 2006 increased 60% to \$13.1 million from \$8.2 million in the first half of 2005.

License and collaborative fee revenues were \$0.7 million for the quarter ended June 30, 2006, compared with \$2.7 million for the same period of 2005. Contract revenues totaled \$4.7 million for the three months ended June 30, 2006, compared with \$0.9 million for the same period of 2005, reflecting an increase in contract manufacturing services performed under XOMA's existing contract with NIAID to develop three anti-botulinum neurotoxin monoclonal antibody therapeutics, which is 100% funded with federal funds from NIAID under Contract No. HHSN266200500004C, offset by a reduction in clinical trial services performed for Genentech in the 2005 quarter. Royalties were \$2.1 million for the second quarter of 2006 compared with \$1.6 million in the year-ago quarter, reflecting increases in royalty revenues from the sale of Genentech's RAPTIVA® and royalties from the initiation of sales of Genentech's LUCENTIS™ on the last day of the second quarter. Royalty percentages on BCE

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licenses range from 0.5% to 3% of net sales, and the royalty on LUCENTIS™ is toward the lower end of this range.

### ***Expenses***

XOMA's research and development expense for the second quarter of 2006 totaled \$12.1 million, compared with \$9.5 million for the same period of 2005. The \$2.6 million increase primarily reflects increases in spending on XOMA's contract with NIAID, its development efforts on XOMA 052 and NEUPREX®, and its collaboration with Lexicon Genetics, Inc. ("Lexicon", Nasdaq: LEXG), partially offset by decreased spending on its collaboration agreements with Genentech, Millennium Pharmaceuticals, Inc (Nasdaq: MLNM), and, primarily as a result of Novartis AG's ("Novartis", NYSE: NVS) acquisition of Chiron Corporation, Novartis.

General and administrative expense for the three months ended June 30, 2006, was \$4.4 million compared with \$3.7 million for the 2005 quarter. The increase of \$0.7 million resulted primarily from expenses relating to higher legal and consulting expenses.

XOMA recorded a net interest benefit for the second quarter totaling \$2.7 million. This net benefit consists primarily of interest payable of \$1.1 million, offset by an interest expense benefit of \$4.1 million primarily resulting from a decrease in fair value of the embedded derivative on XOMA's convertible debt. XOMA's second quarter 2005 interest expense of \$1.1 million consisted primarily of interest payable on its outstanding convertible notes.

### ***Liquidity and Capital Resources***

Cash, cash equivalents and short-term investments at June 30, 2006, totaled \$34.9 million compared with \$43.5 million at December 31, 2005. The \$8.6 million decrease from December 31, 2005, primarily reflects cash used in operations of \$18.5 million and cash used in the purchase of fixed assets of \$5.3 million, partially offset by cash provided by financing activities of \$15.1 million, primarily from the \$12.5 million in notes issued for cash in XOMA's convertible debt exchange. Cash used in operations during the second quarter of 2006 was \$4.8 million compared with \$13.5 million during the second quarter of 2005.

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

### ***Long Term Debt***

At June 30, 2006, XOMA had \$58.1 million of 6.5% convertible senior notes due in 2012, including the embedded derivative of \$5.5 million. Long term debt to Novartis totaled \$15.8 million, representing XOMA's cumulative draw down against a \$50.0 million loan facility established to facilitate XOMA's participation in its oncology collaboration with Novartis, plus accrued but unpaid interest.

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**Product Highlights**

**RAPTIVA® (Efalizumab): Royalty from Genentech**

Worldwide sales of RAPTIVA® in the second quarter of 2006 were \$39.2 million, with \$22.3 million coming from Genentech's sales in the U.S. and \$16.9 million from Serono SA's sales internationally. Worldwide sales in the second quarter of 2005 were \$28.6 million.

Worldwide sales of RAPTIVA® in the first half of 2006 were \$74.2 million compared with \$49.7 million for the first half of 2005. U.S. sales of RAPTIVA® for the first half of 2006 were \$43.6 million compared with \$37.9 million in the first half of 2005. International sales of RAPTIVA® for the first half of 2006 were \$30.6 million; sales outside of the U.S. for the same period of 2005 were \$11.8 million.

**LUCENTIS™ Approval: Royalty from Genentech**

On June 30, 2006, the FDA granted marketing approval to Genentech for LUCENTIS™, a monoclonal antibody therapy manufactured pursuant to a bacterial cell expression ("BCE") license from XOMA to treat neovascular (wet) age-related macular degeneration. XOMA will receive royalties on sales of LUCENTIS™.

**Oncology Therapeutic Antibodies Program: Collaboration with Novartis**

In 2005, XOMA and Chiron Corporation (now Novartis) initiated separate Phase I clinical trials in advanced chronic lymphocytic leukemia ("CLL") and multiple myeloma ("MM") with CHIR-12.12 (now HCD122), the first product candidate selected under the collaboration. Both of these studies are ongoing and XOMA hopes to announce preliminary results from them by the end of 2006.

**BPI Program: NEUPREX®**

NEUPREX® (opebacan) is an injectable formulation of rBPI<sub>21</sub>, a modified recombinant fragment of human bactericidal/permeability-increasing protein ("BPI"). BPI is a human host-defense protein made by a type of white blood cell that is involved in the body's defenses against microbial infection.

In March of 2006, XOMA began an Investigator Sponsored Trial ("IST") of NEUPREX® at the Southwestern Medical Center in Dallas for patients with severe burns. In July, the first patient was dosed under this trial. This IST joins with another IST initiated in October of 2003 for pediatric open heart surgery patients, which is expected to complete enrollment during the third quarter of 2006. Later this year, XOMA plans to sponsor a third trial for NEUPREX® in allogeneic HSCT. In addition to their conventional medical application in oncology, the HSCT studies may provide proofs of concept for the use of NEUPREX® in acute radiation syndrome as a possible biodefense indication.

**XOMA 052**

XOMA 052 (formerly XMA005.2) is a high-affinity, Human Engineered™ monoclonal antibody with potent inhibitory activity against its inflammatory target. XOMA developed this antibody independently and continues to own all rights to it. XOMA is currently evaluating XOMA 052 in preclinical studies. Possible indications include osteoarthritis and rheumatoid arthritis. Pre-clinical studies continued during the second quarter of 2006. XOMA plans to file an IND in December of 2006 and expects to start clinical testing for XOMA 052 in the first half of 2007.

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### **Subsequent Events**

On July 14, 2006, the EMEA's Committee for Orphan Medicinal Products recommended to the European Commission that opebacan (NEUPREX®) be granted orphan medicinal product designation. The European Commission is expected to act on the committee's recommendation in September or October of 2006. XOMA is also evaluating the possibility of submitting a marketing authorization application in Europe for NEUPREX® for meningococemia under the EMEA's "exceptional circumstances" approval mechanism.

On July 19, 2006, Cubist Pharmaceuticals, Inc. ("Cubist", Nasdaq: CBST) announced that it was ceasing further investment in the development of HepeX-B, including the suspension of XOMA's process development work and manufacturing of quantities of HepeX-B sufficient for Phase 3 clinical trials. On July 28, 2006, XOMA announced that it had placed its production process development work for Cubist on hold and issued a notice of contract termination to Cubist.

On July 28, 2006, XOMA was awarded a \$16.3 million contract with NIAID to produce monoclonal antibodies for the treatment of botulism to protect U.S. citizens against the harmful effects of botulinum neurotoxins used in bioterrorism. Under the three-year contract, XOMA will create and produce an innovative injectable product comprised of three anti-type A-botulinum neurotoxin monoclonal antibodies to support entry into Phase I safety human clinical trials. This contract is 100% funded with federal funds from NIAID under Contract No. HHSN266200600008C/N01-A1-60008. This contract follows NIAID's \$15.0 million contract award to XOMA in 2005 for antibody development work.

### **Investor Conference Call**

XOMA has scheduled an investor conference call and webcast to discuss its second quarter 2006 results for today, August 9, 2006, beginning at 5:00 pm EST (2:00 pm PST). The webcast can be accessed via XOMA's website at <http://www.xoma.com> and will be archived on the site until close of business on November 7, 2006. To obtain phone access to the live conference call in the U.S. and Canada, dial 1-877-407-9205. International callers should dial 1-201-689-8054. No conference ID is necessary. An audio replay will be available beginning two hours following the conclusion of the call through 11:59 pm Eastern (8:59 pm Pacific) on August 24, 2006. Access numbers for the replay are 1-877-660-6853 (U.S./Canada) or 1-201-612-7415 (International). Two access numbers are required for the replay: account number 286 and conference ID # 208075.

### **About XOMA**

XOMA is a leader in the discovery, development and manufacture of therapeutic antibodies, with a therapeutic focus that includes cancer and immune diseases. XOMA has royalty interests in RAPTIVA® (efalizumab), a monoclonal antibody product marketed worldwide (by Genentech and Serono, SA) to treat moderate-to-severe plaque psoriasis, and LUCENTIS™ (ranibizumab injection), a monoclonal antibody product marketed worldwide (by Genentech and Novartis AG) to treat neovascular (wet) age-related macular degeneration.

The Company has built a premier antibody discovery and development platform that includes access to seven of the leading commercially available antibody phage display libraries and XOMA's proprietary Human Engineering™ and BCE technologies. More than 45 companies have signed BCE licenses. XOMA's development collaborators

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include Lexicon, Novartis, and Schering-Plough. With a fully integrated product development infrastructure, XOMA's product development capabilities extend from preclinical sciences to product launch. For more information, please visit the Company's website at [www.xoma.com](http://www.xoma.com).

*Certain statements contained herein related to the sufficiency of XOMA's cash resources, levels of future expenses and cash, future sales of approved products, as well as other statements related to current plans for product development and existing and potential collaborative and licensing relationships, or that otherwise relate to future periods, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on assumptions that may not prove accurate. Actual results could differ materially from those anticipated due to certain risks inherent in the biotechnology industry and for companies engaged in the development of new products in a regulated market.*

*Among other things, the period for which XOMA's 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, or if funds are not otherwise available on acceptable terms; expense levels and cash utilization may be other than as expected due to unanticipated changes in XOMA's 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 competition, if physicians do not adopt the products as treatments for their patients or if remaining regulatory approvals are not obtained or maintained.*

*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-Q and in other SEC filings. Consider such risks carefully when considering XOMA's prospects.*

Condensed Financial Statements Follow

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

	<b>June 30,</b>	<b>December 31,</b>
	<b>2006</b>	<b>2005</b>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,798	\$ 20,804
Short-term investments	23,054	22,732
Receivables, net	5,602	5,186
Related party receivables	96	98
Prepaid expenses	1,217	975
Debt issuance costs	477	493
Total current assets	<u>42,244</u>	<u>50,288</u>
Property and equipment, net	21,940	19,056
Related party receivables – long-term	75	93
Debt issuance costs – long-term	2,187	2,683
Deposits	457	457
Total assets	<u>\$ 66,903</u>	<u>\$ 72,577</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>(NET CAPITAL DEFICIENCY)</b>		
Current liabilities:		
Accounts payable	\$ 3,525	\$ 5,648
Accrued liabilities	5,613	5,717
Accrued interest	1,472	1,652
Deferred revenue	4,849	3,527
Total current liabilities	<u>15,459</u>	<u>16,544</u>
Deferred revenue – long-term	5,075	4,333
Convertible debt – long-term	58,109	60,000
Interest bearing obligation – long-term	15,793	12,373
Total liabilities	<u>94,436</u>	<u>93,250</u>
Commitments and contingencies	—	—
Shareholders' equity (net capital deficiency):		
Preference shares, \$.05 par value, 1,000,000 shares authorized		
Series A, 135,000 designated, no shares issued and outstanding	—	—
Series B, 8,000 designated, 2,959 shares issued and outstanding; aggregate liquidation preference of \$29.6 million	1	1
Common shares, \$.0005 par value, 210,000,000 shares authorized, 97,409,289 and 86,312,712 shares outstanding at June 30, 2006 and December 31, 2005, respectively	49	43
Additional paid-in capital	674,698	655,041
Accumulated comprehensive income	(71)	(66)
Accumulated deficit	(702,210)	(675,692)
Total shareholders' equity (net capital deficiency)	<u>(27,533)</u>	<u>(20,673)</u>
Total liabilities and shareholders' equity (net capital deficiency)	<u>\$ 66,903</u>	<u>\$ 72,577</u>

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2006	2005	2006	2005
<b>Revenues:</b>				
License and collaborative fees	\$ 731	\$ 2,655	\$ 1,385	\$ 3,180
Contract and other revenue	4,681	933	7,775	2,192
Royalties	2,100	1,571	3,956	2,780
Total revenues	<u>7,512</u>	<u>5,159</u>	<u>13,116</u>	<u>8,152</u>
<b>Operating costs and expenses:</b>				
Research and development (including contract related of \$2,672 and \$4,611, respectively, for the three and six months ended June 30, 2006, and \$974 and \$1,785 for the three and six months ended June 30, 2005)	12,104	9,547	24,285	19,549
General and administrative	4,386	3,709	9,439	7,460
Total operating costs and expenses	<u>16,490</u>	<u>13,256</u>	<u>33,724</u>	<u>27,009</u>
Loss from operations	(8,978)	(8,097)	(20,608)	(18,857)
<b>Other income (expense):</b>				
Investment and interest income	385	418	842	987
Interest expense	2,681	(1,117)	(6,745)	(1,778)
Other income (expense)	(3)	252	(7)	41,184
Net income (loss) from operations before taxes	<u>(5,915)</u>	<u>(8,544)</u>	<u>(26,518)</u>	<u>21,536</u>
Provision for income taxes	—	38	—	38
Net income (loss)	<u><u>\$ (5,915)</u></u>	<u><u>\$ (8,582)</u></u>	<u><u>\$ (26,518)</u></u>	<u><u>\$ 21,498</u></u>
Basic net income (loss) per common share	<u><u>\$ (0.06)</u></u>	<u><u>\$ (0.10)</u></u>	<u><u>\$ (0.29)</u></u>	<u><u>\$ 0.25</u></u>
Diluted net income (loss) per common share	<u><u>\$ (0.06)</u></u>	<u><u>\$ (0.10)</u></u>	<u><u>\$ (0.29)</u></u>	<u><u>\$ 0.20</u></u>
Shares used in computing basic net income (loss) per common share	<u>96,661</u>	<u>86,253</u>	<u>92,326</u>	<u>85,997</u>
Shares used in computing diluted net income (loss) per common share	<u>96,661</u>	<u>86,253</u>	<u>92,326</u>	<u>115,332</u>