## SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# Form 10-Q

#### (Mark One)

 $\checkmark$ 

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

For the quarterly period ended June 30, 2007

or

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

For the transition period from

Commission file number: 000-24647

to

# **Dynavax Technologies Corporation**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

33-0728374 (IRS Employer Identification No.)

2929 Seventh Street, Suite 100 Berkeley, CA 94710-2753

(510) 848-5100

(Address, including Zip Code, and telephone number, including area code, of the registrant's principal executive offices)

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  $\Box$  No o

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 o  $\$  Accelerated filer  $\square$   $\$  Non-accelerated filer o

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

As of July 31, 2007, the registrant had outstanding 39,740,794 shares of common stock.

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This Quarterly Report on Form 10-Q includes trademarks and registered trademarks of Dynavax Technologies Corporation. Products or service names of other companies mentioned in this Quarterly Report on Form 10-Q may be trademarks or registered trademarks of their respective owners.

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#### FORWARD-LOOKING STATEMENTS

This Quarterly report on Form 10-Q contains 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 which are subject to a number of risks and uncertainties. Our forward-looking statements include discussions regarding our business and financing strategies, future research and development, preclinical and clinical product development efforts, intellectual property rights and ability to commercialize our product candidates, as well as the timing of the clinical development of our products, uncertainty regarding our future operating results and prospects for profitability. Our actual results may vary materially from those in such forward-looking statements as a result of various factors that are identified in "Item 1A – Risk Factors" and elsewhere in this document. All forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update any forward-looking statements.

### PART I. FINANCIAL STATEMENTS

### ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### Dynavax Technologies Corporation Condensed Consolidated Balance Sheets (In thousands, except per share amounts)

	June 30, 2007 (unaudited)	December 31, 2006 (Note 1)
Assets	(,	(
Current assets:		
Cash and cash equivalents	\$ 6,503	\$ 14,154
Marketable securities available-for-sale	40,977	58,677
Investments held by Symphony Dynamo, Inc.	35,098	13,363
Restricted cash	408	408
Accounts receivable	1,102	2,154
Inventory	248	257
Prepaid expenses and other current assets	1,760	673
Total current assets	86,096	89,686
Property and equipment, net	6,040	5,200
Goodwill	2,312	2,312
Other intangible assets, net	3,879	4,382
Other assets	155	1,310
Total assets	\$ 98,482	\$ 102,890
Liabilities, noncontrolling interest and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,405	\$ 2,181
Accrued liabilities	9,636	10,742
Deferred revenues	548	778
Total current liabilities	13,589	13,701
Deferred revenues, noncurrent	10,000	10,000
Liability from Program Option exercised under the SDI collaboration	15,000	—
Other long-term liabilities	82	117
Noncontrolling interest in Symphony Dynamo, Inc.	11,963	2,016
Commitments and contingencies		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 5,000 shares authorized and no shares issued and outstanding at June 30, 2007 and December 31, 2006		
Common stock: \$0.001 par value; 100,000 shares authorized at June 30, 2007 and December 31, 2006; 39,741 and		
39,715 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	40	40
Additional paid-in capital	246,358	244,787
Accumulated other comprehensive income:		
Unrealized gain on marketable securities available-for-sale	35	28
Cumulative translation adjustment	152	144
Accumulated other comprehensive income	187	172
Accumulated deficit	(198,737)	(167,943)
Total stockholders' equity	47,848	77,056
Total liabilities, noncontrolling interest and stockholders' equity	\$ 98,482	\$ 102,890

See accompanying notes.

## Dynavax Technologies Corporation Condensed Consolidated Statements of Operations (In thousands, except per share amounts) (Unaudited)

	Three Mon June		Six Mont June	
	2007	2006	2007	2006
Revenues:				
Collaboration revenue	<b>\$</b> 752	\$ —	\$ 1,499	\$ —
Services and license revenue	461	224	570	224
Grant revenue	587	305	1,715	593
Total revenues	1,800	529	3,784	817
Operating expenses:				
Research and development	19,164	10,762	32,796	17,354
General and administrative	4,206	3,380	8,386	5,983
Acquired in-process research and development	—	4,180	—	4,180
Amortization of intangible assets	252	196	503	196
Total operating expenses	23,622	18,518	41,685	27,713
Loss from operations	(21,822)	(17,989)	(37,901)	(26,896)
Interest and other income, net	1,081	685	2,054	1,420
Loss including noncontrolling interest in Symphony Dynamo, Inc.	(20,741)	(17,304)	(35,847)	(25,476)
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	3,037	2,031	5,053	2,031
Net loss	\$ (17,704)	\$(15,273)	\$(30,794)	\$(23,445)
Basic and diluted net loss per share	\$ (0.45)	\$ (0.50)	\$ (0.78)	\$ (0.77)
Shares used to compute basic and diluted net loss per share	39,741	30,536	39,734	30,524

See accompanying notes.

## Dynavax Technologies Corporation Condensed Consolidated Statements of Cash Flows (In thousands) (Unaudited)

	Six Months Ended June 30.	
	2007	2006
Operating activities		
Net loss	\$ (30,794)	\$ (23,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	712	227
Amount attributed to noncontrolling interest in Symphony Dynamo, Inc.	(5,053)	(2,031)
Acquired in-process research and development	_	4,180
Amortization of intangible assets	503	196
Gain on disposal of property and equipment		(50)
Accretion and amortization on marketable securities	(1,239)	169
Realized loss on sale of marketable securities	1 407	23
Stock-based compensation expense	1,497	1,396
Changes in operating assets and liabilities: Accounts receivable	1 050	400
	1,052	468
Prepaid expenses and other current assets	(1,087)	2
Inventory Other assets	9 1,155	(505)
Accounts payable	1,133	242
Accrued liabilities	(1,106)	1,300
Deferred revenues	(1,100)	(87)
Net cash used in operating activities	(33,357)	(17,915)
Net cash used in operating activities	(55,557)	(17,915)
Investing activities		
Change in investments held by Symphony Dynamo, Inc.	(21,735)	(19,044)
Cash paid for acquisition, net of cash acquired	_	(14,045)
Purchases of marketable securities	(40,504)	(7,653)
Proceeds from sales of marketable securities	—	10,987
Proceeds from maturities of marketable securities	59,450	31,318
(Purchases) disposal of property and equipment, net	(1,587)	41
Net cash (used in) provided by investing activities	(4,376)	1,604
Financing activities	20.000	17 405
Proceeds from purchase of noncontrolling interest by preferred shareholders in Symphony Dynamo, Inc., net of fees	30,000	17,405
Issuance cost associated with common stock offering	(19)	
Proceeds from employee stock purchase plan Proceeds from exercise of stock options	71	57
•	22	149
Net cash provided by financing activities	30,074	17,611
Effect of exchange rate on cash and cash equivalents	8	65
Net (decrease) increase in cash and cash equivalents	(7,651)	1,365
Cash and cash equivalents at beginning of period	14,154	8,725
Cash and cash equivalents at end of period	\$ 6,503	\$ 10,090
	φ 0,505	φ 10,090
Supplemental disclosure of non-cash investing and financing activities		
Disposal of fully depreciated property and equipment	\$ 24	\$ —
Warrants issued in conjunction with the Symphony Dynamo, Inc. transaction	\$ —	\$ 5,646
Liability from Program Option exercised under the SDI collaboration	\$ 15,000	\$
Lability nom riogian option exercised ander the obreonatoriation	φ 13,000	φ <u> </u>

See accompanying notes.

#### Dynavax Technologies Corporation Notes to Condensed Consolidated Financial Statements (Unaudited)

#### 1. Organization and Summary of Significant Accounting Policies

Dynavax Technologies Corporation is a biopharmaceutical company that discovers, develops and intends to commercialize innovative Toll-like Receptor 9, or TLR9, agonist-based products to treat and prevent infectious diseases, allergies, cancer and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation.

#### **Basis of Presentation**

Our accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. In our opinion, these unaudited condensed consolidated financial statements include all adjustments, consisting only of normal recurring adjustments, which we consider necessary to fairly state our financial position and the results of our operations and cash flows. Interim-period results are not necessarily indicative of results of operations or cash flows for a full-year period or any other interim-period. The condensed consolidated balance sheet at December 31, 2006 has been derived from audited financial statements at that date, but does not include all disclosures required by U.S. generally accepted accounting principles for complete financial statements.

These unaudited condensed consolidated financial statements and the notes accompanying them should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2006 as filed with the Securities and Exchange Commission, or SEC, on March 16, 2007.

The unaudited condensed consolidated financial statements include the accounts of Dynavax and our wholly-owned subsidiaries as well as a variable interest entity, Symphony Dynamo, Inc., for which we are the primary beneficiary as defined by Financial Accounting Standards Board, or FASB, Interpretation No. 46 (revised 2003), "Consolidation of Variable Interest Entities," or FIN 46R. All intercompany accounts and transactions have been eliminated. We operate in one business segment, which is the discovery and development of biopharmaceutical products.

### **Use of Estimates**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results may differ from these estimates.

#### **Significant Accounting Policies**

We believe that there have been no significant changes in our critical accounting policies during the six months ended June 30, 2007 as compared with those disclosed in its Annual Report on Form 10-K for the year ended December 31, 2006.

#### **Recent Accounting Pronouncements**

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities", which agreed to address the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. Issue 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The consensus may be applied to earlier periods. Early adoption of the provision of the consensus is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), "The Fair Value Option for Financial Assets and Financial Liabilities", which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In September 2006, the FASB issued SFAS 157, "Fair Value Measurements." SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In July 2006, the FASB released the Final Interpretation No. 48 "Accounting for Uncertainty in Income Taxes" (FIN 48). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease within a twelve month period.

We adopted the provisions of FIN 48 on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of June 30, 2007, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of general and administrative expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to June 30, 2008.

#### 2. Inventory

Inventories as of June 30, 2007 consist of the following (in thousands):

	June 30, 2007	December 31, 2006
Raw materials	\$ 184	\$ 194
Finished goods	64	63
Total	\$ 248	<b>\$</b> 257

#### 3. Intangible Assets

Intangible assets consist of manufacturing process, customer relationships, and developed technology acquired in connection with the acquisition of Rhein Biotech GmbH, or Rhein or Dynavax Europe, in April 2006. Purchased intangible assets other than goodwill are amortized on a straight-line basis over their respective useful lives. The following table presents details of the purchased intangible assets acquired as part of the acquisition (in thousands, except years):

June 30, 2007	Original Estimated Useful Life (in Years)	Gross	Accumulated Amortization	Net
Manufacturing process	5	\$ 3,670	\$ 876	\$ 2,794
Customer relationships	5	1,230	294	936
Developed technology	7	180	31	149
Total		\$ 5,080	\$ 1,201	\$ 3,879

The estimated future amortization expense of purchased intangible assets is as follows (in thousands):

Year ending December 31,	
2007 (remaining six months)	\$ 503
2008	1,006
2009	1,006
2010	1,005
2011	325
Thereafter	34
Total	\$ 3,879

#### 4. Collaborative Research and Development Agreements

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca AB, or AstraZeneca, for the discovery and development of TLR9 agonist-based therapies for the treatment of asthma and chronic obstructive pulmonary disease, or COPD. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We received an upfront payment of \$10 million upon signing the agreement and are eligible to receive research funding, preclinical milestones and future development milestones that in total could approximate \$136 million. Upon commercialization, we are also eligible to receive royalties based on product sales. Collaboration revenue resulting from the performance of research services amounted to \$0.8 million and \$1.5 million for the three and six months ended June 30, 2007, respectively. As of June 30, 2007, our deferred revenue was \$10.5 million associated with the upfront fee and amounts billed in advance for research services per the contract terms.

In 2003, we were awarded government grants totaling \$8.3 million to fund research and development. Certain of these grants have been extended through the first quarter of 2008. Revenue associated with these grants is recognized as the related expenses are incurred. For the six months ended June 30, 2007 and 2006, we recognized revenue of approximately \$1.7 million and \$0.5 million, respectively.

#### 5. Symphony Dynamo, Inc.

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, Symphony Dynamo, Inc., or SDI, agreed to fund up to \$50.0 million for the clinical development of these programs and we licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC, or Holdings, which provided \$20.0 million in funding to SDI at closing and \$30.0 million in April 2007. We are primarily responsible for the development of these programs.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of common stock at \$7.32 per share, representing a 25% premium over the applicable 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. The warrant issued upon closing was assigned a value of \$5.6 million using the Black-Scholes valuation model, and was recorded as a reduction in the noncontrolling interest in SDI and an increase in additional paid in capital.

In consideration for the warrant, we received an exclusive purchase option, defined as the Purchase Option, to acquire all of the programs through the purchase of all of the equity in SDI during the five-year term at specified prices. The Purchase Option exercise price is payable in cash or a combination of cash and shares of Dynavax common stock, at our sole discretion. We also received an option to purchase either the hepatitis B or hepatitis C program, defined as the Program Option. We exercised the Program Option in April 2007 for the hepatitis B program. The exercise of the Program Option requires a payment obligation of \$15 million to Holdings upon the expiration of the SDI collaboration in 2011 if the Purchase Option for all programs is not exercised at any time through the remaining term of the collaboration. The long-term liability for the Program Option is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option. If we do not exercise our exclusive right to purchase the remaining programs licensed under the agreement, the intellectual property rights to those programs at the end of the development period will remain with SDI. The long-term liability of \$15.0 million was offset against the noncontroling interest in SDI.

In accordance with Financial Standards Board Interpretation No. 46 (revised 2003), "Consolidation of Variable Interest Entities", or FIN 46R, we have determined that SDI is a variable interest entity for which we are the primary beneficiary. As a result, the financial position and results of operations of SDI have been included in our consolidated financial statements as of June 30, 2007 and for the period from April 18, 2006 through December 31, 2006. Accordingly, the investments held by SDI in the consolidated balance sheet include the \$50.0 million of funding, less funds spent to date on the development of the programs. The noncontrolling interest in SDI reflects \$50.0 million of funding reduced by (i) the structuring fee and other closing costs of \$2.6 million, (ii) the value assigned to the warrants issued to Holdings upon closing of \$5.6 million, (iii) the Program Option obligation of \$15.0 million, and (iv) SDI's losses through June 30, 2007. Reimbursable expenses incurred under the SDI programs were \$6.6 million for the six months ended June 30, 2007.

#### 6. Commitments

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and August 2009, respectively. The Berkeley Lease can be terminated in September 2009 at no cost to us but otherwise extends automatically until September 2014. The Berkeley Lease provides for periods of escalating rent. The total cash payments over the life of the lease were divided by the total number of months in the lease period and the average rent is charged to expense each month during the lease period. In addition, our Berkeley Lease provided a tenant improvement allowance of \$0.4 million, which is considered a lease incentive and accordingly, has been included in accrued liabilities and other long-term liabilities in the consolidated balance sheets as of June 30, 2007 and December 31, 2006. The Berkeley Lease incentive is amortized as an offset to rent expense over the estimated initial lease term, through September 2009. Total net rent expense related to our operating leases for the six months ended June 30, 2007 and June 30, 2006, was \$1.0 million and \$0.8 million, respectively. Deferred rent was \$0.2 million as of June 30, 2007.

We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$0.4 million annually through 2007. This sublease agreement extends until August 2007.

Future minimum payments under the non-cancelable portion of our operating leases at June 30, 2007, excluding payments from the sublease agreement, are as follows (in thousands):

Year ending December 31,	
2007 (remaining six months)	\$ 1,109
2008	2,255
2009	1,529
Total	1,529 \$ 4,893

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of June 30, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of June 30, 2007 and December 31, 2006. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of June 30, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$11 million through 2008. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Such fees and milestone payments to the Regents could approximate \$1 million in 2007.

In April 2006, Rhein and Green Cross Vaccine Corp. ("Green Cross") entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to SUPERVAX, a hepatitis B vaccine. In exchange, Rhein is required to pay Green Cross a specified profit share until Green Cross's development costs for the product are recouped and thereafter a specified profit share for a designated period of time. To date revenue from SUPERVAX has not been material.

#### 7. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period and potentially dilutive common shares using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, preferred stock, options and warrants are considered to be potentially dilutive common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive. Outstanding warrants and stock options to purchase 6.2 million and 5.6 million shares of common stock as of June 30, 2007 and 2006, respectively, were excluded from the calculation of diluted net loss per share because the effect would have been anti-dilutive.

The following is a reconciliation of the numerator and denominator used in the basic and diluted net loss per share computations (in thousands):

		Three Months Ended June 30,		nths Ended ne 30,
	2007	2006	2007	2006
Numerator:				
Net loss	\$(17,704)	\$(15,273)	\$(30,794)	\$(23,445)
Denominator:				
Weighted-average common shares outstanding used for basic and				
diluted net loss per share	39,741	30,536	39,734	30,524

#### 8. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Other comprehensive income or loss includes certain changes in stockholder's equity not included in the net loss. Comprehensive loss is as follows:

	Six Montl June	
	2007	2006
Net loss	\$ (30,794)	\$ (23,445)
Increase in unrealized gain on marketable securities available-for-sale	7	72
Increase in cumulative translation adjustment	8	65
Comprehensive loss	\$ (30,779)	\$(23,308)

#### 9. Stockholders' Equity

As of June 30, 2007, we have two share-based compensation plans: the 2004 Stock Incentive Plan, which includes the 2004 Non-Employee Director Option Program; and the 2004 Employee Stock Purchase Plan. The 1997 Equity Incentive Plan, or 1997 Plan, expired in the first quarter of 2007. Upon expiration of the 1997 Plan, 273,188 shares previously available for grant expired. Any

outstanding options under the 1997 Plan that are cancelled in future periods will automatically expire and will no longer be available for grant.

Under our stock-based compensation plans, option awards generally vest over a 4-year period contingent upon continuous service and expire 10 years from the date of grant (or earlier upon termination of continuous service). The fair value of each option is estimated on the date of grant using the Black-Scholes option valuation model and the following weighted-average assumptions:

		Employee St	tock Options			/ee Stock ase Plan
		Three Months Ended June 30,		ths Ended e 30,		ths Ended ie 30,
	2007	2006	2007	2006	2007	2006
Weighted-average fair value	\$2.78	\$3.79	\$3.75	\$3.99	\$2.64	\$2.65
Risk-free interest rate	4.8%	5.1%	4.8%	4.8%	5.0%	4.7%
Expected life (in years)	4.0	5.8	4.6	5.7	1.2	1.2
Volatility	0.7	0.8	0.8	0.8	0.7	0.7
Expected dividends	_	_				

Expected volatility is based on historical volatility of our stock and comparable peer data. The expected life of options granted is estimated based on historical option exercise and employee termination data. Executive level employees, who hold a majority of the options outstanding, and non-executive level employees were each found to have similar historical option exercise and termination behavior and thus were grouped and considered separately for valuation purposes. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

We recognized the following amounts of stock-based compensation expense (in thousands):

		onths Ended me 30,		ths Ended e 30,
	2007	2006	2007	2006
Employee and director stock-based compensation expense	\$ 674	\$ 731	\$ 1,471	\$ 1,388
Other stock-based compensation expense	15	(1)	26	8
Total	\$ 689	\$ 730	\$ 1,497	\$ 1,396

The fair value of the options is amortized to expense on a straight-line basis over the vesting periods of the options. Compensation expense recognized was based on awards ultimately expected to vest and reflects estimated forfeitures at an annual rate of 11%. As of June 30, 2007 the total unrecognized compensation cost related to non-vested options granted amounted to \$8.5 million, which is expected to be recognized over the options' remaining weighted-average vesting period of 1.8 years.

Activity under the our stock option plans was as follows:

	Options Available for Grant	Number of Options Outstanding	Weighted-Average Exercise Price Per Share
Balance at December 31, 2006	1,997,141	3,421,339	\$5.26
Options authorized	400,000		—
Options granted	(925,685)	925,685	\$5.99
Options exercised	—	(5,666)	\$3.86
1997 Plan shares expired	(273,188)		—
Options cancelled:			
Options forfeited (unvested).	190,984	(190,984)	\$5.91
Options expired (vested)	1,621	(1,621)	\$8.09
Balance at June 30, 2007	1,390,873	4,148,753	\$5.40

The following table summarizes outstanding options that are net of expected forfeitures (vested and expected to vest) and options exercisable under our stock option plans as of June 30, 2007:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding options (vested and expected				
to vest)	3,692,987	\$5.30	7.9	\$1,374,460
Options exercisable	1,624,568	\$4.49	6.7	\$1,260,978

#### **Employee Stock Purchase Plan**

As of June 30, 2007, 496,000 shares were reserved and approved for issuance under the Purchase Plan, subject to adjustment for a stock split, any future stock dividend or other similar change in our common stock or capital structure. To date, employees acquired 82,032 shares of our common stock under the Purchase Plan. At June 30, 2007, 413,770 shares of our common stock remained available for future purchases.

#### **10. Subsequent Events**

In July 2007, we announced that Deerfield Management, a healthcare investment fund and its affiliates, or Deerfield, committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield's commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loans for TOLAMBA is contingent upon the positive outcome of the chamber study and subsequent field study. If the TOLAMBA program is discontinued, Dynavax has no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the average share price in the 15-day period prior to achievement of the milestone. Deerfield received 1.25 million warrants upon execution of the loan agreement at an exercise price of \$5.13 per share. Additional warrants are required to be issued and priced on successful completion of milestones and, if all milestones are successfully achieved, Deerfield would receive a total of 5.55 million warrants during the term of the loan agreement.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve a number of risks and uncertainties. Our actual results could differ materially from those indicated by forward-looking statements as a result of various factors, including but not limited to those set forth under "Risk Factors" and those that may be identified from time to time in our reports and registration statements filed with the Securities and Exchange Commission.

The following discussion and analysis is intended to provide an investor with a narrative of our financial results and an evaluation of our financial condition and results of operations. This discussion should be read in conjunction with the unaudited Condensed Consolidated Financial Statements and related Notes included in Item 1 of this quarterly report and the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K.

#### Overview

Dynavax Technologies Corporation is a biopharmaceutical company that discovers, develops and intends to commercialize innovative Toll-like Receptor 9, or TLR9, agonist-based products to treat and prevent infectious diseases, allergies, cancer and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. Our TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation.

Our product candidates include: HEPLISAVTM, a hepatitis B vaccine in Phase 3; TOLAMBATM, a ragweed allergy immunotherapy; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B in Phase 1. Our preclinical asthma and chronic obstructive pulmonary disease (COPD) program is partnered with AstraZeneca AB, or AstraZeneca. Our preclinical work on a vaccine for influenza is partially funded by the National Institute of Allergy and Infectious Diseases. Our colorectal cancer trials and our preclinical hepatitis C therapeutic program are funded by Symphony Dynamo, Inc., or SDI.

#### HEPLISAV

HEPLISAV, our product candidate for hepatitis B prophylaxis, is based on proprietary ISS that specifically targets TLR9 to stimulate an innate immune response. HEPLISAV combines ISS with HBV surface antigen (HBsAg) and is designed to significantly enhance the level, speed and longevity of protection. Previously reported clinical trials results have shown 100% seroprotection after two doses in subjects 18 to 39 years of age, and after three doses in difficult-to-immunize subjects 40 to 70 years of age.

Our ongoing multi-center Phase 3 pivotal trial known as PHAST (Phase 3 HeplisAv Short-regimen Trial), which began in Canada in late 2006 and in Germany in June 2007, enrolled over 2,400 subjects 11 to 55 years of age, and compares a two-dose regimen of HEPLISAV administered at 0 and 1 month to the conventional three dose regimen of Engerix-B<sup>®</sup> marketed by GlaxoSmithKline.

In June 2007, we initiated a safety and immunogenicity study in the U.S., a second clinical trial designed to support the licensure of HEPLISAV. In the U.S. study, consistent with the PHAST trial, subjects 11 to 55 years of age are receiving a two-dose regimen of HEPLISAV, at 0 and 1 month. The primary endpoint of this trial will be measured four weeks after the second dose.

In the second half of 2007, we plan to initiate a lot-to-lot consistency study comparing three consecutive lots of HEPLISAV containing Hepatitis B surface antigen manufactured at Dynavax Europe. Approximately 2,000 subjects are anticipated to be enrolled in this trial in the U.S., Canada and Germany. The data from the PHAST trial, U.S. safety study, and subsequent lot-to-lot consistency trials will contribute to a safety database of approximately 4,000 subjects to support a planned BLA submission by the end of 2008.

Also in the second half of 2007, we plan to initiate a Phase 2 trial in Canada in patients with end-stage renal disease (ESRD) to evaluate the safety and immunogenicity of two different doses of HEPLISAV. The trial will enroll adults 40 to 70 years of age who have progressive loss of renal function and are either pre-dialysis or hemodialysis patients. This is a difficult-to-immunize patient population for whom conventional hepatitis B vaccines have shown limited efficacy. We intend to focus our development activities and resources on maximizing the potential of the demonstrated superiority of HEPLISAV over conventional hepatitis B vaccine in adults, and its potential in patients with ESRD.

#### Allergy Franchise

In July 2007, we announced that Deerfield Management, a healthcare investment fund and its affiliates, committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs.

#### TOLAMBA

TOLAMBA, our product candidate for the treatment of ragweed allergy, consists of ISS linked to the purified major allergen of ragweed, Amb a 1. TOLAMBA is designed to target the underlying cause of seasonal allergic rhinitis caused by ragweed. The linking of ISS to Amb a 1 ensures that both ISS and ragweed allergen are presented simultaneously to the same immune cells, producing a highly specific and potent inhibitory effect and suppressing the Th2 cells responsible for inflammation associated with ragweed allergy.

In the fourth quarter of 2007, we plan to initiate a 300-patient, randomized, placebo-controlled environmental exposure chamber study of TOLAMBA. Patients will be screened and selected by exposure to ragweed allergen in the chamber to identify those with confirmed severe ragweed allergic disease on the basis of symptomatic response in the chamber. Patients will be enrolled and randomized to placebo or TOLAMBA treatment, then treated and re-exposed in the chamber to determine the effect of the six-week, six-injection TOLAMBA regimen. Efficacy will be measured by the difference in total nasal symptom scores (TNSS) at baseline and after treatment as compared to placebo. We anticipate receiving data from the chamber study in the first half of 2008.

To date, TOLAMBA has been administered to over 1,100 patients, and has been safe and well-tolerated. A Phase 2 study conducted in 2001-2002 showed 55% reduction (p=0.03) in TNSS in the first season which was maintained (p=0.02) in the second season with no additional therapy. This was a single site study with well-characterized, severe allergic patients. The Phase 2 study conducted in 2004-2005 at 19 centers in the U.S. showed a 21% reduction in symptoms in the first year (p=0.04) which was also maintained in the second year with no additional therapy (p=0.02). However, the largest study of TOLAMBA (the DARTT study), conducted in 2006 in 738 patients at 30 U.S. sites, failed to enroll patients with measurable ragweed-allergic disease; therefore, the effect of the treatment could not be measured and the study did not achieve its primary endpoints.

#### Peanut Allergy Immunotherapy

Our peanut allergy program involves direct linkage of critical peanut allergens to a proprietary TLR9 agonist. This approach is designed to mask the IgE binding sites of the native allergen to ensure the safety of the intervention, and to induce an allergen-specific Th1 to Th2 immune shift, to reprogram the immune response in allergic patients. Our approach to peanut allergy provided protection in a mouse model of peanut induced anaphylaxis. Subject to successful completion of product selection and optimization activities and preclinical studies, we plan to initiate clinical studies in 2009.

#### Cat Allergy Immunotherapy

Our cat allergy program, similar to our approach to peanut allergy, involves direct linkage of the major cat allergen to a proprietary TLR9 agonist. Subject to successful completion of product selection and optimization activities and preclinical studies, we plan to initiate clinical studies in 2009. We anticipate that the clinical development path for a disease-modifying cat allergy therapy to be focused on challenge studies, in which both patient selection and study timing can be tightly controlled.

#### Symphony Dynamo, Inc.

In April 2006, we entered into a series of related agreements with Symphony Capital Partners, LP to advance specific Dynavax ISS-based programs for cancer therapy, hepatitis B therapy and hepatitis C therapy through certain stages of clinical development. Pursuant to the agreements, SDI agreed to fund up to \$50.0 million for the clinical development of these programs and we licensed to SDI our intellectual property rights related to these programs. SDI is a wholly-owned subsidiary of Symphony Dynamo Holdings LLC, or Holdings, which provided \$20.0 million in funding to SDI at closing and \$30.0 million in April 2007. We are primarily responsible for the development of these programs.

Pursuant to the agreements, we issued to Holdings a five-year warrant to purchase 2,000,000 shares of our common stock at \$7.32 per share, representing a 25% premium over the 60-day trading range average of \$5.86 per share. The warrant exercise price is subject to reduction to \$5.86 per share under certain circumstances. The warrant may be exercised or surrendered for a cash payment upon consummation of an all cash merger or acquisition of Dynavax, the obligation for which would be settled by the surviving entity. In consideration for the warrant, we received an exclusive purchase option to acquire all of the programs through the purchase of all of the equity in SDI during the five-year term at specified prices, defined as the Purchase Option. The Purchase Option exercise price is payable in cash or a combination of cash and shares of our common stock, at our sole discretion. We also received an option to purchase either the hepatitis B or hepatitis C program, defined as the Program Option. Dynavax exercised the Program Option in April 2007 for the hepatitis B program. The exercise of the Program Option requires a payment obligation of \$15 million to Holdings upon the expiration of the SDI collaboration in 2011 if the purchase option for all programs is not exercised at any time through the remaining term of the collaboration. The long-term liability for the Program Option is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option. If we do not exercise our exclusive right to purchase the remaining programs licensed under the agreement, the intellectual property rights to those programs at the end of the development period will remain with SDI.

In cancer, we believe that the potent and multifaceted biological activities of ISS offer a number of distinct approaches to cancer therapy in a wide range of tumor types. In December 2006, we initiated a Phase 1 dose escalation clinical trial of our cancer product candidate in combination with a standard chemotherapeutic regimen for metastatic colorectal cancer. In addition, a Phase 2 study has been completed in non-Hodgkin's lymphoma (NHL) of ISS in combination with Rituxan™ (rituximab). In December 2006, we announced preliminary data from this Phase 2 study based on 23 patients with histologically confirmed CD20+, B-cell follicular NHL who had relapsed after at least one prior treatment regimen for lymphoma. This study showed a possible correlation between biomarker response to ISS and clinical outcomes; patients with high biomarker induction had a doubling of response rate and progression free survival versus patients with low biomarker induction. The combination of rituximab and our ISS was well-tolerated, and adverse events were minimal. We previously reported a Phase 1, dose-escalation trial of our ISS in combination with rituximab in 20 patients with NHL in which dose-dependent pharmacological activity was demonstrated without significant toxicity.

We anticipate that additional cancer product candidates will advance into clinical trials in solid tumors in 2007, and our hepatitis C therapeutic product candidate is also planned to enter the clinic in 2007.

#### Hepatitis B Immunotherapy

We are developing a novel therapy to treat chronic hepatitis B infection that combines hepatitis B surface antigen and hepatitis B core antigen. In March 2007, we initiated a Phase 1 study of this therapy in 20 healthy subjects, to evaluate the safety and immunogenicity of two dosing regimens. Results from this trial are anticipated in the second half of 2007.

#### AstraZeneca Research Collaboration and License Agreement

In September 2006, we entered into a research collaboration and license agreement with AstraZeneca for the discovery and development of TLR9 agonistbased therapies for the treatment of asthma and chronic obstructive pulmonary disease, or COPD. The collaboration is using our proprietary secondgeneration TLR9 agonist immunostimulatory sequences or ISS. Under the terms of the agreement, we are collaborating with AstraZeneca to identify lead TLR9 agonists and conduct appropriate research phase studies. AstraZeneca is responsible for any development and worldwide commercialization of products arising out of the research program. We have the option to co-promote in the United States products arising from the collaboration.

#### Influenza Vaccine

In the fourth quarter of 2006, we announced preclinical data that indicate our flu vaccine can improve the immunogenicity of standard flu vaccines. The data from mouse and primate models demonstrated that co-administration of our flu vaccine with standard vaccine enhances the immune response of the standard vaccine, allows reduction of standard vaccine dosage, and provides extra layers of protection that are not strain-dependent. Our flu vaccine is based on our proprietary TLR9 agonist-based ISS technology. The preclinical work was funded in part by a research and development grant for a pandemic flu vaccine from the National Institute of Allergy and Infectious Diseases, a division of the National Institutes of Health.

#### **SUPERVAX**

In April 2006, we completed the acquisition of Rhein Biotech GmbH, or Rhein, or Dynavax Europe. As a result, we acquired a hepatitis B vaccine called SUPERVAX that has been tested in more than 600 subjects and has demonstrated safety and 99% seroprotection when administered on a two-dose schedule. SUPERVAX was launched in Argentina in December 2006 and is approved for marketing and sales through a third party partner. We intend to continue registration activities for SUPERVAX as a two-dose vaccine for adolescents for commercialization through partners in select countries outside of North America and Europe.

#### **Critical Accounting Policies and the Use of Estimates**

We believe that there have been no significant changes in our critical accounting policies during the six months ended June 30, 2007 as compared with those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2006.

#### **Results of Operations**

#### Revenues

Revenues consist of amounts earned from collaborations, services, license fees and grants. Collaboration revenue includes revenue recognized under our collaboration agreement with AstraZeneca. Services and license fees include research and development and contract manufacturing services, license fees and royalty payments. Grant revenue includes amounts earned under government and private agency grants.

The following is a summary of our revenues (in thousands, except percentages):

	Three Months Ended June 30,		Increase (Decrease) from 2007 to 2006		Six Months Ended June 30,			Increase (Decrease) from 2007 to 2006					
	2007		2006		\$	%		2007	2	2006		\$	%
Revenues:	 												
Collaboration revenue	\$ 752	\$	—	\$	752	100%	\$	1,499	\$	—	\$	1,499	100%
Services and license revenue	461		224		237	106%		570		224		346	154%
Grant revenue	587		305		282	92%		1,715		593		1,122	189%
Total revenues	\$ 1,800	\$	529	\$	1,271	240%	\$	3,784	\$	817	\$	2,967	363%

Total revenues for the six months ended June 30, 2007 were \$3.8 million, compared to \$0.8 million for the same period in 2006. Total revenues in 2007 consisted of collaboration revenue from AstraZeneca, services and license fees from R&D services provided to customers of Dynavax Europe, and grants primarily awarded by the National Institute of Allergy and Infectious Diseases.

We anticipate that our total revenues will continue to increase in 2007 as compared to 2006 due primarily to research funding under our collaboration with AstraZeneca.

#### Research and Development

Research and development expenses consist of compensation and related personnel costs which include benefits, recruitment, travel and supply costs; outside services; allocated facility costs and non-cash stock-based compensation. Outside services relate to our preclinical experiments and clinical trials, regulatory filings, manufacturing our product candidates, and the costs of selling SUPERVAX formulated bulk vaccine. We expense our research and development costs as they are incurred.

The following is a summary of our research and development expense (in thousands):

	Three Months Ended June 30,		Increase (Decrease) from 2006 to 2007			nths Ended ne 30,	Increase (Decrease) from 2006 to 2007		
Research and development:	 2007	_	2006	\$	%	2007	2006	\$	%
Compensation and related personnel costs	\$ 5,186	\$	3,069	\$ 2,11	7 69%	\$ 9,514	\$ 5,544	\$ 3,970	72%
Outside services	12,127		6,180	5,94	7 96%	19,802	9,046	10,756	119%
Facility costs	1,545		1,241	304	4 24%	2,959	2,208	751	34%
Non-cash stock-based compensation	306		272	34	4 13%	521	556	(35)	(6%)
Total research and development	\$ 19,164	\$	10,762	\$ 8,402	2 78%	\$ 32,796	\$ 17,354	\$ 15,442	89%

Research and development expenses for the six months ended June 30, 2007 increased by \$15.4 million, or 89%, over the same period in 2006. The increase was primarily due to outside services which included a one-time \$5 million payment in June 2007 for a non-exclusive license to certain patents and patent applications for the purpose of commercializing HEPLISAV. The remaining growth in outside services was due to increased clinical trial and clinical material manufacturing costs related to HEPLISAV and expenses incurred to support SDI programs and Dynavax Europe operations. Compensation and related personnel costs increased in 2007 resulting from continued organizational growth to further develop our clinical candidates and the impact of Dynavax Europe.

We anticipate that our research and development expenses will increase significantly in 2007 as compared to 2006, primarily in connection with the advancement of HEPLISAV, TOLAMBA and our programs in cancer, hepatitis B and hepatitis C therapies, asthma and flu.

#### General and Administrative

General and administrative expenses consist primarily of compensation and related personnel costs; outside services such as accounting, consulting, business development, investor relations and insurance; legal costs that include corporate and patent expenses, net of patent cost recoveries; allocated facility costs; and non-cash stock-based compensation.



The following is a summary of our general and administrative expense (in thousands):

		Three Months Ended June 30,		Increase (Decrease) from 2006 to 2007		hs Ended e 30,	Increase (Decrease) from 2006 to 2007		
General and administrative:	2007	2006	\$	%	2007	2006	\$	%	
Compensation and related personnel costs	\$ 1,742	\$ 1,641	\$ 101	6%	\$ 3,529	\$ 2,805	\$ 724	26%	
Outside services	1,181	784	397	51%	2,358	1,464	894	61%	
Legal costs	753	348	405	116%	1,245	632	613	97%	
Facility costs	150	149	1	1%	283	293	(10)	(3%)	
Other	—					(50)	50	(100%)	
Non-cash stock-based compensation	380	458	(78)	(17%)	971	839	132	16%	
Total general and administrative	\$ 4,206	\$ 3,380	\$ 826	24%	\$ 8,386	\$ 5,983	\$ 2,403	40%	

General and administrative expenses for the six months ended June 30, 2007 increased by \$2.4 million, or 40%, over the same period in 2006. The increase primarily reflects additional compensation and related personnel costs associated with overall organizational growth including the operations of Dynavax Europe. Outside services and legal costs increased in 2007 related to higher professional fees incurred in conjunction with various corporate development activities and expenses incurred to support SDI programs and Dynavax Europe operations.

We expect general and administrative expenses to increase modestly in 2007 as compared to 2006, resulting from continued organizational growth and expenses incurred to support the advancement of our clinical development programs and corporate development activities.

#### Amortization of Intangible Assets

Intangible assets resulting from our April 2006 acquisition of Dynavax Europe consist primarily of manufacturing process, customer relationships and developed technology. Amortization of intangible assets was \$0.5 million for the six months ended June 30, 2007.

#### Interest and Other Income, Net

Interest income is reported net of amortization on marketable securities and realized gains and losses on investments. Other income includes gains and losses on foreign currency translation of our activities primarily with Dynavax Europe and gains and losses on disposals of property and equipment. The following is a summary of our interest and other income, net (in thousands):

	Three Mont June		Increase (I from 2006			ths Ended e 30,	Increase (I from 2006	
Interest and other income, net:	2007	2006	\$	%	2007	2006	\$	%
Interest income, net	\$ 1,078	\$ 675	\$ 403	60%	\$ 2,047	\$ 1,410	\$ 637	45%
Other income net	3	10	(7)	(70%)	7	10	(3)	(30%)
Total interest and other income, net	\$ 1,081	\$ 685	\$ 396	58%	\$ 2,054	\$ 1,420	\$ 634	<u>\$45</u> %

Interest and other income, net was \$2.1 million for the six months ended June 30, 2007 compared to \$1.4 million reported for the same period in 2006. The increase was primarily due to approximately \$0.5 million of interest earned on the investments held by SDI and the investment of proceeds from our equity offerings in the fourth quarter of 2006.

#### Amount Attributed to Noncontrolling Interest in Symphony Dynamo, Inc.

Pursuant to the agreements that we entered into with SDI in April 2006 and in accordance with Financial Accounting Standards Board Interpretation No. 46 (revised 2003), "Consolidation of Variable Interest Entities," or FIN 46R, the results of operations of SDI have been included in our consolidated financial statements from the date of formation. We have deducted the losses attributed to the noncontrolling interest from our condensed consolidated statement of operations to the extent that the offsetting amount of the noncontrolling interest in the condensed consolidated balance sheet is zero. For the six months ended June 30, 2007 the loss attributed to the noncontrolling interest was \$5.1 million.

#### **Recent Accounting Pronouncements**

In March 2007, the FASB discussed Emerging Issues Task Force (EITF) Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities", which agreed to address the accounting for nonrefundable advance payments. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payment should be charged to expense. Issue 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The consensus may be applied to earlier periods. Early adoption of the provision of the consensus is not permitted. Accordingly, we must adopt Issue 07-3 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), "The Fair Value Option for Financial Assets and Financial Liabilities", which allows entities to account for most financial instruments at fair value rather than under other applicable generally accepted accounting principles such as historical cost. The accounting results in the instrument being marked to fair value every reporting period with the gain/loss from a change in fair value recorded in the income statement. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In September 2006, the FASB issued SFAS 157, "Fair Value Measurements." SFAS 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, we must adopt SFAS 157 in the first quarter of fiscal 2008 and we are currently evaluating the effect that the adoption will have on our consolidated results of operations and financial condition.

In July 2006, the FASB released the Final Interpretation No. 48 "Accounting for Uncertainty in Income Taxes" (FIN 48). FIN 48 prescribes the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also requires additional disclosure of the beginning and ending unrecognized tax benefits and details regarding the uncertainties that may cause the unrecognized benefits to increase or decrease within a twelve month period.

We adopted the provisions of FIN 48 on January 1, 2007. There was no impact on our consolidated financial position, results of operations and cash flows as a result of adoption. We have no unrecognized tax benefit as of June 30, 2007, including no accrued amounts for interest and penalties. Our policy will be to recognize interest and penalties related to income taxes as a component of general and administrative expense. We are subject to income tax examinations for U.S. incomes taxes and state income taxes from 1996 forward. We are subject to tax examinations in Singapore and Germany from 2003 and 2004 forward, respectively. We do not anticipate that total unrecognized tax benefits will significantly change prior to June 30, 2008.

#### Liquidity and Capital Resources

As of June 30, 2007, we had \$47.5 million in cash, cash equivalents and marketable securities and \$35.1 million in investments held by SDI. Our funds are currently invested in a variety of securities, including institutional money market funds, commercial paper, government and non-government debt securities and corporate obligations.

We have financed our operations since inception primarily through the sale of shares of our common stock, shares of our convertible preferred stock, and ordinary shares in a subsidiary, which have yielded a total of approximately \$222 million in net cash proceeds. To a lesser extent, we have financed our operations through amounts received under collaborative agreements and government grants. We have also financed certain of our research and development activities under our agreements with SDI.

We completed an initial public offering in February 2004, raising net proceeds of approximately \$46.5 million from the sale of 6,900,000 shares of common stock. In the fourth quarter of 2005, we completed an underwritten public offering that resulted in net proceeds of approximately \$33.1 million from the sale of 5,720,000 shares of our common stock. In the fourth quarter of 2006, we completed a follow-on offering raising approximately \$29.3 million from the sale of 7,130,000 shares of common stock. We use these proceeds to fund our current operations.

In August 2006 we entered into an equity line of credit arrangement with Azimuth Opportunity Ltd. Specifically, we entered into a Common Stock Purchase Agreement with Azimuth, which provides that, upon the terms and subject to the conditions set forth therein, Azimuth is committed to purchase up to the lesser of \$30 million of our common stock, or the number of shares which is one less than 20% of the issued and outstanding shares of our common stock as of the effective date of the purchase agreement over the 18-month term of the purchase agreement. From time to time over the term of the purchase agreement, and at our sole discretion, we may present Azimuth with draw down notices constituting offers to purchase our common stock. The per share purchase price for these shares is at a discount ranging from 5.2% to 7.0%. In December 2006, we completed a draw down on our equity line of credit resulting in net proceeds of approximately \$14.8 million from the sale of 1,663,456 shares of our common stock. \$15 million remains available on our equity line of credit.

In July 2007, we announced that Deerfield Management, a healthcare investment fund and its affiliates, or Deerfield, committed up to \$30 million in project financing for a planned chamber study and subsequent field study for TOLAMBA and to advance our preclinical peanut and cat allergy programs. Deerfield's commitment is in the form of loans that can be drawn down over a three-year period, subject to achievement of specific milestones in the programs. Repayment of a portion of the loans for TOLAMBA is contingent upon the positive outcome of the chamber study and subsequent field study. If the TOLAMBA program is discontinued, Dynavax has no obligation to repay Deerfield up to \$9 million of the funds earmarked for that program; any other remaining outstanding principal will be due in July 2010. A portion of the funding, if utilized, will advance our peanut and cat allergy programs. Deerfield is entitled to receive an annual 5.9% cash commitment fee as well as milestone-driven payments in the form of warrants issued or issuable at an exercise premium of 20% over the average share price in the 15-day period prior to achievement of the milestone. Deerfield received 1.25 million warrants upon execution of the loan agreement at an exercise price of \$5.13 per share. Additional warrants are required to be issued and priced on successful completion of milestones and, if all milestones are successfully achieved, Deerfield would receive a total of 5.55 million warrants during the term of the loan agreement.

Cash used in operating activities was \$33.4 million during the six months ended June 30, 2007 compared to \$17.9 million for the same period in 2006. The increase in cash usage over the prior year was due primarily to the increase in our net loss and the amount attributed to the noncontrolling interest in SDI.

Cash used in investing activities was \$4.4 million during the six months ended June 30, 2007 compared to cash provided of \$1.6 million for the same period in 2006. The decrease was attributed to a reduction in the net proceeds from sales and maturities of marketable securities.

Cash provided by financing activities was \$30.1 million during the six months ended June 30, 2007 compared to \$17.6 million for the same period in 2006. Cash provided by financing activities primarily included the proceeds from the purchase of noncontrolling interest by preferred shareholders in Symphony Dynamo, Inc.

We currently anticipate that our cash and marketable securities, investments held by SDI, and available funds under our Azimuth equity line of credit and Deerfield financing arrangement will enable us to maintain our operations for at least the next twelve months. Because of the significant time it will take for any of our product candidates to complete clinical trials, achieve regulatory approval and generate significant revenue, we will require substantial additional capital resources. We may raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may attempt to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations.

Additional financing may not be available on acceptable terms, if at all and therefore may adversely affect our ability to operate as a going concern. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, scale back or eliminate some or all of our research or development programs, fail to meet the diligence obligations under existing licenses or enter into collaborative arrangements at an earlier stage of development on less favorable terms than we would otherwise choose.

#### **Contractual Obligations**

The following summarizes our significant contractual obligations as of June 30, 2007 and the effect those obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual Obligations:	Total	Less th	an 1 Year	1-	3 Years	4-5 Years	
Future minimum payments under our operating lease	\$ 4,893	\$	2,228	\$	2,665	\$ —	
Long-term liability from the Program Option exercised under the SDI collaboration	15,000					15,000	
Total	\$ 19,893	\$	2,228	\$	2,665	\$ 15,000	

We lease our facilities in Berkeley, California, or the Berkeley Lease, and Düsseldorf, Germany, or the Düsseldorf Lease, under operating leases that expire in September 2014 and August 2009, respectively. The Berkeley Lease can be terminated at no cost to us in September 2009 but otherwise extends automatically until September 2014. We have entered into a sublease agreement under the Berkeley Lease for a certain portion of the leased space with scheduled payments to us totaling \$0.4 million annually through 2007. This sublease agreement extends until August 2007.

In April 2007 we exercised an option to repurchase our hepatitis B program from Symphony Dynamo. The exercise of the Program Option triggers a payment obligation of \$15 million upon the expiration of the SDI collaboration if the Purchase Option for all programs is not exercised. The price for the Program Option is payable in cash only and will be fully creditable against the exercise price for any subsequent exercise of the Purchase Option.

During the fourth quarter of 2004, we established a letter of credit with Silicon Valley Bank as security for our Berkeley Lease in the amount of \$0.4 million. The letter of credit remained outstanding as of June 30, 2007 and is collateralized by a certificate of deposit which has been included in restricted cash in the consolidated balance sheets as of June 30, 2007 and December 31, 2006. Under the terms of the Berkeley Lease, if the total amount of our cash, cash equivalents and marketable securities falls below \$20.0 million for a period of more than 30 consecutive days during the lease term, the amount of the required security deposit will increase to \$1.1 million, until such time as our projected cash and cash equivalents will exceed \$20.0 million for the remainder of the lease term, or until our actual cash and cash equivalents remains above \$20.0 million for a period of 12 consecutive months.

In addition to the non-cancelable commitments included above, we have entered into contractual arrangements that obligate us to make payments to the contractual counterparties upon the occurrence of future events. In the normal course of operations, we have entered into license and other agreements and intend to continue to seek additional rights relating to compounds or technologies in connection with our discovery, manufacturing and development programs. Under the terms of the agreements, we may be required to pay future up-front fees, milestones and royalties on net sales of products originating from the licensed technologies. We consider these potential obligations to be contingent and have summarized all significant arrangements below.

We rely on research institutions, contract research organizations, clinical investigators and clinical material manufacturers. As of June 30, 2007, under the terms of our agreements, we are obligated to make future payments as services are provided of approximately \$11 million through 2008. These agreements are terminable by us upon written notice. We are generally only liable for actual effort expended by the organizations at any point in time during the contract, subject to certain termination fees and penalties.

Under the terms of our exclusive license agreements with the Regents of the University of California, as amended, for certain technology and related patent rights and materials, we pay annual license or maintenance fees and will be required to pay milestones and royalties on net sales of products originating from the licensed technologies. Such fees and milestone payments to the Regents could approximate \$1 million in 2007.

In April 2006, Rhein and Green Cross Vaccine Corp. entered into an exclusive license agreement whereby Green Cross granted Rhein an exclusive license relating to SUPERVAX, a hepatitis B vaccine. In exchange, Rhein is required to pay Green Cross a specified profit share until Green Cross's development costs for the product are recouped and thereafter a specified profit share for a designated period of time. To date SUPERVAX revenue has not been material.

#### **Off-balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as defined by rules recently enacted by the SEC and Financial Accounting Standards Board, and accordingly, no such arrangements are likely to have a current or future effect on our financial position. As

described above, SDI is not an off-balance sheet arrangement as it is considered a variable interest entity and included in our financial statements.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, we maintain our portfolio of cash equivalents and investments in a variety of securities, including commercial paper, money market funds, government and non-government debt securities and corporate obligations. Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant negative impact on the realized value of our investments.

*Interest Rate Risk.* We do not use derivative financial instruments in our investment portfolio. Due to the short duration and conservative nature of our cash equivalents and marketable securities, we do not expect any material loss with respect to our investment portfolio.

*Foreign Currency Risk.* We have certain investments outside the U.S. to support the operations of Dynavax Europe and have some exposure to foreign exchange rate fluctuations. The cumulative translation adjustment reported in the consolidated balance sheet as of June 30, 2007 was \$0.2 million primarily related to translation of Dynavax Europe activities from Euro to U.S. dollars.

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

#### (a) Evaluation of disclosure controls and procedures

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the CEO and CFO concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or Exchange Act, as of the end of period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

#### (b) Changes in internal controls

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

#### PART II. OTHER INFORMATION

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

From time to time in the ordinary course of business, we receive claims or allegations regarding various matters, including employment, vendor and other similar situations in the conduct of our operations. We do not believe any of the current claims or allegations are material to our current business or operations.

#### ITEM 1A. RISK FACTORS.

Various statements in this Quarterly Report on Form 10-Q are forward-looking statements concerning our future products, timing of development activities, expenses, revenues, liquidity and cash needs, as well as our plans and strategies. These forward-looking statements are based on current expectations and we assume no obligation to update this information. Numerous factors could cause our actual results to differ significantly from the results described in these forward-looking statements, including the following risk factors.

#### We have incurred substantial losses since inception and do not have any commercial products that generate significant revenue.

We have experienced significant net losses in each year since our inception. Our accumulated deficit was \$198.7 million as of June 30, 2007. To date, our revenue has resulted from collaboration agreements, services and license fees from customers of Dynavax Europe, and government and private agency grants. The grants are subject to annual review based on the achievement of milestones and other factors and are scheduled to terminate in 2007. We anticipate that we will incur substantial additional net losses for the foreseeable future as the result of our investment in research and development activities.

We do not have any products that generate significant revenue. Clinical trials for certain of our product candidates are ongoing. These and our other product candidates may never be commercialized, and we may never achieve profitability. Our ability to generate revenue depends upon:

- demonstrating in clinical trials that our product candidates are safe and effective, in particular, in the current and planned trials for our product candidates;
- obtaining regulatory approvals for our product candidates; and
- entering into and maintaining successful collaborative relationships.

If we are unable to generate significant revenues or achieve profitability, we may be required to reduce or discontinue our current and planned operations or raise additional capital on less favorable terms.

#### If we are unable to secure additional funding, we will have to reduce or discontinue operations.

We believe our existing capital resources will be adequate to satisfy our capital needs for at least the next twelve months. Because of the significant time and resources it will take to develop and commercialize our product candidates, we will require substantial additional capital resources in order to continue our operations, and any such funding may not allow us to continue operations as currently planned. We expect capital outlays and operating expenditures to increase over the next several years as we expand our operations, and any change in plans may increase these outlays and expenditures. We may be unable to obtain additional capital on acceptable terms, or at all and we may be required to delay, reduce the scope of, or eliminate some or all of our programs, or discontinue our operations.

# The success of our TLR9 product candidates depends on achieving successful clinical results and regulatory approval. Failure to obtain regulatory approvals could require us to discontinue operations.

None of our TLR9 product candidates have been approved for sale. Any product candidate we develop is subject to extensive regulation by federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory agencies. Our success is primarily dependent on our ability to obtain regulatory approval for our most advanced TLR9 product



candidates. Approval processes in the United States and in other countries are uncertain, take many years and require the expenditure of substantial resources.

We will need to demonstrate in clinical trials that a product candidate is safe and effective before we can obtain the necessary approvals from the FDA and foreign regulatory agencies. If we identify any safety issues associated with our product candidates, we may be restricted from initiating further trials for those products. Moreover, we may not see sufficient signs of efficacy in those studies. The FDA or foreign regulatory agencies may require us to conduct additional clinical trials prior to approval.

Many new drug candidates, including many drug candidates that have completed Phase 3 clinical trials, have shown promising results in early clinical trials and subsequently failed to establish sufficient safety and efficacy to obtain regulatory approval. Despite the time and money expended, regulatory approvals are uncertain. Failure to successfully complete clinical trials and show that our products are safe and effective would have a material adverse effect on our business and results of operations.

# Our clinical trials may be extended, suspended, delayed or terminated at any time. Even short delays in the commencement and progress of our trials may lead to substantial delays in the regulatory approval process for our product candidates, which will impair our ability to generate revenues.

We may extend, suspend or terminate clinical trials at any time for various reasons, including regulatory actions by the FDA or foreign regulatory agencies, actions by institutional review boards, failure to comply with good clinical practice requirements, concerns regarding health risks to test subjects or inadequate supply of the product candidate. In addition, our ability to conduct clinical trials for some of our product candidates is limited due to the seasonal nature. Even a small delay in a trial for any product candidate could require us to delay commencement of the trial until the target population is available for testing, which could result in a delay of an entire year.

Our registration and commercial timelines depend on results of the current and planned clinical trials and further discussions with the FDA. Any extension, suspension, termination or unanticipated delays of our clinical trials could:

- adversely affect our ability to timely and successfully commercialize or market these product candidates;
- result in significant additional costs;
- potentially diminish any competitive advantages for those products;
- adversely affect our ability to enter into collaborations, receive milestone payments or royalties from potential collaborators;
- cause us to abandon the development of the affected product candidate; or
- limit our ability to obtain additional financing on acceptable terms, if at all.

# If we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or long-term use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after commercialization.

In addition, we or our contract manufacturers will be required to adhere to federal regulations setting forth current good manufacturing practice. The regulations require that our product candidates be manufactured and our records maintained in a prescribed manner with respect to manufacturing, testing and quality control activities. Furthermore, we or our contract manufacturers must pass a pre-approval inspection of manufacturing facilities by the FDA and foreign regulatory agencies before obtaining marketing approval and will be subject to periodic inspection by the FDA and corresponding foreign regulatory agencies under reciprocal agreements with the FDA. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.

Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

#### Our most advanced product candidates in clinical trials rely on a single lead ISS compound, 1018 ISS, and most of our earlier stage programs rely on ISS-based technology. Serious adverse safety data relating to either 1018 ISS or other ISS-based technology may require us to reduce the scope of or discontinue our operations.

Our most advanced product candidates in clinical trials are based on our 1018 ISS compound, and substantially all of our research and development programs use ISS-based technology. If any of our product candidates in clinical trials produce serious adverse safety data, we may be required to delay or discontinue all of our clinical trials. In addition, as all of our clinical product candidates contain ISS, a common safety risk across therapeutic areas may hinder our ability to enter into potential collaborations and if adverse safety data are found to apply to our ISS-based technology as a whole, we may be required to significantly reduce or discontinue our operations.

#### We rely on third parties and our facility in Düsseldorf, Germany to supply materials necessary to manufacture our clinical product candidates for our clinical trials. Loss of these suppliers or key employees in Düsseldorf, or failure to timely replace them may delay our clinical trials and research and development efforts and may result in additional costs, which could preclude us from manufacturing our product candidates on commercially reasonable terms.

We rely on a number of third parties and our facility in Düsseldorf for the multiple steps involved in the manufacturing process of our product candidates, including, for example, ISS, a key component material that is necessary for our product candidates, the combination of the antigens and ISS, and the fill and finish. Termination or interruption of these relationships may occur due to circumstances that are outside of our control, resulting in higher cost or delays in our product development efforts.

We and these third parties are required to comply with applicable FDA current good manufacturing practice regulations and other international regulatory requirements. If one of these parties fails to maintain compliance with these regulations, the production of our product candidates could be interrupted, resulting in delays and additional costs. Additionally, these third parties and our manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates.

We have relied on a single supplier to produce our ISS for clinical trials. To date, we have manufactured only small quantities of ISS ourselves for research purposes. If we were unable to maintain or replace our existing source for ISS, we would have to establish internal ISS manufacturing capability which would result in increased capital and operating costs and delays in developing and commercializing our product candidates. We or other third parties may not be able to produce ISS at a cost, quantity and quality that are available from our current third-party supplier.

We currently utilize our facility in Düsseldorf to manufacture the hepatitis B surface antigen for HEPLISAV. We may enter into manufacturing agreements with one or more commercial-scale contract manufactures to produce additional supplies of HEPLISAV as required for new clinical trials and commercialization, or we may have to establish internal commercial-scale manufacturing capability for HEPLISAV, incurring increased capital and operating costs, delays in the commercial development of HEPLISAV and higher manufacturing costs than we have experienced to date.

# We rely on contract research organizations to conduct our clinical trials. If these third parties do not fulfill their contractual obligations or meet expected deadlines, our planned clinical trials may be delayed and we may fail to obtain the regulatory approvals necessary to commercialize our product candidates.

We rely on third parties to conduct our clinical trials. If these third parties do not perform their obligations or meet expected deadlines our planned clinical trials may be extended, delayed or terminated. Any extension, delay or termination of our clinical trials would delay our ability to commercialize our products and could have a material adverse effect on our business and operations.

If any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications or marketing claims, we may be unable to generate significant revenues, if any.



Even if we obtain regulatory approval for our product candidates and are able to successfully commercialize them, our products may not gain market acceptance among physicians, patients, health care payors and the medical community. The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to successfully market any approved product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

We intend to seek partners for purposes of commercialization of HEPLISAV in selected markets worldwide. Marketing challenges vary by market and could limit or delay acceptance in any particular country. We believe that market acceptance of HEPLISAV will depend on our ability to offer increased efficacy and improved ease of use as compared to existing or potential new hepatitis B vaccine products.

# A key part of our business strategy is to establish collaborative relationships to commercialize and fund development of our product candidates. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

We will need to establish collaborative relationships to obtain domestic and international sales, marketing and distribution capabilities for our product candidates. We also intend to enter into collaborative relationships to provide funding to support our research and development programs. The process of establishing collaborative relationships is difficult, time-consuming and involves significant uncertainty. Moreover, even if we do establish collaborative relationships, our collaborators may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons. If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

# Many of our competitors have greater financial resources and expertise than we do. If we are unable to successfully compete with existing or potential competitors despite these disadvantages we may be unable to generate revenues and our business will be harmed.

We compete with pharmaceutical companies, biotechnology companies, academic institutions and research organizations, in developing therapies to treat or prevent infectious diseases, allergy, asthma and cancer, as well as those focusing more generally on the immune system. Competitors may develop more effective, more affordable or more convenient products or may achieve earlier patent protection or commercialization of their products. These competitive products may render our product candidates obsolete or limit our ability to generate revenues from our product candidates. Many of the companies developing competing technologies and products have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing than we do.

Existing and potential competitors may also compete with us for qualified scientific and management personnel, as well as for technology that would be advantageous to our business. If we are unable to compete successfully, we may not be able to obtain financing, enter into collaborative arrangements, sell our product candidates or generate revenues.

# We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees would affect our ability to develop and commercialize our product candidates and achieve our objectives.

We are highly dependent on the principal members of our management, operations and scientific staff, including our Chief Executive Officer, Dr. Dino Dina. We experience intense competition for qualified personnel. Our future success also depends in part on the continued service of our executive management team, key scientific and management personnel and our ability to recruit, train and retain essential scientific personnel for our drug discovery and development programs, including those who will be responsible for overseeing our preclinical testing and clinical trials as well as for the establishment of collaborations with other companies. If we lose the services of any key personnel, our research and product development goals, including the identification and establishment of key collaborations, operations and marketing efforts could be delayed or curtailed.

# We may develop, seek regulatory approval for and market our product candidates outside the United States, requiring a significant commitment of resources. Failure to successfully manage our international operations could result in significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates.

We may introduce certain of our product candidates in various markets outside the United States. Developing, seeking regulatory approval for and marketing our product candidates outside the United States could impose substantial burdens on our resources and divert management's attention from domestic operations. International operations are subject to risk, including:

- the difficulty of managing geographically distant operations, including recruiting and retaining qualified employees, locating adequate facilities and establishing useful business support relationships in the local community;
- compliance with varying international regulatory requirements, laws and treaties;
- securing international distribution, marketing and sales capabilities;
- adequate protection of our intellectual property rights;
- legal uncertainties and potential timing delays associated with tariffs, export licenses and other trade barriers;
- adverse tax consequences;
- the fluctuation of conversion rates between foreign currencies and the U.S. dollar; and
- geopolitical risks.

If we are unable to successfully manage our international operations, we may incur significant unanticipated costs and delays in regulatory approval or commercialization of our product candidates, which would impair our ability to generate revenues.

# We rely on our licenses from the Regents of the University of California. Impairment of these licenses or our inability to maintain them would severely harm our business.

Our current research and development efforts depend upon our license arrangements with the Regents of the University of California, or UC. Our dependence on these licenses subjects us to numerous risks, such as disputes regarding the creation or use of intellectual property by us and UC, or scientific collaborators. Additionally, our agreements with UC generally contain diligence or milestone-based termination provisions. Our failure to meet any obligations pursuant to these provisions could allow UC to terminate our agreements or convert exclusive to non-exclusive licenses. In addition, our license agreements with UC may be terminated or may expire by their terms, and we may not be able to maintain the exclusivity of these licenses. If we cannot maintain licenses that are advantageous or necessary to the development or the commercialization of our product candidates, we may be required to expend significant time and resources to develop or license similar technology.

# If third parties successfully assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent development or commercialization of our product candidates.

We may be exposed to future litigation by third parties based on claims that our product candidates or proprietary technologies infringe their intellectual property rights, or we may be required to enter into litigation to enforce patents issued or licensed to us or to determine the scope or validity of our or another party's proprietary rights, including a challenge as to the validity of our issued and pending claims. We are involved in various interference and other administrative proceedings related to our intellectual property which has caused us to incur certain legal expenses. If we become involved in any litigation and/or other significant interference proceedings related to our intellectual property or the intellectual property of others, we will incur substantial additional expenses and it will divert the efforts of our technical and management personnel.

Two of our potential competitors relative to HEPLISAV, Merck and GSK, are exclusive licensees of broad patents covering hepatitis B surface antigen. In addition, the Institute Pasteur also owns or has exclusive licenses to patents covering hepatitis B surface antigen. While some of these patents have expired or will soon expire outside of the United States, they remain in force in the United States and are likely to be in force when we commercialize HEPLISAV or a similar product in the United States. To the extent we are



able to commercialize HEPLISAV in the United States while these patents are issued, Merck and/or GSK or the Institute Pasteur may bring claims against us.

If we are unsuccessful in defending or prosecuting our issued and pending claims or in defending potential claims against us, for example, as may arise to the extent we were to commercialize HEPLISAV or any similar product candidate in the United States, we could be required to pay substantial damages and we may be unable to commercialize our product candidates or use our proprietary technologies unless we obtain a license from these or other third parties if a license is available at all. A license may require us to pay substantial fees or royalties, require us to grant a cross-license to our technology or may not be available to us on acceptable terms, if at all. In addition, we may be required to redesign our technology so it does not infringe a third party's patents, which may not be possible or could require substantial funds and time. Any of these outcomes could require us to change our business strategy and could materially impact our business and operations.

Another of our potential competitors, Coley, has issued U.S. patent claims, as well as patent claims pending with the U.S. Patent and Trademark Office, or PTO, that may be asserted against our ISS products. In June 2007, we entered into an agreement with Coley under which we received a non-exclusive license to certain Coley patents and patent applications for the purpose of commercializing HEPLISAV. We may need to obtain a license to one or more of these patent claims held by Coley by paying fees or royalties or offering rights to our own proprietary technologies in order to commercialize one or more of our other formulations of ISS in the U.S. Such a license may not be available to us on acceptable terms, if at all, which could preclude or limit our ability to commercialize our products.

# If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, the value of our product candidates will decrease.

Our success depends on our ability to:

- obtain and protect commercially valuable patents or the rights to patents both domestically and abroad;
- operate without infringing upon the proprietary rights of others; and
- prevent others from successfully challenging or infringing our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use only to the extent that these rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We try to protect our proprietary rights by filing and prosecuting United States and foreign patent applications. However, in certain cases such protection may be limited, depending in part on existing patents held by third parties, which may only allow us to obtain relatively narrow patent protection. In the United States, legal standards relating to the validity and scope of patent claims in the biopharmaceutical field can be highly uncertain, are still evolving and involve complex legal and factual questions for which important legal principles remain unresolved.

The biopharmaceutical patent environment outside the United States is even more uncertain. We may be particularly affected by this uncertainty since several of our product candidates may initially address market opportunities outside the United States. For example, we expect to market HEPLISAV, if approved, in various foreign countries with high incidences of hepatitis B, including Canada, Europe and selected markets in Asia, where we may only be able to obtain limited patent protection.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- we might not receive an issued patent for any of our patent applications or for any patent applications that we have exclusively licensed;
- the pending patent applications we have filed or to which we have exclusive rights may take longer than we expect to result in issued patents;
- the claims of any patents that are issued may not provide meaningful protection or may not be valid or enforceable;
- we might not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our collaborators may not provide a competitive advantage;

- patents issued to other parties may limit our intellectual property protection or harm our ability to do business;
- other parties may independently develop similar or alternative technologies or duplicate our technologies and commercialize discoveries that we attempt to patent; and
- other parties may design around technologies we have licensed, patented or developed.

We also rely on trade secret protection and confidentiality agreements to protect our interests in proprietary know-how that is not patentable and for processes for which patents are difficult to enforce. We cannot be certain that we will be able to protect our trade secrets adequately. Any disclosure of confidential data in the public domain or to third parties could allow our competitors to learn our trade secrets. If we are unable to adequately obtain or enforce proprietary rights we may be unable to commercialize our products, enter into collaborations, generate revenues or maintain any advantage we may have with respect to existing or potential competitors.

#### We have licensed some of our development and commercialization rights to certain of our development programs in connection with our Symphony Dynamo funding arrangement and will not receive any future royalties or revenues with respect to this intellectual property unless we exercise an option to repurchase some or all of the programs in the future. We may not obtain sufficient clinical data in order to determine whether we should exercise our option prior to the expiration of the development period, and even if we decide to exercise, we may not have the financial resources to exercise our option in a timely manner.

In 2006, we granted an exclusive license to the intellectual property for certain ISS compounds for cancer, hepatitis B and hepatitis C therapeutics to Symphony Dynamo, Inc., or SDI, in consideration for a commitment from Symphony Capital Partners, LP and its co-investors to provide \$50 million of committed capital to advance these programs. As part of the arrangement, we received an option granting us the exclusive right, but not the obligation, to acquire certain or all of the programs at specified points in time at specified prices during the term of the five-year development period. The development programs under the arrangement are jointly managed by SDI and us, and there can be no assurance that we will agree on various decisions that will enable us to successfully develop the potential products, or even if we are in agreement on the development plans, that the development efforts will result in sufficient clinical data to make a fully informed decision with respect to the exercise of our option. If we do not exercise the purchase option prior to its expiration, then our rights in and with respect to the SDI programs will terminate and we will no longer have rights to any of the programs licensed to SDI under the arrangement. In April 2007, we exercised our option for the hepatitis B program. The exercise of this program option triggers a payment obligation of \$15 million to Holdings upon the expiration of the SDI collaboration in 2011 if the purchase option for all programs is not exercised.

If we elect to exercise the purchase option, we will be required to make a substantial payment, which at our election may be paid partially in shares of our common stock. As a result, in order to exercise the option, we will be required to make a substantial payment of cash and possibly issue a substantial number of shares of our common stock. We do not currently have the resources to exercise the option and we may be required to enter into a financing arrangement or license arrangement with one or more third parties, or some combination of these in order to exercise the option, even if we paid a portion of the purchase price with our common stock. There can be no assurance that any financing or licensing arrangement will be available or even if available, that the terms would be favorable to us and our stockholders. In addition, the exercise of the purchase option will likely require us to record a significant charge to earnings and may adversely impact future operating results.

#### We face product liability exposure, which, if not covered by insurance, could result in significant financial liability.

While we have not experienced any product liability claims to date, the use of any of our product candidates in clinical trials and the sale of any approved products will subject us to potential product liability claims and may raise questions about a product's safety and efficacy. As a result, we could experience a delay in our ability to commercialize one or more of our product candidates or reduced sales of any approved product candidates. In addition, a product liability claim may exceed the limits of our insurance policies and exhaust our internal resources. We have obtained limited product liability insurance coverage in the amount of \$1 million for each occurrence for clinical trials with umbrella coverage of an additional \$4 million. This coverage may not be adequate or may not continue to be available in sufficient amounts, at an acceptable cost or at all. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. A product liability claim, product recalls or other claims, as well as any claims for uninsured liabilities or in excess of insured liabilities, would divert our management's attention from our business and could result in significant financial liability.



# We face uncertainty related to coverage, pricing and reimbursement and the practices of third party payors, which may make it difficult or impossible to sell our product candidates on commercially reasonable terms.

In both domestic and foreign markets, our ability to achieve profitability will depend in part on the negotiation of a favorable price or the availability of appropriate reimbursement from third party payors. Existing laws affecting the pricing and coverage of pharmaceuticals and other medical products by government programs and other third party payors may change before any of our product candidates are approved for marketing. In addition, third party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Because we intend to offer products, if approved, that involve new technologies and new approaches to treating disease, the willingness of third party payors to reimburse for our products is particularly uncertain. We will have to charge a price for our products that is sufficiently high to enable us to recover our considerable investment in product development. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to achieve profitability and could harm our future prospects and reduce our stock price.

# We use hazardous materials in our business. Any claims or liabilities relating to improper handling, storage or disposal of these materials could be time consuming and costly to resolve.

Our research and product development activities involve the controlled storage, use and disposal of hazardous and radioactive materials and biological waste. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We are currently in compliance with all government permits that are required for the storage, use and disposal of these materials. However, we cannot eliminate the risk of accidental contamination or injury to persons or property from these materials. In the event of an accident related to hazardous materials, we could be held liable for damages, cleanup costs or penalized with fines, and this liability could exceed the limits of our insurance policies and exhaust our internal resources. We may have to incur significant costs to comply with future environmental laws and regulations.

#### Our stock price is subject to volatility, and your investment may suffer a decline in value.

The market prices for securities of biopharmaceutical companies have in the past been, and are likely to continue in the future to be, very volatile. The market price of our common stock is subject to substantial volatility depending upon many factors, many of which are beyond our control, including:

- progress or results of any of our clinical trials or regulatory efforts, in particular any announcements regarding the progress or results of our planned trials;
- our ability to establish and maintain collaborations for the development and commercialization of our product candidates;
- our ability to raise additional capital to fund our operations;
- technological innovations, new commercial products or drug discovery efforts and preclinical and clinical activities by us or our competitors;
- changes in our intellectual property portfolio or developments or disputes concerning the proprietary rights of our products or product candidates;
- our ability to obtain component materials and successfully enter into manufacturing relationships for our product candidates or establish manufacturing capacity on our own;
- our ability to enter into collaborations;
- maintenance of our existing exclusive licensing agreements with the Regents of the University of California;
- changes in government regulations, general economic conditions, industry announcements;
- issuance of new or changed securities analysts' reports or recommendations;
- actual or anticipated fluctuations in our quarterly financial and operating results; and

volume of trading in our common stock

One or more of these factors could cause a decline in the price of our common stock. In addition, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs, and divert management's attention and resources, which could harm our business, operating results and financial conditions.

# Anti-takeover provisions of our certificate of incorporation, bylaws and Delaware law may prevent or frustrate a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Provisions of our certificate of incorporation and bylaws may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting or other rights of the holders of our common stock. These provisions include:

- authorizing our Board of Directors to issue additional preferred stock with voting rights to be determined by the Board of Directors;
- limiting the persons who can call special meetings of stockholders;
- prohibiting stockholder actions by written consent;
- creating a classified board of directors pursuant to which our directors are elected for staggered three year terms;
- providing that a supermajority vote of our stockholders is required for amendment to certain provisions of our certificate of incorporation and bylaws; and
- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, we are subject to the provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our Board of Directors.

# We will continue to implement additional financial and accounting systems, procedures or controls as we grow our business and organization and to satisfy new reporting requirements.

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and other requirements may increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to comply with new reporting requirements. Specifically, we have integrated the operations, technologies, products and personnel of Dynavax Europe into our operations and Dynavax Europe's operations will be required to be included in our assessment of internal controls over financial reporting under Section 404 by the end of 2007. There can be no assurance that we will be able to maintain a favorable assessment as to the adequacy of our internal control over financial reporting. If we are unable to reach an unqualified assessment, or our independent auditors are unable to issue an unqualified attestation as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial reporting which could harm our business and could impact the price of our common stock.

#### 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

The Company held its Annual Meeting of Shareholders on June 13, 2007. The proposals voted on by the Company's shareholders and the voting results were as follows:

### **Proposal 1: Election of Class I Directors**

The election of directors was approved as follows:

	For	Withhold
Dino Dina, M.D	34,417,951	1,118,010
Dennis Carson, M.D.	34,440,967	1,094,994
Denise M. Gilbert, Ph.D.	34,458,184	1,077,777

### Proposal 2: Ratification of Appointment of Independent Registered Public Accounting Firm

Ernst & Young LLP was ratified as the Company's independent registered public accounting firm for fiscal year 2007 as follows:

For	Against	Abstain
34,862,566	50,947	622,448

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

None.

### **ITEM 6. EXHIBITS**

Exhibit Number	Document
10.32†	License Agreement, dated June 26, 2007, between Coley Pharmaceuticals Group, Inc. and Dynavax Technologies Corporation
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
+ We have	been granted confidential treatment with respect to cortain portions of this agreement. Omitted portions have been filed congrately with the

\* We have been granted confidential treatment with respect to certain portions of this agreement. Omitted portions have been filed separately with the Securities and Exchange Commission.

#### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto due authorized, in the City of Berkeley, State of California.

Date: August 3, 2007

Date: August 3, 2007

### DYNAVAX TECHNOLOGIES CORPORATION

By: /s/ DINO DINA, M.D. Dino Dina, M.D. President, Chief Executive Officer and Director (Principal Executive Officer)

By: /s/ DEBORAH A. SMELTZER Deborah A. Smeltzer Vice President, Operations and Chief Financial Officer (Principal Financial Officer)

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

### Ехнівіт 10.32

LICENSE AGREEMENT

### COLEY PHARMACEUTICAL GROUP, INC.

And

## DYNAVAX TECHNOLOGIES CORPORATION

LICENSE AGREEMENT

Dated June 26, 2007

#### LICENSE AGREEMENT

This LICENSE AGREEMENT (this "<u>Agreement</u>"), effective as of June 26, 2007 (the "<u>Effective Date</u>"), is between Coley Pharmaceutical Group, Inc., a Delaware corporation located at 93 Worcester Street, Suite 101, Wellesley, Massachusetts 02481 USA, and its Affiliates (collectively, "<u>Coley</u>"), and Dynavax Technologies Corporation, a Delaware corporation having a principal place of business at 2929 Seventh Street, Suite 100, Berkeley, California 94710 USA and its Affiliates ("<u>Licensee</u>") (each, a "<u>Party</u>" and collectively, the "<u>Parties</u>").

#### **RECITALS**

WHEREAS, Coley is the owner or licensee of certain rights, title, and interests in proprietary technologies involving immunomodulatory oligonucleotides; and

WHEREAS, Licensee has developed and/or is developing or evaluating a vaccine containing an HBsAg Antigen (as hereinafter defined) for the prevention of infection by Hepatitis B Virus in humans; and

WHEREAS, Licensee desires to obtain a license under the Patents (as hereinafter defined) in the Field (as hereinafter defined) and in the Territory (as hereinafter defined), and Coley desires to grant Licensee such rights and license; and

NOW, THEREFORE, in consideration of the premises and covenants contained herein and other good and valuable consideration, the adequacy of which is hereby acknowledged, and intending to be legally bound, the Parties hereby agree as follows:

#### 1. DEFINITIONS.

#### 1.1 General.

Unless otherwise specified, references in this Agreement to any section are references to such section of this Agreement and, unless otherwise specified, references in any section or definition to any clause are references to such clause of such section or definition. Terms which are defined in this Agreement shall apply equally to the singular and plural forms of the terms defined. Whenever the context may permit or require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The term "including" means including, without limiting the generality of any description proceeding such term. Each reference herein to any Person shall include a reference to such Person's permitted successors and assigns. Unless otherwise specified, references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto. References to "dollars" or "\$" are to United States dollars.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



## 1.2 Defined Terms.

As used in this Agreement, the following terms shall have the following respective meanings:

(a) "<u>Affiliate</u>" shall mean any individual or entity directly or indirectly controlling, controlled by or under common control with a Party to this Agreement. For purposes of this definition, the term "control" means (i) direct or indirect ownership of more than fifty percent (50%) of the voting interest in the entity in question, or more than fifty percent (50%) interest in the income of the entity in question; <u>provided</u>, <u>however</u>, that if local law requires a minimum percentage of local ownership, in addition to the foregoing clause, control will also be established by direct or indirect beneficial ownership of one hundred percent (100%) of the maximum ownership percentage that may, under such local law, be owned by foreign interests; or (ii) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise).

(b) "Agreement" shall have the meaning set forth in the first paragraph of this Agreement.

(c) "<u>Antigen</u>" shall mean the **[ \* ]** antigen.

(d) "<u>Business Day</u>" shall mean a day other than a Saturday or Sunday on which banking institutions in New York, New York are open for business.

(e) "Claim" shall mean any claim, demand, action or other proceedings (including for personal injury, death or disability) by a Third Party.

(f) "<u>Coley</u>" shall have the meaning set forth in the first paragraph of this Agreement.

(g) "Coley Indemnified Party" shall have the meaning set forth in Section 10.1.

(h) "Commercially Reasonable Efforts" shall have the meaning set forth in Section 4.1.

(i) "<u>Compound</u>" shall mean an immunomodulatory oligonucleotide identified by Licensee as [\*], having a [\*] and the nucleotide base sequence [\*].

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(j) "<u>Confidential Information</u>" shall mean any confidential and proprietary scientific, technical, commercial, marketing or other business information or Data furnished, directly or indirectly (including in connection with meetings with Regulatory Authorities or Third Parties), and whether in writing, orally or otherwise, by one Party or one of its Affiliates (the "<u>Disclosing Party</u>") to the other Party or one of its Affiliates (the "<u>Receiving Party</u>") to the other Party or one of its Affiliates (the "<u>Receiving Party</u>") pursuant to or in connection with this Agreement (including the negotiation of this Agreement) or the activities or transactions contemplated hereby or thereby.

(k) "Data" shall mean all data and other information included or referenced in a Submission.

(l) "Delivery Method" for the Licensed Product shall mean [\*] delivery.

(m) "Develop" shall mean to engage in Development.

(n) "<u>Development</u>" shall mean all activities related to research, preclinical and other non-clinical testing, test method development, process development, Manufacturing scale-up, qualification and validation, quality assurance/quality control and clinical trials, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of any application for Regulatory Approval, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval.

(o) "Disclosing Party" shall have the meaning set forth in Section 1.2(j).

(p) "Effective Date" shall have the meaning set forth in the first paragraph of this Agreement.

(q) "EU Major Market Country" shall mean [\*].

(r) "<u>Exploit</u>" and cognates thereof shall mean to make, have made, import, use, sell, or offer for sale, including to Develop, register, modify, enhance, improve, Manufacture, have Manufactured, store, formulate, export, transport, distribute, promote, market, or otherwise dispose of.

(s) "FDA" shall mean the United States Food and Drug Administration or any successor entity.

(t) "<u>Field</u>" shall mean the use of the Licensed Product for the prevention of infection by Hepatitis B Virus in humans. The Field specifically excludes any product for the prevention of disease, indications or disorders other

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than Hepatitis B Virus in humans and any product for the treatment of any disease, indications or disorders.

(u) "<u>First Commercial Sale</u>" shall mean, with respect to the Licensed Product and a particular country in the Territory, the first transaction by Licensee or a Sublicensee that transfers to an arm's-length Third Party purchaser, for value, title and right of physical possession of the Licensed Product for use in the Field in the country (other than named patient sales). Notwithstanding the provisions of the preceding sentence, transfer of possession and title to an Affiliate shall not constitute a First Commercial Sale unless the Affiliate is an end user of the Licensed Product.

(v) "Indemnitee" shall have the meaning set forth in Section 10.3.

(w) "Indemnitor" shall have the meaning set forth in Section 10.3.

(x) "<u>Iowa Agreement</u>" shall mean that certain License Agreement by and between CpG ImmunoPharmaceuticals, Inc. (the predecessor corporation to Coley) and UIRF, dated March 31, 1997, as amended March 7, 2001, as it exists on the Effective Date. A redacted copy of the Iowa Agreement is attached hereto as <u>Exhibit B</u>.

(y) "Large Pharmaceutical Company" shall mean any pharmaceutical or biotechnology company that has at least [\*] in aggregate annual pharmaceutical net sales for its most recently-completed fiscal year (consisting of 12 consecutive months) based on data provided by IMS International, or if such data is not available, such other reliable data as determined by Licensee and agreed to in writing by Coley, such agreement not to be unreasonably withheld.

(z) "<u>Liability</u>" shall have the meaning set forth in Section 10.1.

(aa) "<u>Licensed Product</u>" shall mean a prophylactic vaccine containing the Compound co-formulated with the Antigen for delivery by the Delivery Method. No Licensed Product(s) may be developed for the prevention, treatment or control of any cancer nor may any clinical trial be conducted with clinical endpoints of prevention, treatment or control of any cancer.

(bb) "Licensee" shall have the meaning set forth in the first paragraph of this Agreement.

(cc) "Licensee Indemnified Party" shall have the meaning set forth in Section 10.2.

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(dd) "<u>Manufacture</u>" and "<u>Manufacturing</u>" shall mean, with respect to a product or compound, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such product or compound.

(ee) "<u>Net Sales</u>" shall mean the gross amount invoiced by Licensee and its Affiliates and its Sublicensees for sales of the Licensed Product for end use or consumption to Third Parties that are not Affiliates or Sublicensees of the selling party (unless such purchasing Affiliate or Sublicensee is the end user of the Licensed Product, in which case the amount billed therefore shall be deemed to be the same amount that would be billed to a Third Party end user in an arms-length transaction) in the Territory, less the total of the following deductions to the extent they are included in the gross invoiced sale price of the Licensed Product or otherwise directly paid or incurred by Licensee or its Affiliates or its Sublicensees with respect to the sale of the Licensed Product:

(i) trade, cash, and/or quantity discounts not already reflected in the amount invoiced;

(ii) excise, sales and other consumption taxes and customs duties to the extent included in the invoice price;

(iii) freight, insurance and other transportation charges to the extent included in the invoice price;

(iv) amounts repaid or credited by reason of rejections and defects;

(v) returns or retroactive price reductions;

(vi) payments and rebates directly related to the sale of the Licensed Product, and

any other specifically identifiable amounts included in gross amounts invoiced for the Licensed Product [\*]. Any such exclusions shall be negotiated in good faith between the Parties and, if they are unable to agree, resolved in accordance with the dispute resolution mechanism in Section 11.3, as determined in accordance with Licensee's accounting methods (which are in accordance with its or its Sublicensee's accounting standards as generally and consistently applied).

In the case of any sale or other disposal for value, such as barter or counter-trade, of the Licensed Product or part thereof, other than in an arm's length transaction exclusively for money, Net Sales shall be calculated as above on the fair market value of the consideration received by Licensee or its Affiliates or Sublicensees.

(ff) "OHRI Agreement" shall mean the License Agreement, effective as of September 1, 1998 between The Ottawa Health Research Institute

at

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the Ottawa Hospital (successor in interest to The Loeb Health Research Institute at Ottawa Hospital) ("<u>OHRI</u>") and Coley Pharmaceutical Group, Inc. (formerly known as CpG ImmunoPharmaceuticals, Inc.), as amended on September 25, 2001. A redacted copy of the OHRI Agreement is attached hereto as Exhibit C.

(gg) "Party" and "Parties" shall have the meaning set forth in the first paragraph of this Agreement.

(hh) "<u>Patents</u>" shall mean the patents and patent applications listed on Exhibit A including (a) utility models, petty patents, design patents and certificates of invention, (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patent or patent application, and (c) any unissued or ungranted foreign or international equivalent of any of the foregoing.

(ii) "<u>Permitted Assignment</u>" shall have the meaning set forth in Section 11.1;

(jj) "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, or similar entity or organization, including a government or political subdivision, department or agency of a government, or an academic or research institution.

(kk) "Receiving Party" shall have the meaning set forth in Section 1.2(j).

(ll) "<u>Regulatory Approval</u>" shall mean the marketing authorization (including pricing approval or reimbursement approval, if applicable to the sale) of the Licensed Product in a country in the Territory, in each case by the appropriate Regulatory Authority.

(mm) "<u>Regulatory Authority</u>" shall mean, with respect to each country in the Territory, the government agency or health authority that regulates and is responsible for granting approvals for the Manufacture, marketing and/or sale of pharmaceutical products in such country.

(nn) "Regulatory Milestone" shall have the meaning set forth in Section 3.2.

(oo) "Regulatory Milestone Payment" shall have the meaning set forth in Section 3.2.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(pp) "Royalty Payments" has the meaning set forth in Section 3.3(a).

(qq) "<u>Royalty Period</u>" shall mean the initial partial Royalty Quarter commencing on the date of the First Commercial Sale in any country in the Territory and every complete or partial Royalty Quarter thereafter with respect to which Licensee has the obligation to make Royalty Payments under Section 3.

(rr) "<u>Royalty Report</u>" shall have the meaning set forth in Section 3.3(b).

(ss) "<u>Royalty Quarter</u>" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

(tt) "Royalty Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

(uu) "Submission" shall mean an application to obtain Regulatory Approval by a Regulatory Authority.

(vv) "<u>Sublicensee</u>" shall mean a Third Party who has been granted the right by Licensee strictly for the purpose of commercializing the Licensed Product.

(ww) "<u>Term</u>" shall have the meaning set forth in Section 6.1.

(xx) "Territory" shall mean all the countries of the world.

(yy) "Third Party" shall mean any Person other than Coley or Licensee.

(zz) "Third Party Claim" shall mean all claims of any Third Party that are subject to indemnification as provided for in Sections 10.1 or 10.2.

(aaa) "<u>UIRF</u>" shall mean the University of Iowa Research Foundation.

(bbb) "<u>Valid Claim</u>" shall mean any claim from an issued and unexpired Patent that (a) has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be taken or has been taken within the time allowed for appeal, (b) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, and (c) provides exclusionary and enforceable rights with respect to the claimed subject matter.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(ccc) "Withholding Taxes" shall have the meaning set forth in Section 3.1(a).

# 2. LICENSE GRANT.

## 2.1 Non-Exclusive License Grant to Licensee.

Subject to the terms of this Agreement, Coley shall grant, and hereby grants, to Licensee and Licensee hereby accepts, a non-exclusive, royalty-bearing license, with the right to grant sublicenses as defined in Section 2.2, below, under the Patents, including the patents listed in Exhibit A which are subject to the terms of the OHRI Agreement and the UIRF Agreement (i) to Exploit the Licensed Product in the Field in the Territory and (ii) to Manufacture or have Manufactured the Compound in connection with such Exploitation of the Licensed Product.

## 2.2 Right to Grant Sublicenses.

(a) Sublicensees.

Licensee shall have the right to grant sublicenses to Sublicensees solely to Exploit the Licensed Product on behalf of Licensee provided that: (i) it shall be a condition of any such sublicense that the Sublicensee agrees to be bound by all of the applicable obligations set forth in this Agreement; (ii) if Licensee grants such sublicense, Licensee shall be deemed to have guaranteed that such Sublicensee shall fulfill all of Licensee's obligations under this Agreement applicable to the subject matter of such sublicense; and (iii) such sublicense shall not reduce or delay payments otherwise due and owing to Coley by Licensee under this Agreement

## (b) Large Pharmaceutical Company.

Licensee shall have the right to grant **[\*]** of all of the provisions of this Agreement to a Large Pharmaceutical Company provided that: (i) it shall be a condition of the sublicense that the Large Pharmaceutical Company agrees to be bound by all of the applicable obligations set forth in this Agreement; (ii) if Licensee grants such sublicense, Licensee shall be deemed to have guaranteed that such Large Pharmaceutical Company shall fulfill all of Licensee's obligations under this Agreement applicable to the subject matter of such sublicense; and (iii) the sublicense shall not reduce or delay payments otherwise due and owing to Coley by Licensee under this Agreement.

Any sublicense agreement with a Large Pharmaceutical Company shall provide in the event of an early termination of this Agreement (other than a termination for convenience by Licensee pursuant to Section 6.2 (a) or by Coley pursuant to Section 6.2 (b) (ii)) for the termination of the sublicense and the conversion of the sublicense to a license directly between Coley and the Large Pharmaceutical Company on substantially the same terms as this Agreement. Further, if Licensee has agreed to grant a sublicense to a Large Pharmaceutical Company and [\*] For the avoidance of doubt, [\*]

## 2.3 Limitations.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



**Regulatory Milestone Payment** 

\*]

Except as specifically provided in Section 2.1 (including the right to grant sublicenses pursuant to Section 2.2), Licensee shall have no rights to use the Patents for any other purpose. Licensee acknowledges and agrees that Coley's right to terminate the Agreement in the event that Licensee takes any of the actions described in Section 6.2 (c) was expressly bargained for and agreed to by the parties and is a necessary condition for obtaining and maintaining the licenses provided in this Section 2. No other rights, express or implied, are granted to Licensee pursuant to this Agreement except as expressly granted herein.

#### 2.4 Option.

Effective upon written notice to Coley, Licensee may [\*]

## 3. PAYMENTS AND ROYALTIES.

#### 3.1 Up-Front Payment.

In partial consideration of (i) Coley's investment in the Patents and (ii) the license granted to Licensee pursuant to Section 2.1, Licensee shall make a nonrefundable, non-creditable up-front license fee payment of Five Million Dollars (\$5,000,000.00). Such up-front license fee shall be payable by Licensee within two business days of the execution of this Agreement by both Parties.

#### 3.2 Regulatory Milestone Payments.

At any point in time when a Regulatory Milestone (as defined below) is achieved for the Licensed Product by either Licensee, its Affiliates or Sublicensees, Licensee shall promptly notify Coley of the achievement of said Regulatory Milestone and shall pay Coley the amount corresponding to the Regulatory Milestone achieved hereunder (the "<u>Regulatory Milestones</u>") set forth below (each, a "<u>Regulatory Milestone Payment</u>"). Each Regulatory Milestone Payment shall be immediately due and payable by Licensee. Each Regulatory Milestone Payment shall be payable only once.

**Regulatory Milestone Payments** 

#### 3.3 Royalty Payments.

(a) <u>Royalty Payments Due</u>. Licensee and its Sublicensees shall pay to Coley royalty payments on the Net Sales of the Licensed Product in the amounts set forth below ("<u>Royalty Payments</u>"):

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



(i) With respect to Net Sales of the Licensed Product during the period in which the Licensed Product is covered by a Valid Claim, Licensee shall pay Coley a royalty of [\*] percent ([\*]%) of such Net Sales.

Royalty Payments shall be due for sale of the Licensed Product under this Section 3.3(a) if there is a Valid Claim in either the country in which the Licensed Product is sold or in the country in which the Licensed Product is Manufactured. In any event, only one (1) Royalty Payment shall be due under this Section 3.3(a) for the Licensed Product sold even if more than one Valid Claim covers the Licensed Product. Royalty Payments shall **[\*]** for royalties or payments made to Third Parties by Licensee for Third Parties' technologies which are utilized or incorporated into or otherwise required to be paid regarding the Licensed Product. Coley shall be solely responsible for any payments owed to UIRF and OHRI due to the rights granted to Licensee pursuant to Section 2.1.

(b) <u>Tender of Royalty Payments and Royalty Reports</u>. Within **[\*]** after the conclusion of each Royalty Quarter, Licensee shall tender payment of any Royalty Payments due under this Agreement and shall concurrently deliver to Coley a report on the Net Sales activity of Licensee during such Royalty Quarter (the "<u>Royalty Report</u>"). If no Royalty Payment is due, the Royalty Report shall so state. All such Royalty Reports shall be considered Confidential Information of Licensee under this Agreement. Royalty Reports shall contain at least the following information:

(i) Net Sales of the Licensed Product sold by Licensee and Sublicensee(s) on a country-by-country basis (including number of units sold during the applicable Royalty Quarter); and

(ii) total Royalty Payments due with respect to Net Sales of the Licensed Product sold by Licensee and Sublicensee(s) in each country.

(c) <u>Period During Which Royalties Are Payable</u>. Royalty Payment obligations under this Section 3.3 shall become effective on a country-bycountry basis upon the First Commercial Sale of the Licensed Product and continue thereafter until there are no Valid Claims covering the Licensed Product in such country. Upon expiration of the period during which Licensee or Sublicensee is obligated to make Royalty Payments with respect to the Licensed Product, on a country-by-country basis, the rights granted to Licensee pursuant to Section 2.1 with respect to the Licensed Product shall become perpetual, irrevocable, fully paid-up and royalty-free.

## 3.4 Withholding; Payments.

(a) Any payments made by Licensee or Sublicensee to Coley under this Agreement shall be reduced by the amount that Licensee or Sublicensee is required to withhold pursuant to any applicable tax law ("<u>Withholding Taxes</u>").

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Licensee shall submit reasonable proof of payment of the Withholding Taxes to Coley within a reasonable period of time after such Withholding Taxes are remitted to the proper taxing authority.

(b) Any payments due under this Section 3 shall be made in dollars, using a mutually acceptable method of payment. With respect to sales of the Licensed Product invoiced in a currency other than dollars, the Net Sales and amounts due to Coley hereunder shall be expressed in the domestic currency of the Person making the sale, together with the dollar equivalent of the amount payable to Coley For each Royalty Quarter and each currency, such dollar equivalent shall be calculated using an exchange rate equal to [\*], or, if not so available, as otherwise agreed by the Parties.

(c) Payments shall be made via wire transfer to:

[\*]

#### 3.5 Late Payments.

Any payments due under this Section 3 that are not made on or before the date specified under the terms of this Agreement shall bear interest, to the extent permitted by law, at a rate equal at all times to the prime rate of interest announced publicly from time to time by Citibank, N.A., plus [\*] percent ([\*]%), but in no case higher than the maximum rate permitted by applicable law, for the number of days delinquent.

#### 3.6 Audit of Records.

(a) <u>Records</u>. Licensee and Sublicensees shall keep and maintain records of sales, importations, and other dispositions of the Licensed Product. The records required by this Section 3.6 shall be maintained and available for inspection for a period of [\*] following the Royalty Year to which they pertain.

(b) <u>Audit</u>. Coley shall have the right, at Coley's expense, to examine, through an independent certified public accounting firm reasonably acceptable to Licensee, those records of Licensee and Sublicensee as may be reasonably necessary to confirm the accuracy of the Royalty Reports. Any such examination shall be made only upon not less than [\*] prior written notice to Licensee or Sublicensee, as the case may be, during regular business hours, and within [\*] after the end of Royalty Period; provided, however, that such examination shall not take place more often than [\*] per Royalty Year and shall not cover such records for more than the preceding [\*] Royalty Years. Such accounting firm shall disclose to Coley only the final audited Royalty Payment amounts to be paid by Licensee or Sublicensee. Upon the completion of an audit hereunder for any Royalty Year, the calculation of amounts payable with respect to

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

such year shall be binding and conclusive upon Coley, and Licensee and its Sublicensees shall be released from any liability or accountability with respect to amounts payable for such year.

(c) <u>Audit Costs</u>. In the event that any such inspection shows an underreporting or an underpayment in excess of [\*] percent ([\*]%) for any Royalty Year, then (i) Licensee or Sublicensee, as the case may be, shall pay the reasonable costs of such examination charged by such accounting firm and in any event shall pay any additional sum, including interest charges as provided in Section 3.5 on any such additional sum shown to be due to Coley and (ii) such audit will not count against the [\*] per Calendar Year limit set forth in Section 3.6 (b) above.

## 4. DEVELOPMENT; DILIGENCE OBLIGATIONS.

4.1 **Diligence Generally**. Licensee shall use commercially reasonable efforts consistent with the efforts and resources normally used for a product of its own discovery of similar market potential at a similar stage in its product life, taking into account the competitiveness of the market place, the proprietary position of the product, the regulatory structure involved, the profitability of the applicable products and other relevant factors ("Commercially Reasonable Efforts"), (a) to pursue the Exploitation of the Licensed Product in the U.S. and in one or more EU Major Market Countries and (b) to undertake investigations and actions required to obtain appropriate Regulatory Approval therefor. The Parties agree that the diligence obligations set forth in this Section 4.1 shall [\*] and the Parties further agree that [\*].

## 5. SUPPLY OF MATERIALS; MARKING.

## 5.1 Manufacture of Compound and Manufacturing Information.

(a) Supply of Compound. Coley shall not be obligated to supply any quantities of the Compound to Licensee or Sublicensee(s).

(b) Licensee agrees that, to the extent required by the Iowa Agreement and applicable law, the Licensed Product produced for sale in the United States and embraced by a Valid Claim under a Patent Right listed on <u>Exhibit A</u> with UIRF identified as an Assignee will be Manufactured substantially in the United States, unless any waiver of such requirement is obtained.

(c) <u>Manufacturing Information</u>. In the event that Licensee or Sublicensee(s) Manufacture(s) or has a Third Party Manufacture Compound and uses information and/or intellectual property rights which result in a Regulatory Authority mandating changes to specifications for any immunomodulatory oligonucleotide and, as a result, Coley is unable to obtain or Manufacture reasonable quantities of other immunomodulatory oligonucleotides and/or other immunomodulatory oligonucleotides in

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compliance with the mandate by such Regulatory Authority with respect to such materials, Licensee or Sublicensee(s), as the case may be, shall use commercially reasonable efforts to provide Coley and its licensees with a license on commercially reasonable terms to the necessary information and/or intellectual property rights to Manufacture the Compound and/or other immunomodulatory oligonucleotides in compliance with such specifications for any immunomodulatory oligonucleotide or the applicable mandate. In the event that Coley or Sublicensee(s) Manufacture(s) or has a Third Party Manufacture Compound and uses information and/or intellectual property rights which result in a Regulatory Authority mandating changes to specifications for the Compound and, as a result, Licensee or its Sublicensee(s) is unable to obtain or Manufacture reasonable quantities of the Compound in compliance with the mandate by such Regulatory Authority with respect to such materials, Coley shall use commercially reasonable efforts to provide Licensees and its sublicensees with a license on commercially reasonable terms to the necessary information and/or intellectual property rights to Manufacture the Compound in compliance with such specifications for the Compound or the applicable mandate.

### 5.2 Marking.

Licensee shall comply with the requirements as to the marking of the Licensed Product set forth in Article 7 of the Iowa Agreement.

# 6. TERM AND TERMINATION.

### 6.1 **Term**.

The term of this Agreement shall begin on the Effective Date and, unless earlier terminated pursuant to this Section 6, continue on a country-by country basis until the expiration or termination of the last Valid Claim with respect to such country (the "<u>Term</u>").

#### 6.2 Termination.

(a) <u>Termination by Either Party; Termination by Licensee</u>. Upon a material breach of this Agreement by either Party, the non-breaching Party may provide written notice to the breaching Party specifying the material breach. If the breaching Party fails to cure the material breach during a [\*] period (or in the case of a material breach of Section 4.1, a [\*] period) following the date on which the notice of breach is provided then the non-breaching Party shall have the right to terminate this Agreement. If such breach is not reasonably cured within such [\*] but (1) the breaching Party is making a bona fide effort to cure any such breach, such termination shall be delayed in order to permit the breaching Party a reasonable period of time to remedy the breach, or (2) if the breaching Party initiates a dispute resolution proceeding pursuant to Section 11.3 with respect to such breach prior to the expiration of such [\*] period, then such termination shall not become effective until [\*] following the final conclusion of the

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dispute resolution proceeding if termination is permitted by such resolution. Licensee shall have the right to terminate this Agreement for convenience upon [ \* ] prior written notice to Coley.

### (b) <u>Termination by Coley</u>.

(i) Coley shall have the right upon written notice to Licensee to terminate this Agreement for non-payment of any amount due hereunder from Licensee to Coley if such non-payment shall continue uncured for a period ending (1) [\*] following notice of such non-payment given by Coley to Licensee or, (2) if Licensee initiates a dispute resolution proceeding pursuant to Section 11.3 with respect to such payment prior to the expiration of such [\*] period, then [\*] following the final conclusion of the dispute resolution proceeding if termination is permitted by such resolution.

(ii) Coley may terminate this Agreement in the event that Licensee or its Affiliates take any action, direct or indirect: (a) to challenge the validity, scope, or enforceability of the Patents licensed to Licensee hereunder; or (b) to oppose, object to, provoke an interference toward or initiate or support any reexamination proceedings challenging the Patents; provided that it shall not be grounds for terminating this Agreement if Licensee challenges the validity, scope, or enforceability of the Patents licensed to Licensee hereunder in defense of an action for infringement of the Patents brought by Coley arising from Licensee's activities outside of the scope of this Agreement.

#### (c) Termination for Insolvency.

(i) To the extent permitted by law, upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors (a "<u>Bankruptcy Event</u>") by either Party, Coley, in the case of a Bankruptcy Event by Licensee, or Licensee, in the case of a Bankruptcy Event by Coley, may terminate this Agreement; provided, however, that, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the subject Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

(ii) This Section 6.2(c) is without prejudice to any rights the non-Affected Party may have arising under any bankruptcy, reorganization, insolvency or similar laws, and Licensee expressly reserves the right to maintain its license in effect pursuant to Section 11.17 with respect to a Bankruptcy Event involving Coley.

(d) <u>No Limitation on Other Rights</u>. Nothing in this Agreement shall be construed to limit the rights of Licensee, upon a material breach by Coley, to maintain its license in full force and effect and pursue any remedies otherwise available at law or equity.

## 6.3 Effects of Expiration or Termination.

(a) Surviving Provisions. The provisions of Sections 3 (with respect to payment obligations accruing prior to the date of expiration or

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termination), 6, 7, 8, 9, 10, and 11 shall survive expiration or termination of this Agreement for any reason.

(b) <u>Licensee Rights</u>. Subject to the provisions of Section 6.3(a), (i) upon expiration of the Term, the rights granted to Licensee pursuant to Section 2.1 shall become perpetual, irrevocable, fully paid-up and royalty-free, and (ii) subject to the following sentence, upon termination of this Agreement by Coley pursuant to Section 6.2(a), 6.2(b) or 6.2(c), the rights granted to Licensee pursuant to Section 2.1 shall terminate. Upon termination of this Agreement by Coley pursuant to Section 6.2(a), 6.2(b) or 6.2(c), (i) Licensee shall [\*] and (ii) Licensee shall with respect to any sales of the Licensed Product made prior to the termination of this Agreement [\*], continue to provide Royalty Reports and to pay royalties on all Net Sales of the Licensed Product as required hereunder.

(c) <u>Obligations Survive</u>. Any termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to termination.

## 7. CONFIDENTIALITY.

#### 7.1 Nondisclosure Obligation.

Each Party shall use the Confidential Information of the other Party only in accordance with the activities contemplated by this Agreement and shall not disclose to any Third Party any Confidential Information of the other Party, without the prior written consent of the other party or as expressly provided below. This obligation shall not apply to Confidential Information that:

(a) is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party to the Receiving Party, as documented by business records;

(b) at the time of disclosure or thereafter becomes published or otherwise part of the public domain without breach of this Agreement by the Receiving Party;

(c) is subsequently disclosed to the Receiving Party by a Third Party who has the right to make such disclosure; or

(d) is developed by the Receiving Party independently of Confidential Information received from the Disclosing Party and such independent development can be properly demonstrated by the Receiving Party.

#### 7.2 Permitted Disclosures.

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Notwithstanding the provisions of Section 7.1, a Receiving Party may make the following disclosures of Confidential Information received from the Disclosing Party:

(a) disclosures to governmental or other regulatory agencies in order to gain approval to conduct Licensed Product trials or to market the Licensed Product, but such disclosure may be only to the extent reasonably necessary to obtain such authorizations upon consultation with the other Party;

(b) disclosures to agents, consultants, Affiliates and/or other Third Parties as necessary for the research and development, Manufacturing and/or marketing of the Licensed Product, or to complete a Permitted Assignment (as defined in Section 11.1), (or for such Persons to determine their interest in performing such activities or such Permitted Assignment), in accordance with this Agreement on the condition that such Third Parties are or agree to be bound by confidentiality obligations substantially as restrictive and long as those contained in this Agreement; or

(c) disclosures required by law or court order, provided that notice is promptly delivered to the Disclosing Party in order to provide it with an opportunity to seek a protective order or other similar order with respect to such Confidential Information and the Receiving Party thereafter discloses only the minimum information reasonably required to be disclosed in order to comply with the request, whether or not a protective order or other similar order with respect to such Confidential Information and the Receiving Party thereafter discloses only the minimum information reasonably required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the Disclosing Party.

## 7.3 Partial Disclosures.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because one or more individual elements of such Confidential Information are in the public domain or in the possession of such Party unless every feature of the Confidential Information has been disclosed in accordance with the provisions herein.

## 7.4 Publicity.

Neither Coley nor Licensee shall issue any press release or other public disclosure relating to this Agreement except as mutually agreed. The joint press release announcing the execution of this Agreement shall be substantially in the form as Exhibit D attached. Notwithstanding any other provision contained in this Section 7.4, either Party may make such public disclosure relating to this Agreement as may be required by applicable law. Prior to any public disclosure relating to this Agreement pursuant to the preceding sentence, the Party proposing to make such disclosure shall provide reasonable notice thereof and the proposed contents of such disclosure to the other

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Party and shall consult in good faith with the other Party regarding the timing and contents of any such disclosure.

# 8. MAINTENANCE AND ENFORCEMENT OF PATENTS.

## 8.1 Responsibility for Patents.

Coley, by counsel it selects, shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain all Patents in Coley's name and in countries designated by Coley at the sole discretion of Coley.

## 8.2 Infringement by Third Parties.

The Parties agree to provide each other written notice promptly after becoming aware of any infringement of the Patents in the Field (irrespective of the delivery method used for the vaccine). Coley shall have the right, but not the obligation, under its own control and at its own expense, to prosecute any Third Party infringement of the Patents and/or to defend the Patents in any declaratory judgment action brought by a Third Party which alleges invalidity, unenforceability, or non-infringement of the Patents. Subject to Section 8.4 below, Coley may enter into any settlement, consent judgment, or other voluntary final disposition of any infringement or declaratory judgment action hereunder without the prior written consent of Licensee.

#### 8.3 Infringement Claims.

If the Manufacture, sale or use of the Compound as used in the Licensed Product in the Field results in any claim, suit or proceeding filed by a Third Party alleging patent infringement by Coley or Licensee or Sublicensee, such Party shall promptly notify the other Party in writing. In the event that one Party is sued subject to Section 8.4, the Party subject to such claim shall have the exclusive right to defend and control the defense of any such claim, suit or proceeding, at its own expense, using counsel of its own choice; provided, however, that if Coley or Licensee and Coley together are sued with respect to the Licensed Product sold by Licensee or Sublicensee, Coley shall have the exclusive right to take control of such defense. Licensee shall have the right to retain its own counsel at its sole cost and expense, and shall have the right to consult with Coley in any proceeding under this Section 8.3. The Party subject to the claim shall keep the other Party hereto reasonably informed of all material developments in connection with any such claim, suit or proceeding. The Party not subject to the claim shall cooperate in all reasonable respects with the Party subject to the claim in the defense of the claim.

#### 8.4 Settlements.

No settlements, consent judgments, or other voluntary final dispositions of a dispute adversely affecting the rights or obligations of a Party or Sublicensee, including the rights or obligations of the Party under this Agreement, shall be entered into in connection with any dispute, claim or

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proceeding described in Section 8.2 or 0 without the prior written consent of the adversely affected Party or Sublicensee, such consent not to be unreasonably withheld or delayed. Without limiting the foregoing, no settlements, consent judgments, or other voluntary final dispositions of any dispute, claim or proceeding described in Section 8.2 or 0 adversely affecting the rights or obligations of Coley under the Patents shall be entered into without the prior written consent of Coley, such consent not to be unreasonably withheld or delayed. The Parties shall comply with the provisions of Section 8.4 of the Iowa Agreement with respect to any settlement, consent judgment, or other voluntary final disposition of any suit relating to the subject matter of this Agreement.

#### 8.5 Recoveries and Damages.

Any recoveries and damages received as a result of a dispute, claim or proceeding described in Section 8.2 or 8.3 or any settlement, consent judgment, or other voluntary final disposition thereof shall first go toward reimbursing the Parties or Sublicensee for their respective costs and expenses of such suit. Thereafter, any remainder shall be [\*].

#### 8.6 Subject to Iowa Agreement.

To the extent related to Patents under the Iowa agreement, the provisions of this Section 8 are subject to in all respects the provisions of the Iowa Agreement, including Article 8 thereof.

## 9. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PARTIES.

#### 9.1 Representations and Warranties of Each Party to the Other.

Each Party hereby represents and warrants to the other Party hereto, effective as of the Effective Date, that:

(a) Such Party is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;

(b) The execution and performance of this Agreement by such Party has been duly authorized by all requisite corporate action;

(c) Such Party has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, including the right, power and authority to grant the licenses granted herein;

(d) The execution and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any loan agreement, guaranty, financing agreement,

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agreement affecting the Licensed Product or the Compound, or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter documents or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which it or any of its property is bound;

(e) The execution and performance by such Party of this Agreement and its compliance with the terms and provisions hereof do not and will not violate any law or regulation applicable to it; and

(f) This Agreement has been duly authorized by all necessary corporate action on the part of such Party, has been executed and delivered by such Party and constitutes such Party's legal, valid and binding obligation, enforceable against such Party in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles.

#### 9.2 Covenants of Licensee.

Licensee hereby covenants with Coley that:

(a) It will comply with all of the obligations applicable to sublicensees of Coley under the Iowa Agreement and OHRI Agreement;

(b) Licensee will not market or actively promote the Licensed Product for off-label use outside the Field; and

(c) Licensee agrees not to take any further action, direct or indirect, in connection with current patent opposition proceedings in Europe for the Patents, shall withdraw its participation in such proceedings, and shall not initiate any additional opposition proceedings for the Patents currently in opposition proceedings by the European Patent Office. Licensee agrees to take any actions reasonably requested by Coley in connection with its withdrawal from opposition proceedings, shall not directly or indirectly oppose, object to, provoke an interference toward or initiate or support any re-examination proceedings challenging the Patents and agrees to withdraw any challenge to the Patents, other than in defense of an action for infringement of the Patents.

## 9.3 Representations, Warranties and Covenants of Coley.

Coley hereby represents, warrants and covenants to Licensee, effective as of the Effective Date, that:

(a) Coley owns or possesses adequate licenses or other rights to use the Patents in the Field and to grant the rights and licenses herein; and

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(b) (i) The Patents existing as of the Effective Date are subsisting and have not been held by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part; (ii) there are no claims, judgments or settlements against or amounts with respect thereto owed by Coley or any of its Affiliates relating to the Patents, (iii) except as listed in Exhibit E, no claim or litigation has been brought or threatened by any Person alleging (A) that any Patent is invalid or unenforceable or (B) the Patents or the disclosing, copying, making, assigning, licensing or Exploitation of the Patents or products embodying the Patents, including the Exploitation of the Licensed Product, violates, infringes or otherwise conflicts with any intellectual property or proprietary right of any Third Party; (iv) the conception, development and reduction to practice of the Patents existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person; and (v) it has not received notice of any claim or litigation asserted or commenced against it that would have an adverse effect on the rights granted to Licensee under this Agreement.

(c) (i) The OHRI Agreement and Iowa Agreement are in full force and effect, Coley has the right to grant any and all sublicenses granted under this Agreement under each of the OHRI Agreement and Iowa Agreement and (ii) Coley has not received notice of termination and is not aware of any facts or information that would, with the passage of time result in the termination of the OHRI Agreement or Iowa Agreement, respectively.

(d) Except as may be listed on Exhibit A , to the best of Coley's knowledge, there are no patents or patent applications owned or controlled by Coley as of the effective date of this Agreement that, but for the licenses granted in this Agreement, would be infringed by the Exploitation of the Licensed Product by the Licensee or its Sublicensees. If any such patent or patent application is identified during the Term, at Licensees option it shall be included in the Patents licensed under this Agreement, without the payment of additional consideration by Licensee to Coley.

#### 9.4 Bayh-Dole.

Both Parties acknowledge that the U.S. Public Health Service may have certain rights, as provided in Bayh-Dole (Public Law 96-517 of 1980), to the Patents.

# **10. INDEMNIFICATION AND LIMITATION OF LIABILITY.**

## 10.1 Indemnification by Licensee.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Licensee shall indemnify, defend and hold harmless Coley, and each of its employees, officers, directors and agents (each, a "<u>Coley Indemnified Party</u>"), from and against any and all liability, loss, damage, cost, and expense, including reasonable attorneys' fees and reasonable expenses of litigation (collectively, a "<u>Liability</u>"), arising out of any Third Party Claim which the Coley Indemnified Party may incur, suffer or be required to pay to the extent resulting from or arising in connection with (i) the breach by Licensee of any covenant, representation or warranty contained in this Agreement; (ii) any negligent or wrongful act or omission of Licensee (its directors, officers, or agents, or distributors thereof) which is the proximate cause of injury, death or property damage to a Third Party; (iii) actual or asserted violations of any applicable law or regulation (other than patent or other intellectual property law or regulation) by Licensee, Sublicensees or distributors by virtue of which the Licensed Product in the Field Manufactured, distributed or sold by Licensee, Sublicensees or distributors shall be alleged or determined to be adulterated, mislabeled or otherwise not in compliance with any such applicable law or regulation; (iv) claims for bodily injury, death, product liability, warranty of fitness or merchantability, or property damage attributable to the development, Manufacture, distribution, sale or use of the Licensed Product in the Field by Licensee, Sublicensees or distributed or sold by Licensee, Sublicensees or distributors ordered by a governmental agency or required by a confirmed product failure as reasonably determined by Licensee, Sublicensees or distributors ordered by a breach by Coley of this Agreement or (B) any manufacturing agreement into which Coley may enter pursuant to Section 5.1 or (C), in the case of clauses (ii) through (v), any negligent act or omission or intentional misconduct on the part of Coley or any Liability for which Coley is required to provide indemnificatio

## 10.2 Indemnification by Coley.

Coley shall indemnify, defend and hold harmless Licensee and its employees, officers, directors and agents and its Sublicensees (each, a "Licensee Indemnified Party") from and against any Liability arising out of any Third Party Claim, which Licensee Indemnified Party may incur, suffer or be required to pay to the extent resulting from or arising in connection with (i) the breach by Coley of any covenant, representation or warranty contained in this Agreement; (ii) any negligent or wrongful act or omission by Coley (or any of its licensees, licensors or their respective directors, officers, or agents, or distributors thereof) which is the proximate cause of injury, death or property damage to a Third Party; (iii) any Third Party Claim that the granting of the rights and licenses herein by Coley violates any rights of any Third Party, or (iv) claims for bodily injury, death, product liability, warranty of fitness or merchantability, or property damage attributable to the development, Manufacture, distribution, sale or use of the Compound or pharmaceutical products incorporating the Compound by Coley, any of its licensees other than Licensee or their respective agents or distributors; except to the extent that such Liability arises in connection with or is otherwise attributable to (A) a breach by Licensee of this Agreement or (B), in the case of clauses (ii) through (v), any negligent act or omission or intentional misconduct on the part of Licensee or any Liability for which Licensee is required to provide indemnification under Section 10.1.

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## 10.3 Indemnification Procedure.

Any Person seeking indemnification under this Section 10 (the "<u>Indemnitee</u>") shall promptly notify the Party from whom indemnification is sought (the "<u>Indemnitor</u>") in writing of any Claim, and, subject to Section 8.3, the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to assume the defense thereof with counsel mutually satisfactory (consent not to be unreasonably withheld or delayed) to the other Party by giving written notice to the Indemnitee and the other Party within thirty (30) days after receipt of written notice of such Claim from the Indemnitee; provided, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid (a) by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between the Indemnitee and any other party represented by such counsel in such proceeding; or (b) by Indemnitee in all other cases. In no event shall the Indemnitor be liable for any Liabilities that result from any unreasonable delay by the Indemnitee in providing the written notice pursuant to the first sentence of this Section 10.3. In the event that it is ultimately determined that the Indemnitor is not obligated to indemnify, defend or hold harmless an Indemnitee from and against such Claim, the Indemnitor in its defense of such Claim with respect to the Indemnitee. The Indemnitee and its employees and agents shall reasonably cooperate with, and at the expense of, the Indemnitor and its legal representatives in the investigation of any Claim covered by this Section 10.

#### 10.4 Settlements.

Neither Party may settle a Claim without the consent of the other Party if such settlement would (a) impose any monetary obligation on the other Party, (b) require the other Party to submit to an injunction, or (c) otherwise limit the other Party's rights under this Agreement, such consent not to be unreasonably withheld or delayed in the case of clauses (b) and (c). Any payment made by a Party to settle a Claim shall be, unless otherwise provided in Section 10.1 or 10.2, as the case may be, at its own cost and expense.

## 10.5 Limitation of Liability.

With respect to any claim by one Party against the other Party arising out of the performance or failure of performance of the other Party under this Agreement, the Parties expressly agree that, except for a Party's indemnification obligations pursuant to Section 10.1 or 10.2 with respect to Third Party claims, the liability of such Party to the other Party for such breach shall be limited under this Agreement or otherwise at law or equity to direct damages only and in no event shall a Party be liable for punitive, special, incidental, multiple, exemplary or consequential damages.

# 10.6 Insurance.

(a) <u>Licensee</u>. Prior to or immediately upon the first administration of the Licensed Product in the Field to a human in accordance with this Agreement, and for a period of

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[\*] after the last sale of the Licensed Product in the Field hereunder, Licensee shall obtain and/or maintain, at its expense, product liability insurance in amounts which are reasonable and customary in the industry for companies of comparable size and activities. Such product liability insurance shall insure against liability for personal injury, physical injury, and property damage. Licensee shall provide proof of insurance to Coley upon request. Licensee may satisfy this requirement by a representation that it is self-insured and/or maintains Third Party liability insurance in amounts sufficient to meet the foregoing requirement.

(b) <u>Coley</u>. Prior to or immediately upon the first administration of the Licensed Product in the Field to a human in accordance with this Agreement, as notified by Licensee to Coley, and for a period of **[\*]** after the last sale of the Licensed Product in the Field hereunder, as notified by Licensee to Coley, Shall obtain and/or maintain, at its expense, product liability insurance in amounts which are reasonable and customary in the industry for companies of comparable size and activities. Such product liability insurance shall insure against liability for personal injury, physical injury, and property damage. Coley shall provide proof of insurance to Licensee upon request. Coley may satisfy this requirement by a representation that it is self-insured and/or maintains Third Party liability insurance in amounts sufficient to meet the foregoing requirement.

#### 10.7 Warranty Disclaimer.

EXCEPT AS EXPRESSLY MADE UNDER THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS, NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, WITH RESPECT, IN THE CASE OF COLEY, TO THE PATENTS OR, IN THE CASE OF LICENSEE, TO THE LICENSED PRODUCT OR THE COMPOUND USED THEREIN.

#### 10.8 Performance by Subcontractors.

The Parties recognize that the Licensee may perform some or all of its obligations under this Agreement through Third Party subcontractors, provided, however, that the Licensee shall remain responsible and liable for the performance by its Third Party subcontractors and shall cause its Third Party subcontractors to comply with the provisions of this Agreement in connection therewith.

#### **11. MISCELLANEOUS.**

#### 11.1 Assignment.

Neither this Agreement nor any or all of the rights and obligations of a Party shall be assigned, delegated, sold, transferred, sublicensed (except as otherwise provided herein) or otherwise disposed of, by operation of law or otherwise, to any Third Party without the prior written

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consent of the other Party, which shall not be unreasonably withheld, and any attempted assignment, delegation, sale, transfer, sublicense or other disposition, by operation of law or otherwise, of this Agreement or of any rights or obligations hereunder contrary to this Agreement shall be a material breach of this Agreement by the attempting Party and shall be void and without force or effect; <u>provided</u>, <u>however</u>, that either Party may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its assets or stock, in the event of its merger or consolidation or change in control or similar transaction, or, in the case of Licensee, in the event of a sale or transfer by Licensee of all or substantially all of its vaccine business related to the Licensed Product in connection with the transfer or sale of all or substantially all of its business related to a Licensed Product (any such transaction described in this proviso, a "<u>Permitted Assignment</u>"). In the event of a Permitted Assignment by Licensee, **[\*]**. In addition, either Party may, without such consent, assign this Agreement and delegate its rights and obligations hereunder, in whole or in part, to an Affiliate; <u>provided</u>, <u>however</u>, that the Party making any such assignment or delegations shall, notwithstanding such assignment or delegation, remain responsible for the full, complete and faithful performance of its obligations hereunder. This Agreement shall be binding upon, and inure to the benefit of, each Party, and its permitted successors and assigns.

#### 11.2 Governing Law.

This Agreement shall be governed by and construed in accordance with the laws of the state of New York, U.S.A. without regard to its conflict of law rules.

#### 11.3 Dispute Resolution.

In the event of any dispute, controversy or claim arising out of, relating to or in connection with any provision of this Agreement, the Parties shall try to settle their differences amicably and in good faith between themselves first, by referring the disputed matter to the respective Chief Executive Officers of each Party, or any direct report designated by such Chief Executive Officer. In the event such executives are unable to resolve such dispute within a thirty (30) day period, either Party may invoke the provisions of this Section 11.3. Except as provided in Section 11.4, any dispute, controversy or claim arising out of or relating to this Agreement, or the breach thereof, including any question regarding this Agreement's existence, termination or validity, shall be referred to and finally settled by binding arbitration, in accordance with the rules of the American Arbitration Association in force on the date the demand for arbitration is filed. The demand for arbitration may be filed by either Party within a reasonable time after the controversy or claim has arisen, but no later than after the date upon which institution of legal proceedings shall be barred by the applicable statute of limitations. There shall be three (3) arbitrators, each Party to designate one arbitrator and the two Party-designated arbitrators to select the third arbitrator. The Party initiating recourse to arbitration shall include in its notice of arbitration its appointment of an arbitration shall be final and conclusively binding, and shall not include any damages expressly prohibited by Section 10.5. Judgment on the arbitral award may be entered in any

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court having jurisdiction thereof. All costs incurred in connection with such arbitration, including reasonable attorneys' fees, shall be borne by the Party which incurs the costs.

## 11.4 No Arbitration of Patent Disputes.

Unless otherwise agreed by the Parties, disputes relating to the scope, validity, enforceability or infringement of Patents shall not be subject to arbitration, and shall be submitted to a court or patent office of competent jurisdiction.

## 11.5 Injunctive Relief and Jurisdiction.

Nothing in this Agreement shall be construed to limit or preclude a Party from bringing any action in any court of competent jurisdiction for injunctive or other provisional relief to competent be other Party to comply with its obligations hereunder, whether before or during the pendancy of arbitration proceedings. The Parties agree that all such suits may, at the option of either Party, be initiated and maintained before the United States District Court for the Southern or Eastern District of New York U.S.A. and both Parties submit to personal jurisdiction and to the service of process, pleadings and notices in connection with any and all actions seeking such injunctive or provisional relief to the court referred to above. Notwithstanding the foregoing, any dispute regarding the validity, scope or enforceability of patents, trademarks or other intellectual property that is or can be the subject of registration with a governmental entity shall be submitted to a court of competent jurisdiction in the territory in which such rights apply.

## 11.6 Waiver.

Any delay or failure in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, nor operate to bar the exercise or enforcement thereof at any time or times thereafter, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time. No waiver of a breach shall be deemed to be a waiver of a different or subsequent breach.

# 11.7 Independent Relationship.

Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

## 11.8 Export Control.

This Agreement is made subject to any restrictions concerning the export of the Licensed Product or technical information from the United States of America which may be imposed upon or related to the Parties from time to time by the government of the United States of America.

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Licensee agrees that it will not export, directly or indirectly, any technical information acquired from Coley under this Agreement, and Licensee agrees that it will not export, directly or indirectly, the Licensed Product using such technical information, to any country for which the United States government or any agency thereof at the time of export requires an export license or other governmental approval, without first obtaining any consent that may be required by applicable law or regulation.

#### 11.9 Entire Agreement; Amendment.

This Agreement (along with the Exhibits attached hereto) sets forth the complete, final and entire agreement of the Parties relating to the subject matter hereof and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect thereto and supersedes and terminates all prior agreements, writings and understandings between the Parties to the extent they relate to the subject matter hereof, including the term sheet agreed to by the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as are set forth herein or otherwise contemplated by this Section 11.9. No terms or provisions of this Agreement shall be varied or modified and no subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

#### 11.10 Notices.

Each notice required or permitted to be given or sent under this Agreement shall be in writing and delivered personally or given by facsimile transmission (with confirmation copy by registered first-class mail) or by registered or certified mail (return receipt requested) or internationally-recognized overnight courier, to the Parties at the addresses and facsimile numbers indicated below.

If to Coley, to:	Coley Pharmaceutical Group, Inc. Wellesley Gateway 93 Worcester Street, Suite 101 Wellesley, MA 02481, U.S.A. Attention: President and CEO Facsimile: 1-781-431-6403
with a copy to:	Coley Pharmaceutical Group, Inc. Wellesley Gateway 93 Worcester Street, Suite 101 Wellesley, MA 02481, U.S.A. Attention: Senior Vice President and General Counsel Facsimile: 1-781-431-6403
If to Licensee, to:	Dynavax Technologies Corporation 2929 Seventh Street, Suite 100

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Berkeley, California 94710 Attn: Chief Executive Officer

with a copy to:

Dynavax Technologies Corporation 2929 Seventh Street, Suite 100 Berkeley, California 94710 Attn: General Counsel

All notices, requests, reports, approvals or other communications required or permitted under this Agreement shall be in writing (except in the case of verbal communications and teleconferences updating either Party as to the status of work hereunder), and shall be deemed given (a) when delivered personally; (b) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (c) one (1) day after deposited with a commercial express courier specifying next day delivery, with written verification of receipt. No notice of default or termination shall be deemed effective unless delivered by two (2) of the aforementioned delivery routes. Either Party may change its address or its facsimile number by giving the other Party written notice, delivered in accordance with this Section 11.10.

#### 11.11 Force Majeure.

Failure of any Party to perform its obligations under this Agreement (except the obligation to make payments when properly due) shall not subject such Party to any liability or place them in breach of any term or condition of this Agreement to the other Party if such failure is caused by any cause beyond the reasonable control of such non-performing Party, including acts of God, fire, explosion, flood, drought, war (whether or not declared), terrorism, riot, sabotage, embargo, strikes or other labor trouble, failure in whole or in part of suppliers to deliver on schedule materials, equipment or machinery, interruption of or delay in transportation, a national health emergency or compliance with any order or regulation of any government entity acting with color of right unless such governmental order or regulation was the direct result of a Party's failure to comply with applicable law; provided, however, that the Party affected shall promptly notify the other Party of the condition constituting force majeure as defined herein and shall exert reasonable efforts to eliminate, cure and overcome any such causes and to resume performance of its obligations with all possible speed. If a condition constituting force majeure as defined herein exists for more than ninety (90) consecutive days, the Parties shall meet to negotiate a mutually satisfactory solution to the problem, if practicable.

# 11.12 Severability.

If any provision of this Agreement is declared invalid or unenforceable by a court having competent jurisdiction, it is mutually agreed that, except to the extent that either Party would be adversely affected thereby, this Agreement shall endure except for the part declared invalid or unenforceable by order of such court; provided, however, that in the event that the terms and conditions of this Agreement are materially altered, the Parties will, in good faith, renegotiate the terms and conditions of this Agreement to reasonably substitute a valid and enforceable

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provision consistent with the intent of this Agreement for such invalid or unenforceable provision.

#### 11.13 Further Actions.

Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

#### 11.14 Headings.

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

#### 11.15 Waiver of Rule of Construction.

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting party shall not apply.

## 11.16 Counterparts.

This Agreement may be executed in any number of counterparts, each of which shall be an original as against either Party whose signature appears thereon, but all of which taken together shall constitute but one and the same instrument. Copies of executed counterparts of this Agreement transmitted by facsimile shall be considered original executed counterparts provided receipt of such facsimile is confirmed.

#### 11.17 Bankruptcy.

All rights and licenses granted under this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. Licensee, as a holder of such rights under this Agreement, shall retain and may fully exercise any or all of its rights and elections under the Bankruptcy Code. In the event of commencement of a bankruptcy proceeding by or against Coley under the Bankruptcy Code, Licensee shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensee hereunder, and all embodiments of such intellectual property, if not already in its possession, shall be promptly delivered to Licensee.

### BALANCE OF PAGE INTENTIONALLY LEFT BLANK

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

Coley Pharmaceutical Group, Inc.

By: /s/ Robert L. Bratzler Title: President & CEO

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## **Dynavax Technologies Corporation**

By: /s/ Dino Dina Title: President & CEO

# EXHIBIT A

# [\*]

WGS #	SN	Filing Date	INVENTORS	Assignee	TITLE	Status
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<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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# <u>EXHIBIT B</u>

# Iowa Agreement

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

#### EXHIBIT 10.16 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

## LICENSE AGREEMENT

This Agreement is made and entered into as of March 31, 1997 (the "Effective Date") by and between the University of Iowa Research Foundation (hereinafter "UIRF") having offices at 214 Technology Innovation Center, Iowa City, Iowa 52242-5000 and CpG ImmunoPharmaceuticals, Inc. (hereinafter "Licensee"), a Delaware corporation.

WHEREAS, under the patent policy of The University of Iowa ("UI"), all inventions and technology arising during the normal course of research and teaching at the UI are assigned and entrusted to the UIRF to obtain patent or other appropriate intellectual property protection and license said technology;

WHEREAS, Licensee wishes to obtain an exclusive world-wide license in order to practice the above-referenced invention covered by patent rights in the United States and in certain foreign countries, and to manufacture, use and sell in the commercial market the products made in accordance therewith; and

WHEREAS, UIRF wishes to grant such a license to Licensee in accordance with the terms of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises, the parties agree as follows:

## ARTICLE 1.

## DEFINITIONS

1.1 PARENT RIGHTS shall mean U.S. patent application Serial No. [\*\*\*\*\*\*\*\*] filed [\*\*\*\*\*\*\*\*\*], the inventions described and claimed therein, and any divisions, continuations, continuations-in-part to the extent the claims are directed to subject matter specifically described in USSN [\*\*\*\*\*\*\*\*], patents issuing thereon or reissues thereof; and any and all foreign patents and patent applications corresponding thereto; which will be automatically incorporated in and added to this Agreement and shall periodically be added to Appendix A attached to this Agreement and made part thereof.

1.2 LICENSED PRODUCTS shall mean any product the sale, use or manufacture of which would infringe a pending or issued claim of the PATENT RIGHTS but for the license granted hereunder.

# Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

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#### 1.3 LICENSED PROCESSES shall mean the processes claimed in PATENT RIGHTS or some portion thereof.

1.4 NET SALES shall mean the amount billed or invoiced on sales of LICENSED PRODUCTS less: (a) Customary trade, quantity or cash discounts and non-affiliated brokers' or agents' commissions actually allowed and taken; (b) Amounts repaid or credited by reason of rejection or return; (c) To the extent separately stated on purchase orders, invoices or other documents of sale, taxes levied on and/or other governmental charges made as to production, sale, transportation, delivery or use and paid by or on behalf of Licensee; and/or (d) Shipping and insurance charges.

In the event that a LICENSED PRODUCT under this Agreement is sold in combination with another active ingredient or component having independent therapeutic effect or diagnostic utility, then "NET SALES," for purposes of determining royalty payments on the combination, shall be calculated using one of the following methods:

- (e) By multiplying the NET SALES of the combination by the fraction A/A+B, where A is the gross selling price, during the royalty paying period in question, of the LICENSED PRODUCT sold separately, and B is the gross selling price, during the royalty period in question, of the other active ingredients or components sold separately; or
- (f) In the event that no such separate sales are made of the LICENSED PRODUCT or any of the active ingredients or components in such combination package during the royalty paying period in question, NET SALES, for the purposes of determining royalty payments, shall be calculated using the above formula where A is the reasonably estimated commercial value of the LICENSED PRODUCT sold separately and B is the reasonably estimated commercial value of the LICENSED PRODUCT sold separately and B is the reasonably estimated commercial value of the other active ingredients or components sold separately. Any such estimates shall be determined using criteria to be mutually agreed upon by the parties. Such estimates shall be reported to UIRF with the reports to be provided to UIRF pursuant to Section 4.3 hereof.

1.5 AFFILIATE shall mean any company, corporation, or business in which the entity in question owns or controls at-least fifty percent (50%) of the voting stock.

1.6 AGREEMENT YEAR shall mean the annual period commencing upon an anniversary of the Effective Date.

1.7 QIAGEN shall mean QIAGEN GmbH, a German corporation, having its principal address at Max-Volmer-Str. 4, 40724 Hilden, Germany.

# Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

#### **ARTICLE 2.**

#### GRANT

2.1 UIRF hereby grants to Licensee and Licensee hereby accepts, subject to the terms and conditions hereof a worldwide exclusive license under the PATENT RIGHTS to make and have made, to use and have used, to import and have imported, to offer for sale and have offered for sale, and to sell and have sold the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES. Such license shall include the right to grant sublicenses, provided, however, that Licensee shall provide UIRF with a copy of any sublicense agreement promptly upon its execution and that such sublicense agreement must contain terms that do not diminish any of the legal or financial rights of UIRF hereunder, including but not limited to the indemnification and insurance provided under this Agreement. In recognition of the exclusive nature of this license, UIRF agrees that it will not grant licenses under PATENT RIGHTS to others except as required by UIRF's obligations in Paragraph 2.3(a) and that it will not provide any proprietary materials relating to the PATENT RIGHTS to any commercial entities for any commercial purpose unless otherwise approved by Licensee.

2.2 The term of this Agreement and the exclusive license set forth in Paragraph 2.1 shall be from the Effective Date of this Agreement until the expiration of the last to expire of the PATENT RIGHTS or for a period of fifteen years, whichever is longer.

2.3 The granting and acceptance of this license is subject to the following conditions:

- (a) The UI Patent Policy approved in 1983, Public Law 96-517 and Public Law 98-620. Any right granted in this Agreement greater than that permitted under Public Law 96-517 or Public Law 98-620 shall be subject to modification as may be required to conform to the provision of that statute.
- (b) UIRF shall have the right to make and to use for research purposes only and not for any commercial purpose unless otherwise approved by Licensee, the subject matter described and claimed in PATENT RIGHTS. UIRF shall not disclose any confidential information or proprietary materials relating to the PATENT RIGHTS to any other party without prior written consent of Licensee and without use of a confidentiality agreement in the form of Appendix B or a material transfer agreement in the form of Appendix C, an executed copy of which shall be provided to Licensee.
- (c) Licensee shall pay all future costs connected with the commercial development of the LICENSED PRODUCTS, including but not limited to the costs of complying with applicable government testing, approvals and regulations.
- (d) Licensee shall use reasonable efforts to effect introduction of the LICENSED PRODUCTS into the commercial market as soon as practicable,

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consistent with sound and reasonable business practices and judgement; thereafter, until the expiration of this Agreement, Licensee shall endeavor to keep LICENSED PRODUCTS reasonably available to the public.

- (e) UIRF shall have the right to terminate or render this license non-exclusive if Licensee shall not be capitalized with an aggregate investment of at least [\*\*\*\*\* \*\*\*\*\*\*] U.S. dollars (US \$[\*\*\*\*\*\*\*\*]) prior to the first anniversary of the Effective Date.
- (f) UIRF shall have the right to terminate or render this license non-exclusive at any time after three (3) years from the Effective Date if, in UIRF's reasonable judgment, Licensee:
  - (i) has not put the licensed subject matter into commercial use in the country or countries where licensed, directly or through a sublicense, and is not keeping the licensed subject matter reasonably available to the public, or
  - (ii) is not demonstrably engaged in a research, development, manufacturing, marketing, or licensing program, as appropriate, directed toward this end.

In making this determination, UIRF shall take into account the normal course of such programs conducted with sound and reasonable business practice and judgment and shall take into account the reports provided hereunder by Licensee.

(g) All sublicenses granted by Licensee hereunder shall include a requirement that the sublicensee use reasonable efforts to effect introduction of the LICENSED PRODUCTS into the commercial market as soon as practicable, consistent with sound and reasonable business practices and judgement and shall bind the sublicensee to meet Licensee's obligations to UIRF under this Agreement and a copy of this Agreement shall be attached to such sublicense agreements. Copies of all sublicense agreements shall be provided to UIRF.

2.4 Upon expiration of the period of exclusivity of this license, Licensee shall receive a fully paid up perpetual license to make and have made, to use and have used, to import and have imported, to offer for sale and have offered for sale, and to sell and have sold the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES.

2.5 Licensee agrees during the exclusive period of this license in the United States that any LICENSED PRODUCT produced for sale in the United States will be manufactured substantially in the United States unless any waiver of such requirement is obtained. UIRF shall, at Licensee's request and expense, assist Licensee in attempting to obtain such a waiver, should Licensee determine to do so.

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<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

LICENSE AGREEMENT

2.6 UIRF hereby grants to Licensee the right to extend the licenses granted in Paragraph 2.1 to an AFFILIATE subject to the terms and conditions hereof.

2.7 All rights reserved to the United States Government and others under Public Law 96-517 and 98-620 shall remain and shall in no way be affected by this Agreement.

## ARTICLE 3.

## **ROYALTIES, PAYMNTS**

3.1 Licensee shall pay to UIRF a non-refundable license fee in the sum of \$[\*\*\*\*\*\*] as follows:

\$[\*\*\*\*\*] payable within thirty days of the Effective Date

\$[\*\*\*\*\*\*] payable six months after the Effective Date

\$[\*\*\*\*\*] payable twelve months after the Effective Date

\$[\*\*\*\*\*] payable eighteen months after the Effective Date

\$[\*\*\*\*\*\*] payable twenty-four months after the Effective Date

3.2 (a) Licensee shall pay UIRF within forty-five (45) days after the end of each calendar quarter, during the term of the license of Paragraph 2.1, royalties on NET SALES of all LICENSED PRODUCTS sold by Licensee and its AFFILIATES or sublicensees as follows:

In the human field:

[\*]%, if total royalty being paid on the LICENSED PRODUCT to all parties, other than by Licensee to [\*\*\*\*\*\*] and its AFFILIATES for anything other than licenses under issued patents, is less than [\*]%

[\*\*\*\*]%, if total royalty being paid on the LICENSED PRODUCT to all parties, other than by Licensee to [\*\*\*\*\*] and its AFFILIATES for anything other than licenses under issued patents, is greater than or equal to [\*]%, but less than [\*]%

[\*]%, if total royalty being paid on the LICENSED PRODUCT to all parties, other than by Licensee to [\*\*\*\*\*\*] and its AFFILIATES for anything other than licenses under issued patents, is greater than or equal to [\*]%

In the animal field:

[\*\*\*]% on NET SALES of LICENSED PRODUCTS

(b) On sales between Licensee and its AFFILATES or sublicensees for resale, the royalty shall be paid on the resale.

3.3 Commencing in the fifth AGREEMENT YEAR, an annual license maintenance fee

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payment of \$[\*\*\*\*\*\*] shall be payable to the UIRF, payable within forty-five (45) days of the end of each AGREEMENT YEAR. This payment shall be reduced by the amount of any milestones, royalties or non-royalty sub-license income accrued to the UIRF solely during that AGREEMENT YEAR but shall not be reduced by (a) any royalties accruing in any other AGREEMENT YEAR or (b) contract research funding payable to the University of Iowa pursuant to the terms of any Sponsored Research Agreement.

3.4 Licensee shall pay to UIRF the following sums within thirty (30) days of the achievement of the indicated milestones;

3.5 In the case of sublicenses, Licensee shall also pay to UIRF [\*\*\*\*\*\*\*\*\*] percent [\*\*]% of all license issue fees and license maintenance fees, excluding equity investments in Licensee and any funds received by Licensee for the conduct of research.

#### **ARTICLE 4.**

### **REPORTING, CONFIDENTIALITY**

4.1 Prior to signing this Agreement, Licensee has provided to UIRF a written business plan pertaining to the subject matter of the licenses granted hereunder. UIRF hereby acknowledges receipt of such business plan.

4.2 Licensee shall provide brief written annual reports within sixty (60) days after each anniversary of the Effective Date which shall include but not be limited to: summaries of progress on research and development, regulatory approvals, manufacturing, sublicensing, marketing and sales during the preceding twelve (12) months as well as plans for the coming year. If progress differs from that anticipated in the plan provided under 4.1, or in the previous annual report, Licensee shall explain the reasons for the differences and propose a modified plan for UIRF's review and approval. Licensee shall also provide any reasonable additional data UIRF requires to evaluate Licensee's performance.

4.3 (a) Commencing upon the first sale of LICENSED PRODUCTS, Licensee agrees to submit to UIRF within forty-five (45) days after the calendar quarters ending

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March 31, June 30, September 30, and December 31, reports setting forth for the preceding three (3) month period at least the following information:

- i) the number of LICENSED PRODUCTS sold by Licensee, its AFFILIATES and sublicensees;
- ii) total billings for each LICENSED PRODUCT;
- iii) an accounting for all LICENSED PROCESSES used or sold;
- iv) deductions applicable to determine the NET SALES thereof
- v) the amount of royalty due thereon;

and with each such royalty report to pay the amount of royalty due. Such report shall be certified as correct by an officer of Licensee and shall include a detailed listing of all deductions from royalties as specified herein. If no royalties are due to UIRF for any reporting period, the written report shall so state.

b) All payments due hereunder shall be payable in United States dollars. Conversion of foreign currency to US, dollars shall be made at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of each royalty period. Such payments shall be without deduction of exchange, collection or other charges.

(c) All such reports shall be maintained in confidence by UIRF, except as required by law, including Public Law 96-517 and 98-620.

(d) Late payments shall be subject to an interest charge of [\*\*\*\*\*\*\*\*\*\*\*\*\*] percent ([\*\*\*\*\*]%) per month.

4.4 UIRF shall not disclose the contents of the business plan or any report provided by Licensee hereunder to any third party without the prior written consent of Licensee, which consent shall not be unreasonably withheld, except to the extent that disclosure of any such information shall be required by government agencies.

## ARTICLE 5.

#### **RECORD KEEPING**

Licensee shall keep, and shall require its AFFILIATES and sublicensees to keep, accurate and correct records of LICENSED PRODUCTS made, used, imported or sold under this Agreement, appropriate to determine the amount of royalties due hereunder to UIRF. Such records shall be retained for at least three (3) years following a given reporting period. They shall be available during normal business hours for inspection at the expense of UIRF by UIRF's

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Internal Audit Department or by a Certified Public Accountant selected by UIRF and approved by Licensee for the sole purpose of verifying reports and payments hereunder. Such accountant shall not disclose to UIRF any information other than information relating to accuracy of reports and payments made under this Agreement. In the event that any such inspection shows an underreporting and underpayment in excess of [\*\*\*\*] percent ([\*]%) for any twelve (12) month period, then Licensee shall pay the cost of such examination as well as any additional sum that would have been payable to UIRF had the Licensee reported correctly, plus interest.

#### ARTICLE 6.

#### FILING, PROSECUTION AND MAINTENANCE OF PATENTS

6.1 Licensee shall reimburse UIRF for all reasonable expenses heretobefore incurred by UIRF for the preparation, filing, prosecution and maintenance of PATENT RIGHTS and not previously reimbursed by or on behalf of Licensee promptly upon execution of this Agreement and shall reimburse UIRF for all such ongoing expenses within thirty (30) days of receipt of invoices from UIRF. Late payment of these invoices shall be subject to interest charges of [\*\*\*\*\*\*\*\*\*\*\*] percent ([\*\*\*]%) per month. UIRF shall take responsibility for the preparation, filing, prosecution and maintenance of any and all patent applications and patents included in PATENT RIGHTS using patent counsel approved by Licensee, such approval to not be unreasonably withheld. UIRF shall promptly inform Licensee regarding all matters directly pertaining to prosecution of LICENSED PATENTS, and shall seek Licensee's counsel concerning all proposed courses of action affecting the LICENSED PATENTS, including but not limited to in which countries patent prosecution should be obtained and all proposed courses of action in any interference proceedings. UIRF shall cause its patent counsel to provide Licensee with copies of all correspondence regarding PATENT RIGHTS and UIRF shall provide Licensee sufficient opportunity to comment on any document that UIRF intends to file or to cause to be filed with the relevant intellectual property or patent office.

6.2 UIRF and Licensee shall cooperate fully in the preparation, filing, prosecution and maintenance of PATENT RIGHTS and of all patents and patent applications licensed to Licensee hereunder, executing all papers and instruments or requiring members of UIRF to execute such papers and instruments as to enable UIRF to apply for, to prosecute and to maintain patent applications and patents in UIRF's name in any country. Each party shall provide to the other prompt notice as to all matters which come to its attention and which may affect the preparation, filing, prosecution or maintenance of any such patent applications or patents.

6.3 If Licensee elects to no longer pay the expenses of prosecution or maintenance of a patent application or patent included with PATENT RIGHTS, Licensee shall notify UIRF not less than sixty (60) days prior to such action and shall thereby surrender its rights hereunder to such patent or patent application.

#### ARTICLE 7.

#### MARKING

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

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7.1 If a PATENT RIGHT has been or is subsequently issued to UIRF covering any feature or features of the LICENSED PRODUCTS, Licensee agrees to mark each and every package or container in which the LICENSED PRODUCTS are used or sold by or for Licensee with marking complying with the provisions of Title 35, U.S. Code, Section 287, if required, or any future equivalent provisions of the United States relating to the marking of patented devices, or with marking complying with the law of the country where the LICENSED PRODUCTS are shipped, used or sold.

### ARTICLE 8.

#### INFRINGEMENT

8.1 With respect to any PATENT RIGHTS under which Licensee is exclusively licensed pursuant to this Agreement, Licensee or its sublicensee shall have the right to prosecute in its own name and at its own expense any infringement of such patent, so long as such license is exclusive at the time of the commencement of such action. UIRF agrees to notify Licensee promptly of each infringement of such patents of which UIRF is or becomes aware, Before Licensee or its sublicensees commences an action with respect to any infringement of such patents, Licensee shall give careful consideration to the views of UIRF and to potential effects on the public interest in making its decision whether or not to sue and in the case of a Licensee sublicense, shall report such views to the sublicensee.

8.2 If Licensee elects to sue for patent infringement, UIRF agrees to be named as nominal third party plaintiff if necessary to the commencement of any such action, and further agrees to provide any information available to UIRF and needed by Licensee in prosecuting such action. Licensee shall reimburse UIRF for any costs it incurs as part of an action brought by Licensee or its sublicensee, irrespective of whether UIRF shall become a co-plaintiff.

8.3 If Licensee or its sublicensee elects to commence an action as described above, Licensee may reduce, by up to [\*\*\*\*\*] percent ([\*\*]%), the royalty due to UIRF earned under the patent subject to suit by [\*\*\*\*\*] percent ([\*\*]%) of the amount of the expenses and costs of such action, including attorney fees. In the event that such [\*\*\*\*\*] percent ([\*\*]%) of such expenses and costs exceed the amount of royalties withheld by Licensee for any calendar year, Licensee may to that extent reduce the royalties due to UIRF from Licensee in succeeding calendar years, but never by more than [\*\*\*\*\*] percent ([\*\*]%) of the royalty otherwise due in any one year.

8.4 No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of UIRF, which consent shall not be unreasonably withheld.

8.5 Recoveries or reimbursements from such action shall first be applied to reimburse Licensee and UIRF for litigation costs not paid from royalties and then to reimburse UIRF for royalties withheld. Any remaining recoveries or reimbursements shall be divided [\*\*]% to Licensee and [\*\*]% to UIRF.

8.6 In the event that Licensee and its sublicensee, if any, elect not to exercise their right

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to prosecute an infringement of the PATENT RIGHTS pursuant to the above paragraphs, UIRF may do so at its own expense, controlling such action and retaining all recoveries therefrom.

8.7 If a declaratory judgment action alleging invalidity of any of the PATENT RIGHTS shall be brought against Licensee or UIRF, then UIRF, at its sole option, shall have the right to intervene and take over the sole defense of the action at its own expense.

8.8 UIRF shall have no obligation to defend any action for infringement brought against Licensee by a third party. In the event Licensee is sued by a third party, and as a result of the settlement of such suit is required to pay a royalty to a third party on a LICENSED PRODUCT, the amount of royalty paid will be deducted from the royalty payment due to the UIRF for that LICENSED PRODUCT. In the event the settlement prevents the Licensee from continuing sales of a LICENSED PRODUCT, no additional royalties and/or minimum royalties will apply for that LICENSED PRODUCT.

### ARTICLE 9.

### **TERMINATION OF AGREEMENT**

9.1 Upon any termination of this Agreement, and except as provided herein to the contrary, all rights and obligations of the Parties hereunder shall cease, except as follows:

(a) UIRF's right to receive or recover and Licensee's obligation to pay royalties accrued or accruable for payment at the time of any termination;

(b) Licensee's obligation to maintain records and UIRF's right to conduct a final audit as provided in Article 5 of this Agreement; and

(c) Any cause of action or claim of either party, accrued or to accrued because of any breach or default by the other party.

9.2 In the event Licensee fails to make payments due hereunder, UIRF shall have the right to terminate this Agreement upon forty-five (45) days' written notice, unless Licensee makes such payments plus interest within the forty-five (45) day notice period or unless any such payment is contested in good faith, in which event UIRF shall not have the right to terminate this Agreement until the matter is resolved and Licensee still fails to make any such payment. If payments are not so made, UIRF may immediately terminate this Agreement.

9.3 In the event that Licensee shall be in default in the performance of any obligations under this Agreement (other than as provided in 9.2 above which shall take precedence over any other default), and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, UIRF may terminate this Agreement immediately by written notice, unless any such obligation is contested in good faith, in which event UIRF shall not have the right to terminate this Agreement until the matter is resolved and Licensee still fails to perform any such obligation.

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9.4 In the event that Licensee shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it, which petition shall remain unstayed for a period of ninety (90) days, UIRF shall have the right to terminate this entire Agreement immediately upon giving Licensee written notice of such termination.

9.5 In the event the license granted to Licensee hereunder terminates for any reason, any sublicenses granted by Licensee under this Agreement shall continue; provided that, such sublicensee agrees in writing that UIRF is entitled to enforce such agreements directly against such sublicensee.

9.6 Licensee shall have the tight to terminate this Agreement by giving ninety (90) days advance written notice to UIRF to that effect and paying a termination fee of \$[\*\*\*\*\*\*]. Upon termination, a final report shall be submitted and any royalty payments and unreimbursed patent expenses due to UIRF shall become immediately payable.

9.7 Licensee shall have the right during a period of six (6) months following the effective date of any termination to sell or otherwise dispose of the LICENSED PRODUCT existing at the time of such termination, and shall make a final report and payment of all royalties related thereto within sixty (60) days following the end of such period or the date of the final disposition of such inventory, whichever first occurs.

9.8 Termination of this agreement with respect to a particular LICENSED PRODUCT shall not alter the rights and obligations of the parties with respect to the remaining LICENSED PRODUCTS.

## **ARTICLE 10**

#### ASSIGNMENT

10.1 The rights and licenses granted by UIRF in this agreement are specific and may not be assigned or otherwise transferred to any party other than to an AFFILIATE of Licensee without the prior written approval of UIRF, which approval shall not be unreasonably withheld; provided, however, that Licensee, without such approval, may assign subject to Public Law 96- 517 and Public Law 98-620, all of its rights hereunder to the acquiring party in connection with the transfer of all or substantially all of its business and assets to an acquiring party or in the event of its merger or consolidation with that acquiring party, if and only if the assignee shall assume all obligations of Licensee under this Agreement. Any attempted assignment or transfer without any such approval, if required, shall be void and shall automatically terminate all rights of Licensee under this Agreement.

## ARTICLE 11.

## **REPRESENTATIONS AND WARRANTIES: LIMITATIONS**

11.1 Nothing in this agreement shall be construed as:

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- (a) A warranty or representation by UIRF as to the validity or scope of any PATENT RIGHT; or
- (b) A warranty or representation that anything made, used or sold under the license granted in this agreement is or will be free from infringement of patents owned by third parties, or
- (c) Conferring a right to use in advertising, publicity or otherwise the name of the UI or UIRF, or the inventors, unless UIRF has specifically approved the same in writing.

11.2 UIRF represents that, to the best of its knowledge, any patents issued in respect of the PATENT RIGHTS will, when issued, be free of any restrictions except for any non-exclusive rights held by the U.S. Government under the Federal Patent Policy as a result of previous or present sponsorship.

11.3 UIRF EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE PATENT RIGHTS, BIOLOGICAL MATERIAL, INFORMATION SUPPLIED BY UIRF, LICENSED PROCESSES OR LICENSED PRODUCTS CONTEMPLATED BY THIS AGREEMENT. UIRF assumes no responsibilities whatever with respect to design, development, manufacture, use, sale or other disposition by Licensee or AFFILIATES of LICENSED PRODUCTS or LICENSED PROCESSES. The entire risk as to the design, development, manufacture, offering for sale, sale, or other disposition and performance of LICENSED PRODUCTS and LICENSED PROCESSES is assumed by Licensee and AFFILIATES.

## ARTICLE 12.

#### GENERAL

- 12.1 (a) Licensee, its AFFILIATES and sublicensees, shall indemnify, defend and hold harmless UIRF and the University of Iowa and their current or former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (the "Indemnities"), against any liability, damage, loss or expenses (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnities or any one of them in connection with any claims, suits, actions, demands or judgments arising out any theory of product liability (including, but not limited to, actions in the fours of tort, warranty, or strict liability) concerning any product, process or service made, used or sold by Licensee, or its AFFILIATES or sublicensees pursuant to any right or license granted under this Agreement.
- (b) Licensee agrees, at its own expense, to provide attorneys reasonably acceptable to UIRF to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein,

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whether or not such actions are rightfully brought.

(c) Beginning at the time as any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Licensee or by a sublicensee, AFFILIATE or agent of Licensee, Licensee shall, at its sole cost and expense procure and maintain comprehensive general liability insurance in amounts not less than \$[\*\*\*\*\*\*\*] per incident and \$[\*\*\*\*\*\*\*] annual aggregate and naming the Indemnities as additional insureds. During clinical trials of any such product, process or service Licensee shall, at its sole cost and expense, procure and maintain comprehensive general liability insurance in such equal or lesser amounts as UIRF shall require, naming the Indemnities as additional insureds. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Licensee's indemnification under this Agreement. If Licensee elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of \$[\*\*\*\*\*\*] annual aggregate) such self-insurance program must be acceptable to UIRF. The minimum amounts of insurance coverage required shall not be construed to create a limit of Licensee's liability with respect to its indemnification under this Agreement.

(d) Licensee shall provide UIRF with written evidence of such insurance upon request of UIRF. Licensee shall provide UIRF with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if Licensee does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, UIRF shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods.

(e) Licensee shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by Licensee or by a sublicensee, AFFILIATE or agent of Licensee and (ii) a reasonable period after the period referred to in (e)(i) above which in no event shall be less than fifteen (15) years.

12.2 In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the breach thereof, the parties shall try to settle such conflicts amicably between themselves. Subject to the limitation stated in the final sentence of this section, any such conflict which the parties are unable to resolve shall be settled through arbitration conducted in accordance with the rules of the American Arbitration Association. The demand for arbitration shall be filed within a reasonable time after the controversy or claim has arisen, and in no event after the date upon which institution of legal proceedings based on such controversy or claim would be barred by the applicable statutes of limitation. Such arbitration shall be held in Chicago,

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Illinois. The award through arbitration shall be final and binding. Either party may enter any such award in a court having jurisdiction or may make application to such court for judicial acceptance of the award and an order of enforcement, as the case may be. Notwithstanding the foregoing, either party may, without recourse to arbitration, assert against the other party a third-party claim or cross-claim in any action brought by a third party, to which the subject matter of this Agreement may be relevant.

12.3 Should a court of competent jurisdiction later consider any provision of this Agreement to be invalid, illegal, or unenforceable, it shall be considered severed from this Agreement. All other provisions, rights and obligations shall continue without regard to the severed provision, provided that the remaining provisions of this Agreement are in accordance with the intention of the parties.

12.4 No waiver by a Party of any breach of this Agreement, no matter how long continuing or how often repeated, shall be deemed a waiver of any subsequent breach thereof, nor shall any delay or omission on the part of a Party to exercise any right, power or privilege hereunder be deemed a waiver of such right, power or privilege.

12.5 The relationship between the Parties is that of independent contractor and contractee. Licensee shall not be deemed to be an agent of UIRF in connection with the exercise of any rights hereunder, and shall not have any right or authority to assume or create any obligation or responsibility on behalf of UIRF.

12.6 No party hereto shall be deemed to be in default of any provision of this Agreement, or for any failure in performance, resulting from acts or events beyond the reasonable control of such Party, such acts of God, acts of civil or military authority, civil disturbance, war, strives, fires, power failures, natural catastrophes or other "force majeure" events.

#### ARTICLE 13.

#### NOTICES; APPLICABLY LAW

13.1 Any notice, report or payment provided for in this Agreement shall be deemed sufficiently given if in writing and when sent by express courier, certified or registered mail addressed to the party for whom intended at the address set forth below, or to such address as either party may hereafter designate in writing to the other:

(a) For the UIRF:	University of Iowa Research Foundation Attn: Executive Director 100 Oakdale Campus 214 Technology Innovation Center Iowa City, Iowa 52242-5000
(b) For the Licensee:	CpG ImmunoPharmaceuticals, Inc. c/o QIAGEN GmbH Max-Volmer Strasse 4

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40724 Hilden GERMANY Attn: Joachim Schorr Business Development Manager

13.2 This Agreement shall be construed, interpreted and applied in accordance with the laws of the State of Iowa.

13.3 Licensee agrees to comply with all laws and regulations applicable to the subject matter of this Agreement. In particular, it is understood and acknowledged that the transfer of certain commodities and technical data is subject to United States laws and regulations controlling the export of such commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. These laws and regulations among other things, prohibit or require a license for the export of certain types of technical data to certain specified countries. Licensee hereby agrees and gives written assurance that it will comply with all United States laws and regulations controlling the export of commodities and technical data, that it will be solely responsible for any violation of such by Licensee or its AFFILIATES or sublicensees, and that it will defend and hold UIRF harmless in the event of any legal action of any nature occasioned by such violation.

## ARTICLE 14.

#### INTEGRATION

14.1 This Agreement constitutes the final and entire agreement between the parties, and supersedes all prior written agreement with respect to the subject matter hereof, including without limitation the Option Agreement between QIAGEN and UIRF dated August 22, 1995, as extended on March 18, 1996, and the Option Agreement between UIRF and QIAGEN dated May 28, 1996, as extended on September 18, 1996 and January 28, 1997, and any prior or contemporaneous oral understanding regarding the subject matter hereof. Any representation, promise or condition in connection with such subject matter which is not incorporated in this agreement shall not be binding on either party. No modification, renewal, extension or termination of this agreement or any of its provisions shall be binding upon the party against whom enforcement of such modification, renewal, extension or termination is sought, unless made in writing and signed an behalf of such party by a duly authored officer.

IN WITNESS WHEREOF, each of the parties have caused this agreement to be executed by its duly authorized representative.

Signed this 26 day of March, 1997	Signed this 3 day of April,1997		
LICENSOR	LICENSEE		
The University of Iowa Research Foundation	CpG ImmunoPharmaceuticals, Inc.		
By: /s/ W. Bruce Wheaton	By: /s/ Metin Colpan		
Name: W. Bruce Wheaton	Name:		
Title: Executive Director	Title		

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## Appendix A

Patent Rights are indicated on the following page.

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L&C Docket No.	Serial No./ Patent No.	Title and Inventors	Filing Date	Status
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## Appendix B

## Form of Confidentiality Agreement

## **[T3/647063.1]**

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



#### **CONFIDENTIALITY AGREEMENT**

This Agreement is made as of \_\_\_\_\_\_, 1997, by and among the University of Iowa with its principal place of business at \_\_\_\_\_\_ (the "Institution"), and \_\_\_\_\_\_, having an office at \_\_\_\_\_\_ (the "Recipient").

1. <u>Background</u>. The Recipient is interested in receiving certain Proprietary Information (as defined below) from the Institution for the purpose of establishing and/or maintaining a business and/or research relationship between the Institution and the Recipient. The Proprietary Information shall relate to the following subjects: \_\_\_\_\_\_.

2. <u>Proprietary Information</u>. As used in this Agreement, the term "Proprietary Information" shall mean all confidential or proprietary information or materials of the Institution, whether disclosed in writing, orally, or visually, and which is identified by the Institution as confidential, including, without limitation, compounds, business plans, financial statements or technical information.

3. <u>Disclosure of Proprietary Information</u>. The Recipient shall hold in confidence, and shall not disclose to any person other than its employees, agents and consultants, any Proprietary Information. The Recipient shall use such Proprietary Information only for the purpose for which it was disclosed and shall not use or exploit such Proprietary Information for its own benefit or the benefit of another without the prior written consent of the Institution. The Recipient shall disclose Proprietary Information received by it under this Agreement only to those of its employees, agents and consultants who have a need to know such Proprietary Information in the course of the performance of their duties and who are bound by written agreement to protect the confidentiality of such Proprietary Information.

4. <u>Limitation on Obligations</u>. The obligations of the Recipient specified in Section 3 above shall not apply, and the Recipient shall have no further obligations hereunder, with respect to any Proprietary Information to the extent that such Proprietary Information;

- (a) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of the Recipient;
- (b) is in the Recipient's possession at the time of disclosure other than as a result of prior disclosure by the Institution or a breach of any legal obligation by Recipient or third party;
- (c) becomes known to the Recipient through disclosure by sources other than the Institution having no duty of confidentiality to the Institution, whether direct or indirect, with respect to such Proprietary Information and having the legal right to disclose such Proprietary Information;
- (d) is independently developed by the Recipient without reference to or reliance upon the Proprietary Information as can be documented by written records; or
- (e) is required to be disclosed by the Recipient to comply with applicable laws or

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governmental regulations, provided that the Recipient provides prior written notice of such disclosure to the Institution and takes reasonable and lawful actions to avoid and/or minimize the extent of such disclosure.

5. <u>Ownership of Proprietary Information</u>. The Recipient agrees that the Institution is and shall remain the exclusive owner of the Proprietary Information and all patent, copyright, trade secret, trademark and other intellectual property rights therein. No license or conveyance of any such rights to the Recipient is granted or implied under this Agreement.

6. <u>Return of Documents</u>. The Recipient shall, upon the request of the Institution, return to the Institution all drawings, documents, materials and other tangible manifestations of the Proprietary Information received by the Recipient pursuant to this Agreement (and all copies and reproductions thereof) except that one copy of each may be retained by the Recipient's legal department for archival purposes only.

7. <u>Term</u>. The Recipient's obligations under Paragraphs 3 and 4 with respect to each item of Proprietary Information shall extend for a period of five (5) years from the date of initial disclosure to Recipient of such item of Proprietary Information.

#### 8. Miscellaneous.

- (a) This Agreement supersedes all prior agreements, written or oral, between the Institution and the Recipient relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged, in whole or in part, except by an agreement in writing signed by the Institution and the Recipient.
- (b) This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective heirs, successors an assigns.
- (c) This Agreement shall be construed and interpreted in accordance with the laws of the State of Iowa, without giving effect to the conflict of laws provisions thereof.
- (d) The provisions of this Agreement are necessary for the protection of the business and goodwill of the parties and are considered by the parties to be reasonable for such purpose. The Recipient agrees that any breach of this Agreement will cause the Institution substantial and irreparable harm and, therefore, in the event of any such breach, in addition to other remedies which may be available, the Institution shall have the right to seek specific performance and other injunctive and equitable relief.

# Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

The University of Iowa	
------------------------	--

By: \_\_\_\_\_

Title:

### RECIPIENT

Ву:

Title:

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

<sup>53</sup> 

## Appendix C

## Form of Material Transfer Agreement

### **[T3/648340.8]**

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



#### PROPRIETARY REAGENT TRANSFER AGREEMENT FOR REAGENTS SUPPLIED FOR RESEARCH USE ONLY

This Agreement is made as of \_\_\_\_\_\_, 1997 by and among INSTITUTION, having its principal offices at \_\_\_\_\_\_ (the "Institution"), RECIPIENT having an address of \_\_\_\_\_\_ (the "Recipient"), and INVESTIGATOR having an address of \_\_\_\_\_\_ (the "Investigator").

#### WITNESSETH:

WHEREAS, Institution possesses certain reagents in the form of \_\_\_\_\_ [describe] \_\_\_\_\_ and which are further described in U.S. Patent Application No.\_\_\_\_\_ (all such biological materials including all Derivatives thereof are hereinafter referred to as "Reagent"). "Derivatives" as used herein shall mean any material derived from Reagent, or any material resulting from the physical, chemical, or biological manipulation of Reagent; and

WHEREAS, Investigator and Recipient are interested in receiving access to limited quantities of Reagent for the sole purpose of conducting noncommercial research; and

WHEREAS, Institution is willing to make such Reagent available to Investigator on the terms and conditions set forth herein.

NOW THEREFORE, intending to be legally bound, the parties hereto mutually agree as follows:

The Reagent is owned by Institution and will continue to be owned by Institution even after it has been transmitted to Investigator and Recipient;

Investigator and Recipient shall not use the Reagent in any commercial use or for any purpose except for research to be conducted by Investigator at the premises of Recipient.

The Reagent shall be used only in the form provided to you. You shall not [delete or alter or in any way modify any of the DNA sequences in the vectors supplied to you, modify the vectors supplied to you for the expression of other DNA sequences, or remove any DNA sequences from the vectors for use as DNA probes or for expression in other systems whether prokaryotic or eukaryotic without the prior written consent of Institution; —modify as appropriate.]

The Reagent shall not be distributed to any third party, except as provided in Paragraph 5 below, and all rights and interests in such Reagent shall vest and reside in Institution;

Investigator shall keep strict possession of the Reagent and shall only allow access to the Reagent by people who: (1) are doing research at Investigator's direction; and (2) have previously accepted the terms of this Agreement by signing a copy of this Agreement;

Investigator and Recipient agree not to publish or make public disclosures or file patent applications on data, products or improvements derived from or including the Reagent furnished

## Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

herein, except with Institution's prior written approval. Institution will use its best efforts to expeditiously allow Investigator to publish research results in peer review journals.

No license to the Reagent, or any uses therefore other than for the stated research purposes as described and limited herein are granted by this Agreement;

Investigator and Recipient agree not to grant any rights in or to any research conducted utilizing Reagent to any commercial institution without prior written consent of Institution. Institution shall have sole right of first refusal to exclusively license any inventions made in the course of research conducted utilizing Reagent.

Institution disclaims any liability for damages arising from any use, storage, handling or disposal by Investigator or Recipient of the Reagent and Recipient agrees to indemnify and hold Institution harmless against any and all such liability. THE REAGENT IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

This Agreement does not create an agency relationship between Recipient or Investigator and Institution;

Investigator agrees to update Institution on the results of research with this Reagent on a semi-annual basis and to provide yearly research summaries to Institution;

This Agreement is the sole agreement between the parties in respect to the Reagent. This Agreement is personal and non-assignable and terminable at will by Institution upon 10 days notice, at which time all remaining quantities of Reagent shall be delivered to Institution;

Reagent is a valuable proprietary asset of Institution and premature release or disclosure concerning this Reagent could severely injure Institution. Furthermore, damages are not an adequate remedy for breach of this Agreement; rather an injunctive remedy may also be required to preserve Institution's rights;

This Agreement shall be governed and interpreted in accordance with the laws of the State of Iowa and the United States of America.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

<sup>56</sup> 

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

INSTITUTION	
Ву:	
Name:	
Title:	
Date:	
AGREED TO AND ACCEPTED: INVESTIGATOR	RECIPIENT
By:	By:
Name:	Name:
Title:	Title:
Date:	Date:

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

<sup>57</sup> 

#### APPENDIX D

### PROPRIETARY REAGENT TRANSFER AGREEMENT FOR REAGENTS SUPPLIED FOR RESEARCH USE ONLY

This Agreement is made as of \_\_\_\_\_\_, 1996 by and among INSTITUTION, having its principal offices at \_\_\_\_\_\_ (the "Institution"), RECIPIENT having an address of \_\_\_\_\_\_ (the "Recipient"), and INVESTIGATOR having an address of \_\_\_\_\_\_ (the "Investigator").

#### WITNESSETH:

WHEREAS, Institution possesses certain reagents in the form of \_\_\_\_\_ [describe] \_\_\_\_\_ and which are further described in U.S. Patent Application No.\_\_\_\_\_ (all such biological materials including all Derivatives thereof are hereinafter referred to as "Reagent"). "Derivatives" as used herein shall mean any material derived from Reagent, or any material resulting from the physical, chemical, or biological manipulation of Reagent; and

WHEREAS, Investigator and Recipient are interested in receiving access to limited quantities of Reagent for the sole purpose of conducting noncommercial research; and

WHEREAS, Institution is willing to make such Reagent available to Investigator on the terms and conditions set forth herein.

NOW THEREFORE, intending to be legally bound, the parties hereto mutually agree as follows:

(1) The Reagent is owned by Institution and will continue to be owned by Institution even after it has been transmitted to Investigator and Recipient;

Investigator and Recipient shall not use the Reagent in any commercial use or for any purpose except for research to be conducted by Investigator at the premises of Recipient.

The Reagent shall be used only in the form provided to you. You shall not [delete or alter or in any way modify any of the DNA sequences in the vectors supplied to you, modify the vectors supplied to you for the expression of other DNA sequences, or remove any DNA sequences from the vectors for use as DNA probes or for expression in other systems whether prokaryotic or eukaryotic without the prior written consent of Institution;—modify as appropriate.]

The Reagent shall not be distributed to any third party, except as provided in Paragraph 5 below, and all rights and interests in such Reagent shall vest and reside in Institution;

Investigator shall keep strict possession of the Reagent and shall only allow access to the Reagent by people who: (1) are doing research at Investigator's direction; and (2) have previously accepted the terms of this Agreement by signing a copy of this Agreement;

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



Investigator and Recipient agree not to publish or make public disclosures or file patent applications on data, products or improvements derived from or including the Reagent furnished herein, except with Institution's prior written approval. Institution will use its best efforts to expeditiously allow Investigator to publish research results in peer review journals.

No license to the Reagent, or any uses therefore other than for the stated research purposes as described and limited herein are granted by this Agreement;

Investigator and Recipient agree not to grant any rights in or to any research conducted utilizing Reagent to any commercial institution without prior written consent of Institution. Institution shall have sole right of first refusal to exclusively license any inventions made in the course of research conducted utilizing Reagent.

Institution disclaims any liability for damages arising from any use, storage, handling or disposal by Investigator or Recipient of the Reagent and Recipient agrees to indemnify and hold Institution harmless against any and all such liability. THE REAGENT IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED.

This Agreement does not create an agency relationship between Recipient or Investigator and Institution;

Investigator agrees to update Institution on the results of research with this Reagent on a semi-annual basis and to provide yearly research summaries to Institution;

This Agreement is the sole agreement between the parties in respect to the Reagent. This Agreement is personal and non-assignable and terminable at will by Institution upon 10 days notice, at which time all remaining quantities of Reagent shall be delivered to Institution;

Reagent is a valuable proprietary asset of Institution and premature release or disclosure concerning this Reagent could severely injure Institution. Furthermore, damages are not an adequate remedy for breach of this Agreement; rather an injunctive remedy may also be required to preserve Institution's rights;

This Agreement shall be governed and interpreted in accordance with the laws of the State of Iowa and the United States of America.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

<sup>59</sup> 

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

INSTITUTION		
Ву:		
Name:		
Title:		
Date:		
AGREED TO AND ACCEPTED: INVESTIGATOR	RECIPIENT	
INVESTIGATOR	RECIPIENI	
By:	By:	
Name:	Name:	
Title:	Title:	
Date:	Date:	

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

<sup>60</sup> 

## Appendix A

#### PATENT RIGHTS

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## Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

LICENSE AGREEMENT

WG&S ID [*********]	UIRF ID [**********]	SN [***********	FILING DATE [********]	INVENTORS [*****] [******]	<u>TITLE</u> [********* ********]	STATUS [********* *********
[********]	[*****]	[************]	[*******]	[*******] [*******] [******]	[********* *********	[******** *********
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<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

WG&S ID	UIRF ID	SN	FILING DATE	INVENTORS	TITLE	STATUS
[*********]	[*********]	[*********]	[*******]	[*****]	[**************************************	[******]
L J	[****]	L J	L J	L J [******]	L *****	L ] [*************
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Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT 10.17 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

#### CONFIDENTIAL

and

#### Confidential Treatment Requested under: 5 U.S.C. §552(b)(4)

Coley Pharmaceutical Group, Inc. 20 William Street, Suite 115 Wellesley, Massachusetts 02481 March 7th, 2001

University of Iowa Research Foundation 100 Oakdale Campus 214 Technology Innovation Center Iowa City, Iowa 52242-5000 Attn: Executive Director

Re: Amendment to License Agreement

Ladies and Gentlemen:

This letter will serve as an amendment (the <u>"Amendment"</u>) to the License Agreement (the <u>"Agreement"</u>) dated as of March 31, 1997 between Coley Pharmaceutical Group, Inc., formerly known as CpG ImmunoPharmaceuticals, Inc. (<u>"Coley</u>"), and the University of Iowa Research Foundation (<u>"UIRF</u>"). All capitalized terms that are used in this letter and not defined herein shall have the meanings ascribed to them in the Agreement. Except as specifically modified by this Amendment, the parties hereto agree that all of the terms and conditions set forth in the Agreement remain in full force and effect.

#### 1. Amendment to the Definition of PATENT RIGHTS and Update to Appendix A.

The Parties hereby agree that Section 1.1 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"1.1 PATENT RIGHTS shall mean

(a) each of the patents and patent applications listed on <u>Appendix A</u> attached to this Agreement, as amended, and

(b) each patent and patent application of UIRF that relates to immune modulation in which Arthur M. Krieg ("Dr. Krieg") is a named inventor, and

(c) Intellectual property of the University of Iowa or UIRF arising under any University of Iowa research agreement sponsored by Coley, unless Coley elects not to exercise its option to such intellectual property,

## Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(d) together with (i) the inventions described and claimed therein, and any divisions, continuations, continuations-in-part to the extent the claims are directed to the subject matter specifically described in the foregoing patents and patent applications, (ii) any and all patents issuing thereon or reissues thereof, and (iii) any and all foreign patents and patent applications corresponding thereto.

All of the foregoing patents and patent applications will be automatically incorporated in and added to this Agreement and shall periodically be added to <u>Appendix A</u> and made a part thereof."

The Parties also hereby agree that <u>Appendix A</u> to the Agreement shall be updated as of the date hereof to the form of <u>Appendix A</u> attached to this Amendment.

Subject to the following sentence, the Parties further agree that ownership of all rights in and to any inventions, discoveries, information or materials which are discovered, invented, made, conceived, or first reduced to practice by Dr. Krieg while on a leave of absence from The University of Iowa (the " <u>Leave of Absence Inventions</u> ") shall be governed by separate written agreements by and between Coley and Dr. Krieg, and by and among UIRF, the University of Iowa and Dr, Krieg, and not by the Agreement, as amended hereby. If, however, UIRF or the University of Iowa are determined to be an owner of any such Leave of Absence Inventions, then the Parties agree that the University of Iowa's or UIRF's interest in such Leave of Absence Inventions shall be subject to the terms of the Agreement, as amended hereby.

#### 2. Addition of Definitions "Sublicensee" and "Sublicense Revenues."

The Parties hereby agree that ARTICLE 1 of the Agreement shall hereby be amended by inserting the following two additional definitions:

"1.8 SUBLICENSEE shall mean any third party that is not an AFFILIATE of LICENSEE to whom LICENSEE, or an AFFILIATE of LICENSEE, grants a sublicense or an option to sublicense under the PATENT RIGHTS pursuant to Section 2.1 hereof to make and have made, to use and haveused, to import and have imported, to offer for sale and have offered for sale, and/or to sell and have sold the LICENSED PRODUCTS, and/or to practice the LICENSED PROCESSES.

1.9 SUBLICENSE REVENUES shall mean all revenues received by LICENSEE or an AFFILIATE from a SUBLICENSEE pursuant to a sublicense under the PATENT RIGHTS, an option for a sublicense under the PATENT RIGHTS, or a similar agreement providing for the exploitation of the PATENT RIGHTS, in each case granted pursuant to Section 2.1 hereof, including license issue fees, license maintenance fees, milestone fees and royalties, but excluding equity investments in LICENSEE, any funds received by LICENSEE for the conduct of research and development, payments received for manufacturing, and the reimbursement of costs and expenses."

## Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

#### 3. Amendment to Clarify that Term of Agreement is on a Country-by Country Basis.

The Parties hereby agree that Sections 2.2 and 2.4 of the Agreement shall hereby be amended and restated in their entirety to read as follows:

"2.2 The term of this Agreement and the exclusive license set forth in Paragraph 2.1 shall be from the Effective date of this Agreement until the expiration of the last to expire of the PATENT RIGHTS, on a country-by country basis, or for a period of fifteen years, whichever is longer.

2.4 Upon expiration of the period of exclusivity of this license in a particular country under the terms of 2.2 above, LICENSEE shall receive in such country a fully paid up perpetual license to make and have made, to use and have used, to import and have imported, to offer for sale and have offered for sale, and to sell and have sold the LICENSED PRODUCTS, and to practice the LICENSED PROCESSES."

#### 4. Amendment to Royalty Payment Obligations of Coley.

The Parties hereby agree that Section 3.2 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"3.2 (a) Licensee shall pay UIRF within forty-five (45) days after the end of each calendar quarter, during the team of the license of Paragraph 2.1, royalties on NET SALES of all LICENSED PRODUCTS sold by Licensee and its AFFILIATES (but not by its sublicensees) as follows:

In the human field:

[\*\*\*]%, if total royalties being paid on the LICENSED PRODUCT to all parties, other than by LICENSEE to [\*\*\*\*\*\*] and its AFFILIATES for anything other than licenses under issued patents, is less than or equal to [\*\*\*]%.

[\*\*\*\*]%, if total royalties being paid on the LICENSED PRODUCT to all parties, other than by LICENSEE to [\*\*\*\*\*\*] and its AFFILIATES for anything other than licenses under issued patents, is greater than [\*\*\*]%, but less than equal to [\*\*\*]%.

[\*\*\*]%, if total royalties being paid on the LICENSED PRODUCT to all parties, other than by LICENSEE to [\*\*\*\*\*] and its AFFILIATES for anything other than licenses under issued patents, is greater than [\*\*\*]% but less than or equal to [\*\*\*\*]%.

[\*]%, if total royalties being paid on the LICENSED PRODUCT to all parties, other than by LICENSEE to [\*\*\*\*\*\*] and its Affiliates for anything other than licenses under issued patents, is greater than [\*\*\*\*]%.

In the animal field:

[\*\*\*]% of LICENSED PRODUCTS.

(b) Royalties shall not apply to sales among LICENSEE, its AFFILIATES and their respective SUBLICENSEES for resale. On sales between LICENSEE and its AFFILIATES for resale, the royalty shall be paid only on the resale."

# Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

[\*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

#### 5. Amendment to Annual License Maintenance Fee Obligations of Coley.

The Parties hereby agree that Section 3.3 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"3.3 Commencing in the fifth AGREEMENT YEAR, an annual license maintenance fee payment of \$[\*\*\*\*\*\*] shall be payable to the UIRF within forty-five (45) days of the end of each AGREEMENT YEAR. This payment shall be reduced by the amount of any milestones, royalties, and SUBLICENSE REVENUES accrued to the UIRF solely during that AGREEMENT YEAR but shall not be reduced by (a) any royalties accruing in any other AGREEMENT YEAR or (b) contract research funding payable to the University of Iowa pursuant to the terms of any Sponsored Research Agreement."

## 6. Amendment to Milestone Payment Obligations of Coley.

The Parties hereby agree that Section 3.4 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"3.4 Licensee shall pay to UIRF the following sums within thirty (30) days of the achievement of the indicated milestones:

### 

UIRF acknowledges that the milestone payment obligations set forth under Section 3.4 of the Agreement, as amended hereby, will be credited against the amount of any Sublicense Revenues due to UIRF under Section 3.5 of the Agreement, as amended hereby, to the extent such Sublicense Revenues are attributable to milestone payments from a Sublicensee to Coley. For purpose of clarification, the parties specifically agree that in the event Coley receives payment from a Sublicensee for achievement of these milestones in an amount which would require a payment to UIRF under Section 3.5, as amended below, greater than set forth in Section 3.4, Coley shall pay UIRF only the amount due under Section 3.5.

#### 7. Amendment to Sublicense Payment Obligations of Coley.

The Parties hereby agree that Section 3.5 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"3.5 In the case of sublicenses, options to sublicense, and similar agreements to exploit the PATENT RIGHTS, LICENSEE shall also pay to UIRF the following

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



percentages of SUBLICENSE REVENUES received in the manner set forth below:

(ii) [\*\*\*\*\*\*\*] percent ([\*\*]%) of SUBLICENSE REVENUES received by LICENSEE thereafter."

### 8. Amendment to Clarify Survival of Confidentiality Obligations upon Termination.

The Parties hereby agree that Section 9.1 of the Agreement shall hereby be amended by inserting a new paragraph (d) as follows:

"(d) UIRF's obligations of confidentiality under Section 4.4 hereof."

#### 9. SmithKline Beecham PLC and Qiagen GmbH

Coley hereby agrees to pay UIRF \$[\*\*\*\*\*\*] in a deferred manner in accordance with Paragraph 11 of this Amendment (the "<u>Deferred SB/Qiagen</u> <u>Payment</u>").

As consideration for Coley's obligation to pay UIRF the Deferred SB/Qiagen Payment, UIRF hereby irrevocably waives any claim that it might otherwise have for a percentage of the payments received by Coley on or before February 1, 2001 under:

(i) Sections 3.04, 4, 8.01a, 8.01b, and 8.03.1 of the Strategic Alliance Agreement Infectious Diseases dated as of December 18, 1998 between Coley and SmithKline Beecham PLC ("SB"), and Sections 3.1, 3.2 and 4.2 of Amendment No. 1 thereto dated as of December 18, 1999 (collectively, the "<u>SB</u> <u>Amendment</u>"),

(ii) Sections 3.1 and 3.2(a) of the Strategic Alliance Option Agreement Cancer dated as of December 8, 1998, as amended, between Coley and SB (the "<u>SB Option</u>") and

(iii) Sections 3.1 and 3.5 of the Sublicense Agreement dated as of January 5, 1998, as amended, between Coley and Qiagen GmbH (the "Qiagen Agreement").

The SB Agreement, SB Option and the Qiagen Agreement are referred to collectively as the "<u>SB/Qiagen Agreements</u>." Any Sublicense Revenues that have accrued or may accrue under the entire SB/Qiagen Agreements after February 1, 2001 shall be subject to Section 3.5 of the Agreement as amended hereby.

#### 10. Amendment Payments

As consideration for the execution of this Amendment, Coley hereby agrees to pay to UIRF \$[\*\*\*\*\*\*] in cash immediately upon the execution of this Amendment. UIRF

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acknowledges that such \$[\*\*\*\*\*\*] payment will be credited against the amount of any Sublicense Revenues due to UIRF under Section 3.5 of the Agreement, as amended hereby, to the extent such Sublicense Revenues are attributable to the successful completion of Phase I clinical trials for the first three independent LICENSED PRODUCTS in the human field.

As further consideration for the execution of this Amendment, Coley hereby agrees to pay UIRF \$[\*\*\*\*\*\*] in a deferred manner in accordance with Paragraph 11 of this Amendment (the "<u>Deferred Amendment Payment</u>," and together with the Deferred Interim Payments and the Deferred SB/Qiagen Payment, the "<u>Deferred Payments</u>").

#### 11. Deferred Payments; UIRF's Option to Convert into Common Stock

11.1 Payment Terms. Coley shall pay to UIRF the Deferred Payments, together with interest at the rate of [\*\*\*\*] percent ([\*]%) per year, compounded annually on the aggregate outstanding principal amounts of such Deferred Payments plus interest previously accrued on such Deferred Payments from the date such Deferred Payments are incurred, within thirty (30) days after receipt by Coley of a written request for payment from UIRF, in such amounts as UIRF may specify from time to time; *provided, however*, that, subject to Paragraph 11.2 of this Amendment, Coley shall have no obligation to make any payments to UIRF on a Deferred Payment prior to the second anniversary of the date that such Deferred Payment is incurred. Theparties agree that for purposes of this Paragraph 11 of the Amendment, the Deferred SB/Qiagen Payment and the Deferred Amendment Payment shall be incurred by Coley on the date of this Amendment and the Deferred Interim Payments, if any, shall be incurred by Coley on the date Coley makes the relevant cash Interim Payment to UIRF. On or after the fifth anniversary of the date of this Amendment, Coley shall have the right, at any time following ten business days advance written notice to UIRF, to prepay (i.e. prior to receipt of a written request by UIRF) all or any part of the outstanding principal amount of the Deferred Payments, plus accrued but unpaid interest thereon, *provided* that Coley shall concurrently pay a premium equal to [\*\*\*\*] percent ([\*]%) of the amount that is so prepaid, *and provided further* that UIRF may, before the expiration of such ten business day notice period, exercise its conversion rights in accordance with Paragraph 11.2.1, or Paragraph 11.2.2, as applicable.

### 11.2 Option to Convert.

11.2.1 Following an Initial Public Offering. Coley shall promptly inform UIRF of the consummation of an initial public offering of the Common Stock of Coley pursuant to a registration statement filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (an " <u>IPO</u> "). At any time after the consummation of an IPO (the <u>"Option Trigger Date</u> "), UIRF may, during the Conversion Period as defined below, elect to convert all or part of each outstanding Deferred Payment (including interest thereon) into shares of the Common Stock of Coley by executing and delivering to Coley the form of subscription agreement (the <u>"Subscription Agreement"</u>) attached to this Amendment as <u>Exhibit A</u>, specifying therein the Deferred Payment(s), and the aggregate amount(s) thereof, to be converted. For purposes of this Paragraph 11.1.2, the Conversion Period shall commence on the Option Trigger Date and terminate on the later of (i) six months following such Option Trigger Date or (ii) six months following the expiration of any applicable Lock-Up to which UIRF may be bound pursuant to Section 2(f) of the Subscription Agreement.

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11.2.2 Upon a Sale Transaction. Coley shall promptly inform UIRF if Coley enters into a binding written commitment to consummate a Sale Transaction (as defined below), *provided* that UIRF shall maintain such information as confidential pursuant to Section 4.4 of the Agreement. Upon receipt of such notice, UIRF may, at any time prior to the consummation of the Sales Transaction, elect to convert all or part of each outstanding Deferred Payment (including interest thereon) into shares of the Common Stock of Coley by executing and delivering to Coley a Subscription Agreement, specifying therein the Deferred Payment(s), and the aggregate amount(s) thereof, to be converted. As used herein, the term "<u>Sale Transaction</u>" shall mean any consolidation or merger of Coley into or with any other entity or entities which results in the exchange of outstanding shares of capital stock of Coley for securities or other consideration issued or paid or caused to be issued or paid by any such entity or affiliate thereof (other than a merger to reincorporate Coley in a different jurisdiction or a merger or consolidation in which the holders of outstanding shares of the capital stock of Coley become, solely by means of such merger or consolidation, the holders of a majority of the voting securities of such other entity), and any sale, lease, abandonment, transfer or other disposition by Coley of all or substantially all its assets.

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<sup>70</sup> 

11.2.3 Calculation of Number of Conversion Shares. The number of shares to be issued upon a conversion pursuant to Paragraphs 11.2.1 or 11.2.2 of this Amendment shall be equal to the cash amount of the Deferred Payment(s) (including interest) to be so converted (as specified by UIRF in the Subscription Agreement) divided by the Conversion Price. The <u>Conversion Price</u> shall initially be [\*\*\*\*\*] (which is equal to the per share price of the Series E Preferred Stock issued by Coley in its most recent private financing prior to the date hereof), subject to adjustment as follows:

(i) If Coley shall at any time or from time to time after the date of this Amendment effect a subdivision of the outstanding Common Stock, the Conversion Price then in effect immediately before that subdivision shall be proportionately decreased. If Coley shall at any time or from time to time after the date of this Amendment combine the outstanding shares of Common Stock into a smaller number, the Conversion Price then in effect immediately before the combination shall be proportionately increased. Any adjustment under this paragraph (i) shall become effective at the close of business on the date the subdivision or combination becomes effective; and

(ii) If Coley shall at any time or from time to time after the date of this amendment make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in additional shares of Common Stock, then and in each such event the Conversion Price then in effect shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying the Conversion Price then in effect by a fraction:

(1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and

(2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution;

*provided, however,* if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, the Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Conversion Price shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends or distributions.

11.2.4 <u>Option Non-Transferable; Compliance with Securities Act.</u> UIRF acknowledges and agrees that the option provided for in this Section 11 (the "<u>Option</u>") may not be sold, assigned, transferred or conveyed to any third party whatsoever, without the prior written consent of Coley in Coley's sole discretion, other than to the National Institutes of Health (the "NIH") pursuant to the terms of the Inter-Institutional Agreement (the <u>"NIH Agreement"</u>) dated as of November 24, 1999 between UIRF and the NIH (provided that the NIH agrees in

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writing not to further assign the Option without the prior written consent of Coley in Coley's sole discretion). UIRF agrees that the Option, and, if exercised, the shares of Common Stock to be issued upon conversion thereof, are being acquired for investment for UIRF's own account and not with a view toward distribution thereof, and that it will not offer, sell or otherwise dispose of any shares of Common Stock to be issued upon conversion of the Option other than pursuant to the terms and conditions of the Subscription Agreement.

#### 12. No Admission of Liability.

This Amendment has been entered into solely to revise certain terms set forth in the Agreement, and in certain cases to amicably resolve certain disagreements over the interpretation of such terms, and it shall not constitute an admission of liability by either party as to any claim, defense or allegation of the other party.

#### 13. Survival, Acknowledgement and Release.

Each of the parties hereto acknowledges that the Agreement remains in full force and effect in accordance with its terms, as amended hereby, and that the other party hereto is not in breach of any of the terms and conditions of the Agreement, as amended hereby, as of the date of this Amendment. Each of the parties to this Amendment hereby releases and forever discharges the other party, each parent, subsidiary and affiliate of the other party, and their respective representatives, agents, shareholders, officers, directors, employees, successors, and assigns from any and all claims, demands, actions causes of action, debts, dues, liabilities, and controversies of every kind and nature, whether presently known or unknown, vested or contingent, arising or accruing at any time on or before the date hereof, which relate to or arise out of the Agreement or the subject matter thereof.

#### 14. Entire Agreement.

The Agreement and this Amendment and the attachments hereto and thereto constitute the entire agreement and understanding between Coley and UIRF relating to the subject thereof and hereof. No verbal agreement, conversation or representation between any officers, agents, or employees of the parties hereto either before or after the execution of the Agreement or this Amendment shall affect or modify any of the terms or obligations therein or herein contained. Any further amendment to the terms of the Agreement or this Amendment shall be made in writing and signed on behalf of each party by a duly authorized officer.

### 15. Terms Confidential.

Each party hereby acknowledges and agrees that it will not disclose the terms of the Agreement or this Amendment or any other information relating to the subject matter hereof or thereof to any third party without the express written consent of the other party, except that (i) either party may use the text of a written statement approved

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in advance by both parties without further approval, (ii) Coley may disclose the terms of the Agreement and this Agreement to a Sublicensee, and (iii) either party shall have the right to identify the other party and to disclose the terms of this Agreement as required by applicable securities laws or other applicable laws or regulations. Without limiting the generality of the foregoing, either party may disclose the Agreement and this Amendment to the NIH pursuant to a request that the terms thereof be withheld from public disclosure pursuant to Exemption 4 of the Freedom of Information Act, 5 U. S.C. § 552(b)(4).

Please sign below where indicated to acknowledge your agreement to the foregoing Amendment.

Sincerely, COLEY PHARMACEUTICAL GROUP, INC.

By: /s/ Robert Bratzler Name: Bratzler Title: President & CEO

ACKNOWLEDGED AND AGREED TO This 7<sup>th</sup> day of March, 2001 THE UNIVERSITY OF IOWA RESEARCH FOUNDATION

By: /s/ W. Bruce Wheaton

Name: W. Bruce Wheaton

Title: Executive Director and Secretary

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# Exhibit A

# FORM OF SUBSCRIPTION AGREEMENT

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# EXHIBIT C

# OHRI Agreement

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#### EXHIBIT 10.18 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

## LICENSE AGREEMENT

THIS AGREEMENT comes into force as of the first day of September, 1998, ("Effective Date"), by and between The Loeb Health Research Institute at the Ottawa Hospital (hereinafter referred to as "LOEB") located at 725 Parkdale Avenue, Ottawa, Ontario K1 Y 4E9, CANADA and CpG ImmunoPharmaceuticals, Inc. having an address of 55 William Street, Suite 120, Wellesley, MA 02481, USA (hereinafter referred to as "CpG").

### WITNESSETH:

WHEREAS QIAGEN GmbH and LOEB have entered into a Research Agreement effective as of September 1, 1996 (the "Research Agreement") pursuant to which QIAGEN has sponsored a research and development program (the "R&D Program") at LOEB under the direction of Dr. Heather L. Davis (the "Investigator");

WHEREAS, pursuant to Section 6.01 of the Research Agreement, QIAGEN has assigned all of its rights, obligations, terms and conditions under the Research Agreement to CpG;

WHEREAS, LOEB has acquired valuable rights to Inventions derived from the R&D Program and has filed the patent applications listed on <u>Exhibit A</u> attached hereto with respect to such Inventions; and

WHEREAS, pursuant to Section 4.02 of the Research Agreement, LOEB has agreed to promptly notify CpG of any Inventions derived from the R&D Program;

WHEREAS pursuant to Section 4.03 of the Research Agreement, CpG has elected to exercise its option to acquire an exclusive license in the Field to Inventions developed under the Research Agreement for which the patent applications listed on <u>Exhibit A</u> attached hereto have been filed;

NOW, THEREFORE, in consideration of the sum of ten dollars (US\$10.00), the mutual covenants herein contained, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, and intending to be legally bound, LOEB and CpG agree as follows:

# ARTICLE 1

# DEFINITIONS

As used herein, capitalized terms shall have the following meanings:

1.1 **Affiliate** shall mean a corporate or other entity which directly or indirectly controls, is controlled by, or is under common control with a Party, and "control" shall mean the ownership of not less than 50% of the voting shares of a corporation, or decision-making

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authority as to any unincorporated entity. With respect to CpG, Affiliate shall also include any partnership of which CpG is the general partner.

- 1.2 **Commercial Sale** shall mean any transaction between CpG, or an Affiliate of CpG, and a third party which transfers physical possession and title to any Licensed Product to a third party.
- 1.3 **Field** shall mean applications of CpG immunomodulatory nucleic acid sequences for human and veterinary prophylactic and therapeutic purposes independently or in combination with protein(s), other adjuvants, other immunostimulatory agents and/or other nucleic acid sequences.
- 1.4 **Institute Personnel** means any person working at the LOEB, including but not limited to any Investigator, professor, technician, associate, medical professional, or student (including a pre- or post-doctoral student), any independent contractor (including any consultant under an obligation of confidentiality), or any research collaborator, student or consultant who participates in the R&D Program in any manner or who acquires knowledge of any test data, clinical information or any other information resulting from any R&D Program which is deemed a trade secret or confidential or proprietary to CpG or LOEB.
- 1.5 **Invention** shall mean any discovery, new or useful process, method, manufacture, compound, biological material, composition of matter, or software, or any improvement thereof, with application in the Field, whether patentable or unpatentable, which is developed, conceived or first reduced to practice, or demonstrated to have utility during the term of the R&D Program and covered by the Patent Rights. Notwithstanding the foregoing, if any such Invention is not reduced to practice within twelve months following the expiration or termination of the R&D Program, it shall not be deemed an Invention hereunder.
- 1.6 **Investigator(s)** shall mean initially Dr. Heather L. Davis, so long as she is associated with LOEB, and any other Institute Personnel who became or becomes involved in the R&D Program, as agreed by CpG pursuant to Section 2.01 of the Research Agreement between the Parties hereto.
- 1.7 **Joint Invention** shall mean any Invention for which it is determined, in accordance with U.S. patent law, that both: (i) employees, consultants or agents of CpG or any other persons obligated to assign or exclusively license such Invention to CpG or to an institution other than CpG or LOEB for use in the Field, and (ii) employees or agents of LOEB or any other persons obliged to assign such Invention to LOEB, are joint inventors of such Invention.
- 1.8 **Licensed Product** shall mean any product or process which is covered by a Pending or issued claim under Patent Rights or, if not covered by Patent Rights, shall mean any product or process which, to a material degree as determined by mutual agreement of the

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Parties, contains, is based on, or is derived from, identified through or utilizes any Licensed Technology which is not in the public domain. Any product or process which is a Licensed Product at the time of first Commercial Sale shall, for the purposes of Sec. 4.1, 4.3 and 9.1, be treated as a Licensed Product for at least 15 years from the date of first Commercial Sale.

- 1.9 Licensed Technology shall mean any and all information, and all patentable and non-patentable inventions (including, without limitation, the Inventions, Joint Inventions and Patent Rights), improvements, discoveries, claims, formulae, materials, processes, methods, trade secrets, technologies, data and know-how, whether existing in the Investigator's laboratory at LOEB as of the Effective Date or developed by Investigator(s) in the performance of the R&D Program, relating to the Field or the development and/or commercialization of products in the Field, whenever such inventions, improvements, discoveries, claims, formulae, materials, processes, methods, trade secrets, technologies, data and know-how are derived from or directly related to the Inventions. Notwithstanding the foregoing, the patent application PCT/FR94/00483, CON of USSN 08/633,821 entitled "Nucleotide Vector Composition Containing Such Vector and Vaccine for Immunization Against Hepatitis" assigned to the Pasteur Institute INSERM and the University of Ottawa shall not be included in Licensed Technology.
- 1.10 **Net Sales** shall mean the gross invoice price of Licensed Products sold by CpG and/or its Affiliates in arm's length sales to third parties, less the sum of the following deductions where applicable:
  - (a) cash, trade and quantity discounts;
  - (b) sales, use, tariff, import/export duties or other excise taxes imposed upon particular sales;
  - (c) transportation charges;
  - (d) allowances or credits to customers because of rejections or returns; and
  - (e) commission and other fees paid to non-affiliated brokers or non-affiliated sales agents.

In the event that CpG sells Licensed Products to a non-affiliated third party in an arm's length transaction solely for the purpose of having such third party act as a distributor for Licensed Products, "Net Sales" shall be the amount owed CpG by such distributor less the returns as defined above.

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In the event that Licensed Products are sold or used in combination with products or processes having independent therapeutic or prophylactic effect, then Net Sales, for purposes of determining royalty payments on the combination, shall be calculated using one of the following methods:

(i) By multiplying the Net Sales of the combination product or process by the fraction A/A+B, where A is the gross selling price, during the royalty period in question, of Licensed Products when sold separately for the same application, and B is the gross selling price of the other product for the same application, during the royalty period in question, when sold separately; or

(ii) In the event that no such separate sales are made of such Licensed Product(s) or other products or processes in such combination during the royalty period in question, Net Sales, for the purposes of determining royalty payments, shall be calculated using the above formula where A is the reasonably estimated commercial value of the Licensed Products when sold separately, and B is the reasonably estimated commercial value of the other product or processes, when sold separately. Any such estimates shall be mutually agreed upon by the Parties. Such estimates shall be reported to LOEB with the reports to be provided to LOEB pursuant to Section 5.1 hereof.

- 1.11 **Party** shall mean LOEB or CpG and, when used in the plural, shall mean LOEB and CpG.
- 1.12 **Patent Rights** shall mean all rights derived from the patent applications listed on Exhibit A attached hereto (including without limitation provisional applications and invention disclosures), and as such Exhibit A may be amended from time to time by mutual agreement of the Parties, and which are owned or controlled, in whole or in part, by LOEB by way of transfer of rights from any Investigator, claiming, describing, embodying or relating to the Licensed Technology throughout the Territory, including any substitutions, extensions, renewals, continuations, continuations-in-part, divisions, patents of addition, and/or reissues thereof, and any current and future patent or patent application, or portion thereof, which is a foreign counterpart in any country in the Territory to any of the foregoing, including any substitutions, extensions, renewals, continuations, continuations-in-part, divisions, patents of addition and/or reissues thereof.
- 1.13 **Pending** shall mean a claim in a patent application under Patent Rights that has not been completely and finally rejected.
- 1.14 **Publication** means any non-confidential written or oral publication or disclosure resulting from or involving the Licensed Technology, and includes but is not limited to a publication or disclosure in articles, books, journals, theses, the media, trade publications, scientific meetings, seminars, poster sessions, and symposia.
- 1.15 **R&D Program** shall mean research conducted by LOEB, acting through the laboratories of any Investigator(s) pursuant to the terms of the Research Agreement.
- 1.16 **Sublicensee** shall mean any third party to whom CpG, or an Affiliate of CpG, grants a sublicense pursuant to Section 3.2 of this Agreement to develop, make, have made, use, have used, sell, offer for sale, have sold, import or have imported Licensed Products.

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- 1.17 **Sublicense Income** shall mean all sublicensing fees and revenues received by CpG or its Affiliates from Sublicensees in consideration for a sublicense to develop, make, have made, use, have used, sell, offer for sale or have sold, import and have imported Licensed Products, including, but not limited to, milestone payments and license initiation fees. Notwithstanding the foregoing, Sublicense Income shall not include revenue specifically allocated by CpG to, and demonstrably used for, research and development of the Licensed Technology, nor shall it include funds received by CpG for equity investments in CpG which are not in excess of a [\*\*]% premium of the then current fair market value of CpG equity (i.e., that portion of any funds received for equity which is greater than a [\*\*]% premium shall be deemed Sublicense Income).
- 1.18 **Territory** shall mean the entire world.

## **ARTICLE 2**

## **REPRESENTATIONS AND WARRANTIES**

- 2.1 **Representations and Warranties of Both Parties.** Each Party represents and warrants to the other Party that: (i) it is free to enter into this Agreement; (ii) in so doing, it will not violate any other agreement to which it is a party; and (iii) it has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.
- 2.2 Representations and Warranties of LOEB. LOEB hereby represents and warrants that:
  - (a) They are the owners, either solely or, jointly with others, of the patent applications listed on <u>Exhibit A</u>, and have the exclusive right to grant licenses in their interests therein;
  - (b) They are the owners of, either solely or jointly with others, or are the licensees of, all of the Licensed Technology in existence on the date of this Agreement, and have the right to grant licenses or sublicenses of their interest therein;
  - (c) They have used their best efforts to inform CpG of and preserve all patent rights to the Inventions and all patent applications listed on Exhibit A are in full force and effect to the best of their knowledge as of the Effective Date of this License Agreement;
  - (d) They are not aware of any asserted or unasserted claim or demand against the patent applications listed on Exhibit A; and
  - (e) They have not entered into any agreement with any third party which is in conflict with the rights granted to CpG pursuant to this Agreement.

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### 2.3 Disclaimer of Other Warranties.

- (a) EXCEPT AS EXPRESSLY PROVIDED IN SECTION 2.2, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE, OR WARRANTY GIVEN, BY LOEB THAT ANY PATENT WILL ISSUE BASED UPON ANY PENDING PATENT APPLICATION, THAT ANY PATENT WHICH ISSUES WILL BE VALID, OR THAT THE LICENSED TECHNOLOGY OR LICENSED PRODUCTS WILL NOT INFRINGE THE PATENT OR PROPRIETARY RIGHTS OF ANY THIRD PARTY. FURTHERMORE, LOEB MAKES NO OTHER REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE LICENSED TECHNOLOGY OR LICENSED PRODUCTS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
- (b) NEITHER PARTY SHALL BE LIABLE WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR (I) ANY INDIRECT, CONSEQUENTIAL, PUNITIVE OR OTHER DAMAGES OR (II) COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES.

## **ARTICLE 3**

#### LICENSE GRANT

- 3.1 **Grant of License.** LOEB hereby grants to CpG a royalty-bearing exclusive license in the Field and in the Territory to utilize the Licensed Technology and to develop, have developed, make, have made, perform, use, have used, sell, offer for sale, have sold, import or have imported Licensed Products (the" License").
- 3.2 **Right to Sublicense**. Such License shall also include the right to grant sublicenses. CpG shall have the right to screen and select Sublicensees, and to agree on the terms of any sublicense. LOEB shall have the right to inspect and comment upon any sublicense agreement prior to execution of any sublicense agreement. Copies of all executed sublicense agreements shall be provided to LOEB.
- 3.3 **Reservation of Rights.** Notwithstanding any rights granted to CpG hereunder, the LOEB shall retain the right to use Inventions solely for research and educational purposes on a non-commercial basis, subject to confidentiality requirements and LOEB's obligations to preserve patent rights as set forth in Article 7 hereof. For purposes hereof, "research and educational purposes" shall not include the conduct of research sponsored by a commercial entity or the development of products or processes to be licensed to a commercial entity during the term of the Research Agreement or extension thereof other than the work performed under the R&D Program. During the term of this Agreement,

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LOEB can suggest how CpG and third party technology could be used together and may seek CpG's permission to do so under the Research Agreement between the Parties hereto, but shall not use any such third party technology in combination with CpG technology without the prior written consent of CpG.

- 3.4 **CpG's Development Efforts.** CpG shall use all reasonable efforts to develop and commercialize Licensed Products. A Development Plan will be prepared by CpG and submitted to LOEB which shall outline CpG's plans to develop the Licensed Technology on or before December 31, 1999. A written progress report by CpG will be submitted to the LOEB on or prior to each anniversary of the Effective Date summarizing the development work on Licensed Technology for commercial purposes.
- 3.5 **Failure to Use Due Diligence.** In the event that CpG shall fail to use all reasonable efforts to develop and commercialize Licensed Products, LOEB may, upon written notice to CpG to be given pursuant to the mechanism set forth in Section 9.2, with the opportunity to cure or remedy such default as set forth therein convert CpG's License for such Licensed Products and Licensed Technology into a non-exclusive license.
- 3.6 Notwithstanding any other provision of the Research Agreement or this Agreement to the contrary, the parties hereby agree that, if so requested by CpG, the terms for the exclusive license to CpG of any future Joint Invention which is developed pursuant to the R&D Program and owned in part by a party other than CpG or LOEB, but which is not included on Exhibit A as of the Effective Date hereof, will be governed by an interinstitutional agreement to be negotiated between LOEB and any third party owner(s) of any such Joint Invention, provided the third party owner(s) are agreeable to enter into such negotiations with LOEB.

## **ARTICLE 4**

## CONSIDERATION

- 4.1 **Royalties.** In consideration of the exclusive licenses and other rights granted to CpG under this Agreement, CpG agrees to pay to LOEB a royalty, commencing upon the first Commercial Sale of a Licensed Product by CpG, its Affiliates or its Sublicensees, as follows:
  - (a) For Commercial Sales made by CpG or its Affiliates, CpG shall pay the highest applicable royalty as set forth below:
    - (i) For sales of Licensed Products covered by issued or Pending Patent Rights, CpG shall pay to LOEB a royalty equal to [\*\*\*\*] percent ([\*]%) of Net Sales;

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- (ii) For sales of Licensed Products not covered by issued or Pending Patent Rights, CpG shall pay to LOEB a royalty equal to [\*\*\*\*\*] percent ([\*]%) of Net Sales.
- (b) Notwithstanding the foregoing, in the event that the total royalties due to LOEB and all third parties on a Licensed Product exceed [\*\*]% of Net Sales prior to any applicable royalty reduction(s), CpG shall be entitled to a royalty reduction of [\*\*\*\*\*] percent ([\*\*]%) of the royalties owed to third parties on the Licensed Products in excess of [\*\*]%, up to a maximum reduction of [\*\*]% of the royalties due the LOEB according to Section 4.1(a) above. For example, if the total royalty due on a Licensed Product is [\*\*]%, CpG shall pay to LOEB a royalty of [\*\*\*]% (i.e., [\*]% [\*\*\*]%) of Net Sales of the Licensed Product.
- (c) In the event that CpG and/or its Affiliates receive Sublicense Income from any Sublicensee, CpG shall pay to LOEB [\*\*\*] percent ([\*\*]%) of such Sublicense Income from each such Sublicensee.
- (d) In the event that: (i) payments by CpG to LOEB under Section 4.1(c) plus (ii) payments by CpG to one or more third parties of a percentage of such Sublicense Income exceed [\*\*\*\*\*] percent ([\*\*]%) of any such Sublicense Income received by CpG, then payments to LOEB pursuant to Section 4.1(c) will be reduced on a prorata basis with payments owed to such third parties on such Sublicense Income so that the total percentage paid out by CpG to all non-affiliated third parties with respect to Sublicense Income shall not exceed [\*\*\*\*\*] percent ([\*\*]%) of any such amounts received by CpG. For example, if CpG receives Sublicense Income and owes Party X [\*\*\*] percent ([\*\*]%) thereof and Party Y [\*\*\*\*\*\*] percent ([\*\*]%) thereof, bringing the total owed to [\*\*]%, then LOEB's share of such Sublicense Income will be reduced to [\*\*\*\*]% (i.e., by [\*\*\*\*]%, which is [\*\*\*\*]% of the excess of [\*\*\*\*] percent since [\*\*]% is [\*\*\*\*]% of [\*\*]%). Notwithstanding the foregoing, this provision shall only be effective with respect to payments to third parties which are governed by a similar provision and shall not be used to reduced the percentage owed to LOEB pursuant to Sec. 4.1(c) to less than [\*\*\*\*] percent ([\*]%).
- (e) Sublicense Income from all Licensed Products which incorporate CpG DNA as an adjuvant in antigen- or DNA-based vaccines against infectious diseases shall be exempted from the conditions for reductions in payment to the LOEB as stated in Sec. 4.1(d).
- 4.2 **Obligation to Pay Royalties.** The obligation to pay royalties to LOEB under this Article 4 is imposed only once with respect to the same unit of Licensed Product regardless of the number of Patent Rights or the amount of Licensed Technology pertaining thereto.
- 4.3 **Duration of Royalties.** CpG shall not be obligated to make any further royalty payments in any country for any Licensed Product after the end of the period commencing on the date of the first Commercial Sale of the Licensed Product in that country by CpG, its

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Affiliates or Sublicensees and ending either on the date of expiration of a valid, enforceable claim of a Patent Right covering the Licensed Product in that country or fifteen (15) years after the date of the first Commercial Sale, whichever is later.

## **ARTICLE 5**

### PAYMENTS AND REPORTS

- 5.1 **Payment.** All royalty payments due pursuant to Article 4 shall be paid quarterly on March 1, June 1, September 1 and December 1 of each year after the date of first Commercial Sale, for the periods ending December 31, March 31, June 30 and September 30, respectively. Each such payment shall be accompanied by a statement of the amount of Net Sales of Licensed Products sold by CpG and Sublicense Income received by CpG during the relevant period, and the amount of royalties due thereon.
- 5.2 **Mode of Payment, Blocked Currency.** CpG shall make all payments required under this Agreement by check in United States Dollars payable to the Loeb Health Research Institute at the Ottawa Hospital. All royalty payments in any currency other than United States Dollars shall be translated quarterly into United States Dollars at the average of the rates of exchange listed in The Wall Street Journal at which United States Dollars are exchangeable for the cur<sup>r</sup> ency of the country in which the royalty is accrued for the last day of each month of the quarter in which such sales were made.

If, at any time, a product is sold in a country in which conditions or legal restrictions exist which prohibit remittance of royalty payments ("Blocked Country"), CpG or its Affiliates shall accrue the amount of royalties due in such Blocked Country on paper on behalf of the LOEB. For so long as such restrictions or conditions apply, CpG shall be relieved of any further obligation to LOEB with respect to such royalties except for the furnishing to LOEB of the statement required by Section 5.1 and a report on the amount accrued until such times as the legal restrictions is resolved. CpG shall use its best efforts to pay the LOEB such accrued amounts within thirty days of such resolution in the Blocked Country.

- 5.3 **Records Retention**. CpG and its Affiliates shall keep complete and accurate records pertaining to the sale of Licensed Products in the Territory and covering all transactions from which Net Sales and Sublicense Income are derived for a period of five (5) calendar years after the year in which such Net Sales and Sublicense Income occurred, and in sufficient detail to permit LOEB to confirm the accuracy of royalty calculations hereunder.
- 5.4 **Audit Request.** At LOEB's request, CpG and its Affiliates shall pen lit an independent, certified public accountant, appointed by LOEB and acceptable to CpG or its Affiliates, at reasonable times and upon reasonable notice, to examine those records and all other material documents relating to or relevant to the calculation of amounts due to LOEB pursuant to Article 4 in the possession or control of CpG or its Affiliates for a period of

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five (5) years after such royalties have accrued, as may be necessary to (i) determine the correctness of any report or payment made under this Agreement or (ii) obtain information as to the royalties payable for any semi-annual payment period in the case of CpG's or its Affiliate's failure to report or pay pursuant to this Agreement. Said accountant shall treat all such information as confidential information of CpG and shall not disclose to LOEB any information other than information relating to said reports, royalties, and payments. Results of any such examination shall be made available to both Parties. LOEB shall bear the full cost of the performance of any such audit, unless such audit demonstrates underpayment of royalties by CpG of more than [\*\*\*] percent ([\*\*]%) from the amount of the original royalty payment made by CpG. In such event, CpG shall bear the full cost of the performance of such audit.

5.5 **Taxes.** In the event that CpG or its Affiliates are required to withhold any tax to the revenue authorities in any country in the Territory regarding any payment to LOEB due to the laws of such country, LOEB's pro rata portion of such amount shall be deducted by CpG or its Affiliates, and it shall notify LOEB and promptly furnish LOEB with copies of any tax certificate or other documentation evidencing such withholding. Such taxes deducted from payments to the LOEB shall exclude those taxes included under Net Sales under Sec. 1.10. In addition, CpG shall use its best efforts to obtain relief in such tax payments in such countries on behalf of LOEB.

### **ARTICLE 6**

## PATENT PROSECUTION; ENFORCEMENT; INFRINGEMENT

#### 6.1 Patent Prosecution and Maintenance.

(a) CpG shall diligently prepare, file and prosecute all patent applications under Patent Rights in the name of the LOEB using patent counsel engaged by LOEB as set forth below. LOEB shall cooperate in the preparation, filing and prosecution of all Patent Rights licensed hereunder to the extent requested by CpG. Patent Rights shall be filed, prosecuted and maintained in countries specified by CpG, as agreed to by LOEB. LOEB shall retain a patent law film selected and agreed upon jointly by LOEB and CpG, and shall pay all invoices received from such patent law firm in a timely manner. CpG shall have full rights of consultation with LOEB's patent counsel with respect to the Patent Rights to which CpG has exclusive rights hereunder and shall have the right to control the filing, prosecution and maintenance of Patent Rights and shall keep LOEB informed and advised and seek input from LOEB except as otherwise provided herein. Each Party shall provide to the other Party copies of all such applications, official actions, amendments and all papers filed or received relating to the Patent Rights. Notwithstanding the foregoing, CpG shall have the right and obligation, alone or in conjunction with other owners of such rights, to diligently prepare, file and prosecute all Patent Rights which are Joint Inventions and shall keep LOEB

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informed and advised and seek input from LOEB with respect thereto to the same extent set forth above.

- (b) Both Parties agree to cooperate with the other Party to execute all lawful papers and instruments, to make all rightful oaths and declarations and to provide consultation and assistance as may be necessary in the preparation, prosecution, maintenance, and reinforcement of all such patent applications and patents.
- 6.2 **Patent Cost Reimbursement**. For Patent Rights licensed hereunder, CpG shall reimburse LOEB for all reasonable and customary costs and expenses of filing, prosecuting and maintaining such Patent Rights, including legal expenses of the patent counsel, within thirty (30) days after CpG receives an itemized invoice from LOEB for such costs and expenses. CpG may elect to cease paying for further patent expenses on a country-by-country basis for any particular patent or patent application licensed hereunder upon giving sixty (60) days prior written notice to LOEB, whereupon CpG's rights under such patent or patent application in such country pursuant to this Agreement shall terminate. LOEB may thereafter elect to dispose of any such terminated rights at its sole discretion without any further obligations to CpG hereunder.
- 6.3 **Notification of Infringement**. If either Party learns of an infringement or threatened infringement by a third party of any Patent Right licensed hereunder within the Territory, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such infringement. Section 6.4 shall then be applicable.

### 6.4 Patent Enforcement.

(a) CpG and/or Sublicensee(s) shall have the first right, but not the obligation, to institute patent infringement actions against third parties based on any Patent Right licensed under this Agreement. If CpG and/or any Sublicensee does not institute an infringement proceeding against an offending third party, or enter into good faith negotiations regarding a sublicense under such Patent Right with such third party, within one hundred eighty (180) days after receipt of notice from LOEB, (i) with respect to inventions owned solely by LOEB, LOEB shall have the right, but not the obligation, to institute an infringement proceeding, and (ii) with respect to Joint Invention, shall have such rights as are mutually agreed by the other owners of such Joint Invention as appropriate. The costs and expenses of any such action (including fees of attorneys and other professionals) shall be borne by the Party and/or parties instituting the action. Each Party shall execute all necessary and proper documents and take such actions as shall be appropriate to allow the other Party (or, for certain Joint Inventions, other co-owners) to institute and prosecute such infringement actions and such expenses will be borne by the instituting party. Any award paid by third parties as a result of such an infringement action (whether by way of settlement or otherwise) shall be first applied to reimburse the costs and expenses (including attorney's fees) of the Party bringing suit, or to reimburse the costs and expenses (including attorney's

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fees) incurred by the Parties if the suit is brought jointly and to reimburse any additional costs and expenses including attorney's fees incurred by LOEB in cooperating with CpG in such suits. Any remaining amount of the award shall be regarded as Sublicense Income and an amount shall be paid to the LOEB pursuant to Section 4.1(c). Notwithstanding the foregoing, for suits involving Joint Inventions with co-owners who are not Parties, awards shall be shared as mutually agreed, provided that CpG's share of any such recovery shall be treated as set forth above.

- (b) Notwithstanding the foregoing, neither Party shall be entitled to settle or otherwise dispose of any suit brought pursuant to provisions of Section 6.4(a) without the approval of the other Party, which approval shall not be unreasonably withheld.
- 6.5 **Infringement Action by Third Parties.** In the event of the institution of any claim or suit by a third party against CpG for patent infringement arising from the development, manufacture, use or sale of any Licensed Product in the Territory, CpG shall notify LOEB in writing of such suit within ten (10) business days of receiving notice of such suit. CpG shall have the right to defend such claim or suit at its own expense, and LOEB hereby agrees to assist and cooperate with CpG, at CpG's expense, to the extent necessary in the defense of such suit. During the pendency of such claim or action, CpG shall continue to make payments due under this Agreement, but shall be entitled to claim a credit against royalties otherwise payable hereunder of an amount equal to the out-of-pocket unreimbursed costs and expenses incurred by CpG in defending against such claim or suit, provided that such credit shall be no greater than fifty percent (50%) of the amount of such royalties otherwise payable hereunder.

# **ARTICLE 7**

## **PUBLICATION; CONFIDENTIALITY**

7.1 **Notification**. The Parties recognize that it is part of LOEB's function to disseminate knowledge and information and to make it available for the purpose of scholarship. The Parties further recognize that the publication of certain technical information may destroy its commercial value and patentability. Consequently, any proposed Publication by Institute Personnel shall comply with this Article 7. Investigator and LOEB shall furnish a copy to CpG of any proposed Publication or disclosure of data related to the Licensed Technology at least ninety (90) days in advance of presentation or submission for Publication. If CpG does not object in writing to such disclosure within thirty (30) days of receipt, LOEB shall he free to proceed with such disclosure. In the event written objection is made, the Parties shall negotiate in good faith an acceptable version of the proposed Publication, including the release date, within the original ninety (90) day notice period or shall agree to withhold Publication until a mutually agreeable time, all as further described in Section 7.2.

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- 7.2 **Review of Proposed Publications.** CpG will review the proposed Publication, manuscript, abstract, text or any other material provided under Section 7.1 to determine if patentable subject matter which has not been adequately protected by the Patent Rights or Confidential Information of CpG as defined in Sec. 7.4 is disclosed. CpG will notify Institute Personnel within the period prescribed in Section 7.1 if CpG, in its sole discretion, determines that patentable subject matter is or may be disclosed, or if CpG, in its sole discretion, believes confidential or proprietary information of CpG is or may be disclosed. If it is determined by CpG that additional patent applications should be filed, and in the event that the delay needed to complete the filing of any necessary patent application will exceed the period specified in Section 7.1, LOEB and Institute Personnel shall agree to any reasonable extension of the Publication delay. The Publication delay shall not continue beyond thirty (30) days past the date that the proposed Publication or other material was to be presented, submitted or otherwise disclosed. If it is determined by CpG is being disclosed, CpG, LOEB and Institute Personnel will consult among themselves in good faith to arrive at an agreement on mutually acceptable modifications to the proposed Publication to avoid such disclosure within the time period set forth in Section 7.1.
- 7.3 **Use of Name**. Neither Party will use the name of the other in any advertising or other form of publicity without the prior written permission of the other. Notwithstanding the foregoing, either Party may include an accurate description of the terms of this Agreement to the extent required by the laws of any government or other disclosure laws and in internal communications.
- 7.4 **Confidentiality; Exceptions.** Confidential Information shall mean all Patent Rights patent applications, research proposals and results, business plans, development reports. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for five (5) years thereafter, the receiving Party of Confidential Information shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose other than proper performance hereunder any information furnished to it by the other Party pursuant to this Agreement, except to the extent that it can be established by the receiving Party by reasonable proof that such information:
  - (a) was already known to the receiving party at the time of disclosure as can be reasonably proved by such party;
  - (b) became part of the public domain without breach of this Agreement; or
  - (c) was obtained from third parties with the lawful right to disclose such information.

Each party may disclose the other's Confidential Information to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or

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defending litigation, complying with applicable governmental regulations, undertaking basic research with outside collaborators, or conducting preclinical or clinical trials provided that if a Party makes any such disclosure of the other Party's secret or confidential information it will, except where impracticable for necessary disclosures, for example to physicians conducting studies or to health authorities, give reasonable advance notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such information required to he disclosed. LOEB may publish results of the work performed under the Research Agreement upon approval by CpG pursuant to Article 7 of this Agreement.

# ARTICLE 8

### INDEMNIFICATION AND INSURANCE

- 8.1 **Indemnification.** CpG shall indemnify, defend and hold harmless the LOEB, its officers, directors, employees, agents and students from any claims, loss, expense, costs, suits, including attorney's fees and expenses arising out of or connected with any activities of CpG and their Affiliates, licensees or Sublicensees under this Agreement, including without limitation, product liability claims relating to products based on the Licensed Technology or Licensed Products, except to the extent that such claim is due to the gross negligence of the LOEB. The LOEB shall promptly notify CpG of any such claim(s), shall permit CpG to defend such claim(s) and shall cooperate with CpG and its insurance carrier in the defense of the claim(s) at CpG's expense.
- 8.2 **Insurance.** In connection with human clinical trials and/or commercial sales of a Licensed Product, CpG, at its sole cost and expense, shall insure its activities, obtain, keep in force and maintain comprehensive or commercial form of general liability insurance. Such insurance shall name LOEB as an additional insured and shall provide at least US\$[\*\*\*\*\*\*\*] per incident and adequate annual aggregate in amounts as required by the various hospitals and clinics for such human clinical trials of Licensed Products. Upon commercial sales of Licensed Products, CpG and/or its Sublicensees shall obtain, keep in force and maintain comprehensive general product liability insurance of at least US\$[\*\*\*\*\*\*\*] per incident and adequate annual aggregate amounts and shall name LOEB as an additional insured.

## **ARTICLE 9**

### **TERM; TERMINATION**

9.1 **Term.** This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided in Sec. 9.3 hereunder, shall terminate as to the Licensed Technology and as to each country in the Territory, upon the expiration of the last to

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expire of the Patent Rights covering the manufacture, use or sale of such Licensed Technology and/or the manufacture, use or sale of such Licensed Product in such country or a minimum of fifteen (15) years from the date of first Commercial Sale, whichever is later. Upon any such expiration of Patent Rights or end of such fifteen year period in such country whichever is later, CpG shall have a fully paid-up license of perpetual duration in such country, subject to the survival provisions in Section 9.7, including the right of CpG, its Affiliates and/or its Sublicensees to continue developing, making, using or selling such Licensed Technology and Licensed Products without any further obligation to LOEB hereunder.

- 9.2 **Breach.** Failure by either Party to comply with any of the material obligations contained in this Agreement shall entitle the other Party to give to the Party in default notice specifying the nature of the default and requiring it to cure such default. If such default is not cured within sixty (60) days after the receipt of such notice (or, if such default cannot be cured or remedied within such sixty (60) day period, the Party in default does not commence and diligently continue actions to cure or remedy such default), the notifying Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement by giving written notice to take effect within sixty (60) days after such notice unless the defaulting Party shall cure such default within said sixty (60) days. The right of either Party to terminate this Agreement, as hereinafter provided, shall not be affected in any way by its waiver or failure to take action with respect to any previous default.
- 9.3 Termination by CpG. CpG shall have the right to terminate the licenses to Licensed Technology granted hereunder, in whole or as to any Patent Right in any country in the Territory, at any time, and from time to time, by giving notice in writing to LOEB. Such termination shall be effective thirty (30) days from the date such notice is given, and all CpG's rights associated therewith shall cease as of that date, subject to Section 9.4.
- 9.4 **Rights to Sell Stock on Hand.** Upon the termination of any license to Licensed Technology granted herein, other than under Section 9.1, in part or in whole or as to any Patent Right and corresponding Licensed Technology, CpG shall have the right for one (1) year or such longer period as the Parties may reasonably agree to dispose of all Licensed Product or substantially completed Licensed Product then on hand to which such termination applies, and royalties shall be paid to LOEB with respect to such Licensed Products as though this Agreement had not terminated.
- 9.5 **Termination of Sublicenses.** Upon any termination of this Agreement, except under Section 9.1, all sublicenses granted by CpG under this Agreement shall terminate, subject, nevertheless, to Section 9.4, unless any Sublicensee shall agree in writing prior to any such termination to be bound directly to LOEB by the provisions of the relevant sublicense agreement.
- 9.6 Effect of Termination. Upon the termination of any license granted hereunder as to any Patent Right and corresponding Licensed Technology in any country in the Territory other

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than pursuant to Section 9.1, CpG and its Affiliates and Sublicensees shall promptly return to LOEB all relevant records, materials and Confidential Information of LOEB concerning such Patent Rights and corresponding Licensed Technology in such country in the possession or control of CpG or any of its Affiliates or Sublicensees.

- 9.7 **Surviving Rights.** Termination of this Agreement shall not terminate CpG's obligation to pay all royalties which shall have accrued hereunder prior to such termination. The Parties' obligations under ARTICLES 7 and 8 and Sections 6.1(b), 10.1, 10.8 and 10.12 shall survive termination or expiration of this Agreement in addition to those articles surviving by matter of law.
- 9.8 Accrued Rights, Surviving Obligations. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party under this Agreement prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

### **ARTICLE 10**

### MISCELLANEOUS PROVISIONS

## 10.1 Dispute Resolution.

- (a) Except for the right of either Party to apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm, any and all claims, disputes or controversies arising under, out of, or in connection with this Agreement, including any dispute relating to patent validity or infringement, or to the reasonableness of CpG's commercialization efforts, which the Parties shall be unable to resolve within sixty (60) days shall be mediated in good faith. The Party raising such dispute shall promptly advise the other party of such claim, dispute or controversy in a writing which describes in reasonable detail the nature of such dispute. By not later than five (5) business days after the recipient has received such notice of dispute, each Party shall have selected for itself a representative who shall have the authority to bind such Party, and shall additionally have advised the other Party in writing of the name and title of such representative.
- (b) By not later than ten (10) business days after the date of such notice of dispute, the Party against whom the dispute shall be raised shall select a mediation firm reasonably acceptable to both Parties and such representatives shall schedule a date with such firm for a mediation hearing in the Ottawa area. The Parties shall enter into good faith mediation and shall share the costs equally. If the representatives of the Parties have not been able to resolve the dispute within

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fifteen (15) business days after such mediation hearing, the Parties shall have the right to pursue any other remedies legally available to resolve such dispute.

- 10.2 **Relationship of Parties.** Nothing in this Agreement is or shall be deemed to constitute a partnership, agency, employee, franchise or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.
- 10.3 Assignment. Except as otherwise provided herein, neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior written consent of the other; provided, however, that either Party may assign this Agreement to any wholly-owned subsidiary or to any successor by merger or sale of substantially all of its assets to which this Agreement relates in a manner such that the assignee shall remain liable and responsible for the performance and observance of all of the assigning Party's duties and obligations hereunder. This Agreement shall be binding upon the successors and permitted assigns of the parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 10.3 shall be void.
- 10.4 **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 10.5 **Force Majeure.** Neither Party shall be liable to the other for loss or damages nor shall have any right to terminate this Agreement for any default or delay attributable to any act of God, flood, fire, explosion, lightning, windstorm, earthquake, failure of supply of materials or failure or destruction of machinery or equipment, strike, labor difficulties or governmental action, lockout, casualty, accident, war, revolution, civil commotion, act of public enemies, blockage or embargo, injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or subdivision, authority or representative of any such government, or any other cause beyond the reasonable control of such Party, if the Party affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled and for thirty (30) days thereafter. Notwithstanding the foregoing, nothing in this Section 10.5 shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.
- 10.6 **No Trademark Rights.** Except as otherwise provided herein, no right, express or implied, is granted by this Agreement to use in any manner the name "CpG" or "LOEB" or any other trade name or trademark of the other Party in connection with the performance of this Agreement.

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- 10.7 **Headings.** Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.
- 10.8 **No Third Parties Benefited.** Except as set forth in Article 8 hereof, no third party, including any employee of any party to this Agreement, shall have or acquire any rights by reason of this Agreement.
- 10.9 **Public Announcements.** Except as required by law, neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior consent of the other. In the event of a required public announcement, the Party making such announcement shall provide the other with a copy of the proposed text prior to such announcement. Once any written statement is approved for disclosure by both Parties, either Party may make subsequent public disclosures limited to all or a portion of the specific contents of such prior statement without the further approval of the other Party.
- 10.10 **Notices**. All notices and other communications hereunder shall be in writing and shall be deemed given if sent by registered mail, return receipt requested or delivered by hand or commercial express courier to the following address of either Party unless changed by written notice (provided that notice of a change of address shall be effective only upon receipt thereof:

(a) If to CpG, addressed to:

CpG ImmunoPharmaceuticals, Inc. 55 William Street, Suite 120 Wellesley, MA 02481 USA Attn: President

With a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. One Financial Center Boston, MA 02111 Attn: Jeffrey M. Wiesen, Esq.

(b) If to LOEB, addressed to:

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The Loeb Health Research Institute at the Ottawa Hospital 725 Parkdale Avenue Ottawa, Ontario Canada. K1Y 4E9 Attn: Robert Hanlon, M.H.A.; C.H.E. Chief Administrative Officer

- 10.11 **Amendment.** No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party. This Agreement may be executed in a series of counterparts, all of which, when taken together, shall constitute one and the same instrument.
- 10.11 **Waiver.** Subject to applicable statutes of limitation, no provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees, except by an instrument in writing expressly waiving such provision and signed by the waiving Party.
- 10.12 **Governing Law.** This Agreement shall be construed, governed, interpreted and applied in accordance with the laws of the province of Ontario, Canada without application of principles of conflict of law except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent was granted.
- 10.13 **Severability.** Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement and the Parties shall promptly negotiate in good faith a replacement provision to carry out the intention of the invalid, illegal or unenforceable provision to the fullest extent permitted by law.
- 10.14 **Entire Agreement of the Parties.** This Agreement constitutes and contains the entire understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof. In the event of any conflict between the terms of the Research Agreement and this Agreement, the terms of this Agreement shall govern.

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IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by its duly authorized officer as of the day and year first above written:

For LOEB				
By:	/s/ Robert Hanlon	By:	/s/ Michel Chretian, M.D.	
Name:	Robert Hanlon, M.H.A.; C.H.E.	Name:	Michel Christian, M.D.	
Title:	Chief Administrative Officer	Title:	Chief Executive Officer and Scientific Director	
	The Loeb Health Research Institute		The Loeb Health Research Institute	
	at the Ottawa Hospital		at the Ottawa Hospital	
Date:	January 6, 1999	Date:	January 7, 1999	
For CpG:				
By:	/s/ Robert L. Bratzler, Ph.D.			
Name:	Robert L. Bratzler, Ph.D.			
Title:	President, CpG ImmunoPharmaceuticals, Inc.			
Date:	Dec. 23, 1998			

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



# EXHIBIT A

# LICENSED PATENTS

# (As of May 31, 1998)

Patents	Status
1. [************************************	
a) US Provisional #[********] filed [******]	[******]
2. [************************************	
a) US Provisional # [********] filed [*******] and [********] filed [*******]	[******]
3. [************************************	
**************************************	[******]
4. [************************************	
- ************************************	
a) US Provisional [********] filed [******]	[******]

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EXHIBIT 10.19 TO COLEY PHARMACEUTICAL GROUP, INC. FORM S-1 FILED APRIL 20, 2005

#### **CONFIDENTIAL**

Coley Pharmaceutical Group, Inc. Wellesley Gateway 93 Worcester Street, Suite 101 Wellesley, Massachusetts 02481

September 25, 2001

Ottawa Health Research Institute 725 Parkdale Avenue Ottawa, Ontario KIY 4E9 CANADA Attn: Robert Hanlon, M.H.A., C.H.E. Chief Administrative Officer

### Re: Amendment to License Agreement

#### Ladies and Gentlemen:

This letter will serve as an amendment (the <u>"Amendment"</u>) to the License Agreement (the <u>"Agreement"</u>) dated as of September 1, 1998 between Coley Pharmaceutical Group, Inc., formerly known as CpG ImmunoPharmaceuticals, Inc. ("Coley"), and the Loeb Health Research Institute at the Ottawa Hospital (the "LOEB"). The Ottawa Health Research Institute (the <u>"OHRI"</u>) is the successor in interest to, and assignee of, all the rights and obligations of the LOEB under the Agreement. All capitalized terms that are used in this letter and not defined herein shall have the meanings ascribed to them in the Agreement. Except as specifically modified by this Amendment, the parties hereto agree that all of the terms and conditions set forth in the Agreement remain in full force and effect.

### 1. OHRI as a Party

The OHRI, as the assignee of all of the assets and liabilities of the LOEB, has replaced the LOEB as a Party to the Agreement. Consequently, all references in the Agreement to the LOEB are hereby replaced with references to the OHRI.

2. Amendment to the Definition of Commercial Sale.

The Parties hereby agree that Section 1.2 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"1.3 **Commercial Sale** shall mean any transaction for value between Coley, an affiliate of Coley, or a Sublicensee of Coley, as applicable, and a third party, which transaction involves the transfer or other disposition of a Licensed Product to such third party."

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



## 3. Amendment to the Definition of Field.

The Parties hereby agree that Section 1.3 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"1.3 Field shall mean any and all uses of CpG, T- rich or G- rich molecules and any derivatives, modifications, improvements, fragments, analogs, or homologs thereof and any other materials which could not have been discovered or made but for the use of the above described molecules or Coley's confidential information (that is not in the public domain), whether used alone or in combination with other agents, including but not limited to, formulations or delivery systems."

## 4. Amendment to the Definition of Licensed Product.

The Parties hereby agree that Section 1.8 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"1.8 Licensed Product shall mean any product or process which is covered, on a country-by-country and product-by-product basis, by a Pending or issued claim under Patent Rights in such country. In addition, Licensed Product shall also mean, on a product-by-product basis, any product or process not covered by Patent Rights which to a material degree, as determined by mutual agreement of the Parties, contains, is based on, or is derived from, identified through or utilizes any Licensed Technology which is not in the public domain. Any product or process which is a Licensed Product at the time of first Commercial Sale shall, for the purposes of Sections 4.1, 4.3 and 9.1, be treated as a Licensed Product for at least 10 years from the date of first Commercial Sale,"

## 5. Amendment to the Definition of Patent Rights and Update to Exhibit A.

The Parties hereby agree that Section 1.12 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

- "1.12 **Patent Rights** shall mean all rights derived from any and all patents and patent applications (including without limitation provisional applications and invention disclosures) that
  - (a) are listed on <u>Exhibit A</u> attached hereto; or

(b) are owned or controlled, in whole or in part (with the ability to grant licenses or sublicenses), by the OHRI by way of transfer of rights from any Investigator, and that claim, describe, embody or relate to the Licensed Technology throughout the Territory; or

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(c) result from or arise under any OHRI research agreement that is sponsored solely by Coley; or

(d) fall within the Field, name [\*\*\*\*\*\*\*\*\*\*\*\*] as an inventor, and are owned or controlled, in whole or in part (with the ability to grant licenses or sublicenses), by the OHRI (any patent rights outside of the Field in which is [\*] is an inventor will be subject to prevailing OHRI policy governing intellectual property rights of its students);

together with any substitutions, extensions, renewals, continuations, continuations-in-part, divisions, patents of addition, and/or reissues thereof, and any current and future patent or patent application, or portion thereof, which is a foreign counterpart in any country in the Territory to any of the foregoing, including any substitutions, extensions, renewals, continuations, continuations-in-part, divisions, patents of addition and/or reissues thereof.

All of the foregoing patents and patent applications will be automatically incorporated in and added to this Agreement and shall periodically be added to <u>Exhibit A</u> and made a part thereof."

The Parties also hereby agree that Exhibit A to the Agreement shall be updated as of the date hereof to the form of Exhibit A attached to this Amendment.

6. Amendment to Royalty Payment Obligations of Coley.

The Parties hereby agree that Section 4.1 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

- "4.1 Royalties. In consideration of the exclusive licenses and other rights granted to Coley under this Agreement, Coley agrees to pay to the OHRI a royalty, commencing upon the first Commercial Sale of a Licensed Product by Coley, its Affiliates or its Sublicensees, as follows:
  - (a) For Commercial Sales made by Coley or its Affiliates (but not its Sublicensees) of all Licensed Products covered by issued or Pending Patent Rights in a particular country, Coley shall pay the following royalty rates on Net Sales in such country:
    - (i) [\*\*\*\*]%, if the aggregate royalty rate being paid by Coley or its Affiliates on the Licensed Product to all Licensed Product Licensors is less than or equal to [\*\*\*\*]%. For purposes of this Section 4.1(a), the term Licensed Product Licensors shall mean, as to a particular Licensed Product, all third parties (excluding OHRI) to whom Coley or its Affiliates owe(s) a royalty on Commercial Sales of such Licensed Product.

# Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

- (ii) [\*\*\*\*]%, if the aggregate royalty rate being paid by Coley or its Affiliates on the Licensed Product to all Licensed Product Licensors is greater than [\*\*\*\*]% but less than or equal to [\*\*\*\*]%.
- (iii) [\*\*\*\*]%, if the aggregate royalty rate being paid by Coley or its Affiliates on the Licensed Product to all Licensed Product Licensors is greater than [\*\*\*\*]% but less than or equal to [\*\*\*\*]%.
- (iv) [\*\*\*\*]%, if the aggregate royalty rate being paid by Coley or its Affiliates on the Licensed Product to all Licensed Product Licensors is greater than [\*\*\*\*]%.
- (v) [\*\*\*\*]% if the Licensed Product is sold for the treatment or prophylaxis treatment of veterinary diseases.
- (b) For Commercial Sales made by Coley or its Affiliates (but not its Sublicensees) of all Licensed Products that are not covered by issued or Pending Patent Rights in a particular country, Coley shall pay [\*\*\*\*\*] ([\*]%) of the foregoing royalty rates, as applicable, on Net Sales in such country.
- (c) In the event that Coley and/or its Affiliates receive Sublicense Income from any Sublicensee, Coley shall pay to the OHRI [\*\*\*\*\*] ([\*]%) of such Sublicense Income from each such Sublicensee."

#### 7. Amendment to Duration of Royalty Payment Obligations of Coley.

The Parties hereby agree that Section 4.3 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

- "4.3 **Duration of Royalties**. Coley shall not be obligated to make any further royalty payments in any country for any Licensed Product after the end of the period commencing on the date of the first Commercial Sale of the Licensed Product in that country by Coley, its Affiliates or Sublicensees and ending either on the expiration of a valid, enforceable claim of a Patent Right covering the Licensed Product in that country or ten (10) years after the date of the first Commercial Sale, whichever is later."
- 8. Amendment to Term of Agreement.
  - The Parties hereby agree that Section 9.1 of the Agreement shall hereby be amended and restated in its entirety to read as follows:
  - "9.1 **Term.** This Agreement shall commence as of the Effective Date and, unless sooner terminated as provided in Section 9.3 hereunder, shall terminate as to each country in the Territory, upon the expiration of the last to expire valid, enforceable claim of a Patent Right covering such Licensed Product in such country or a minimum of ten (10) years from the date of the first Commercial Sale, whichever is later. Upon any such expiration of Patent Rights or end of such ten year period in such country whichever is later, Coley shall have a fully paid-up license of

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perpetual duration in such country, subject to the survival provisions in Section 9.7, including the right of Coley, its Affiliates and/or its Sublicensees to continue using the Licensed Technology and to develop, have developed, make, have made, perform, use, have used, sell, offer for sale, have sold, import or have imported Licensed Products without any further obligation to the OHRI hereunder."

### 9. Amendment to Restriction on Assignment of Agreement.

The Parties hereby agree that the first sentence of Section 10.3 of the Agreement shall hereby be amended and restated in its entirety to read as follows:

"10.3 Assignment. Except as otherwise provided herein, neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior written consent of the other, whose consent shall not be unreasonably denied; provided, however, that either Party may assign this Agreement to any wholly-owned subsidiary, affiliate or to any successor by merger or sale of substantially all of its assets to which this Agreement relates in a manner such that the assignee shall remain liable and responsible for the performance and observance of all of the assigning Party's duties and obligations hereunder."

#### 10. Issuance of Common Stock to OHRI and Co-Inventors.

OHRI hereby requests of Coley, as consideration for the execution of this Amendment by ORHI, and Coley hereby agrees, subject to the terms and conditions set forth below, to issue Forty Thousand (40,000) shares of its Common Stock (the <u>"Amendment Shares"</u>) as follows: (1) 20,000 shares to OHRI, (2) 14,000 shares to Heather Davis, (3) 4,000 shares to Michael McCluskie, and (4) 2,000 shares to Tong Wu. The issuance of Amendment Shares to OHRI shall be made pursuant to, and subject to the terms and conditions of, the Subscription Agreement attached hereto as <u>Exhibit B</u>, and the issuance of Amendment Shares to the Co-Inventors (as defined below) shall be made pursuant to, and subject to the terms and conditions of, separate written agreements mutually acceptable to Coley and each of the Co-Inventors.

OHRI hereby represents and warrants to Coley that (1) Heather Davis, Michael McCluskie and Tong Wu (collectively, the <u>"Co-Inventors"</u>) are inventors of the Patent Rights, and the only LOEB or OHRI inventors named therein, (2) the allocation of the Amendment Shares as set forth in the preceding paragraph is pursuant to and in compliance with any and all policies or agreements to which OHRI is a party or otherwise bound that relate to the sharing of revenues among inventors of intellectual property rights of OHRI constituting the Patent Rights, and (3) no person has any claim to any portion of the Amendment Shares except as set forth in the preceding paragraph. OHRI hereby agrees to indemnify and hold harmless Coley, its successors and assigns, and their respective officers, directors, employees and agents (collectively, the<u>"Obligees</u>"), from and against any and all losses, damages, costs, expenses and liabilities (including reasonable attorneys' fees) that the Obligees may incur by reason of (1) a breach of OHRI's representations and warranties in the preceding sentence or (2) any obligation with respect to the payment or withholding of taxes that may arise as a result of the issuance of the Amendment Shares to the Co-Inventors.

# 11. Survival.

Each of the Parties hereto acknowledges that the Agreement remains in full force and effect in accordance with its terms, as amended hereby.

# Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

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## 12. Entire Agreement.

The Agreement and this Amendment and the attachments hereto and thereto constitute the entire agreement and understanding between Coley and the OHRI relating to the subject thereof and hereof. No verbal agreement, conversation or representation between any officers, agents, or employees of the parties hereto either before or after the execution of the Agreement or this Amendment shall affect or modify any of the terms or obligations therein or herein contained. Any further amendment to the terms of the Agreement or this Amendment shall be made in writing and signed on behalf of each Party by a duly authorized officer.

# 13. Terms Confidential.

Each Party hereby acknowledges and agrees that it will not disclose the terms of the Agreement or this Amendment or any other information relating to the subject matter hereof or thereof to any third party without the express written consent of the other Party, except that (i) either Party may use the text of a written statement approved in advance by both Parties without further approval, (ii) Coley may disclose the terms of the Agreement and this Agreement to a potential or current Sublicensee, and (iii) either Party shall have the right, following written notice to the other Party, to identify the other Party and to disclose the terms of this Agreement as required by applicable securities laws or other applicable laws or regulations.

Please sign below where indicated to acknowledge your agreement to the foregoing Amendment.

Sincerely,COLEY PHARMACEUTICAL GROUP, INC.By:/s/ Robert L. BratzlerName:Robert L. Bratzler, Ph.D.Title:CEO and President

ACKNOWLEDGED AND AGREED TO This 25 day of September, 2001 THE OTTAWA HEALTH RESEARCH INSTITUTE

By: /s/ Robert Hanlon

Name: Robert Hanlon

Title: Chief Operating Officer

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# Exhibit A

## PATENT RIGHTS

WG&S ID [***********]	<u>SN</u> [***********]	FILING DATE [*******]	<u>INVENTORS</u> [********]	TITLE	<u>STATUS</u> [******]
L J	L J	L J	[****]	L **********************	L J
[*****	[******]	[*******]		L.	[*****
[***********	[**************	[********]			[******]
[***********	[*****]	[********]			[******]
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			[****]		
[*****	[*******	[********]	[*****]	<b>****</b> *************	[******]
[**********]	[*******]	[********]	[*****]	******	[******]
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#### SUBSCRIPTION AGREEMENT

This Agreement is made as of the <u>25</u> day of September 2001, by and between Coley Pharmaceutical Group, Inc., a Delaware corporation (the " <u>Company</u>"), and the Ottawa Health Research Institute (<u>"Purchaser")</u>.

WHEREAS, the Company has requested. and the Purchaser has agreed, to amend certain terms and conditions of the License Agreement dated as of September l, 1998 between the Company and Purchaser (the <u>"Agreement"</u>) pursuant to an Amendment dated as of the date hereof (the <u>"Amendment"</u>); and

WHEREAS, as partial consideration for the Purchaser's agreement to enter into the Amendment, the Company has agreed to issue to the Purchaser shares of the Company's Common Stock on the terms and conditions set forth below;

NOW THEREFORE, the parties hereto, for good and valuable consideration, the sufficiency of which is hereby acknowledged, agrees as follows:

I. <u>Purchase and Sale</u>. Purchaser hereby purchases from the Company, and the Company agrees to sell to Purchaser, Twenty Thousand (20,000) shares of the Company's Common Stock (the <u>"Shares"</u>) as consideration for the Purchaser's agreement to enter into the Amendment, and for no additional consideration. The closing hereunder shall occur at the offices of the Company on the date hereof, or at such other time and place as the parties may mutually agree.

2. <u>Purchaser Representations</u>. Purchaser acknowledges that the Shares to be issued pursuant to this Agreement have not been registered under the Securities Act of 1933, as amended (the "<u>Securities</u> Act"), and Purchaser warrants and represents to the Company as follows:

(a) <u>Enforceability</u>. This Agreement has been duly executed and delivered by Purchaser and constitutes a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors and rules of law governing specific performance, injunctive relief or other equitable remedies, and to limitations of public policy.

(b) <u>Purchase for Own Account</u>. Purchaser is purchasing the Shares solely for Purchaser's own account for investment and not with a view to or for sale or distribution of the Shares or any portion thereof and not with any present intention of selling, offering to sell or otherwise disposing of or distributing the Shares or any portion thereto. Purchaser also represents that the entire legal and beneficial interest of the Shares that Purchaser is purchasing is being purchased for, and will be held for the account of, Purchaser only and neither in whole nor in part for any other person.

(c) <u>Availability of Information</u>. Purchaser has heretofore discussed the Company and its plans, operations and financial condition with Company's officers and Purchaser has heretofore received all such information as Purchaser deems necessary and appropriate to enable Purchaser to evaluate the financial risk inherent in making an investment in the Shares and

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Purchaser further represents and warrants that Purchaser has received satisfactory and complete information concerning the business and financial condition of the Company in response to all inquiries in respect thereof.

(d) <u>Rule 144</u>. Purchaser understands that the Shares are restricted securities within the meaning of Rule 144 promulgated under the Securities Act, and that any sale of the Shares may be made by Purchaser only in accordance with the terms and conditions of Rule 144 (of which it is familiar), as amended from time to time.

(e) <u>Accredited Investor</u>. The Purchaser represents that he, she or it is an "accredited investor" as such term is defined in Rule 501 of Regulation D promulgated under the Securities Act.

(f) Lock-Up. If requested by the Company and the managing underwriter of an offering by the Company of Common Stock or other securities of the Company pursuant to a registration statement under the Securities Act, the Purchaser shall agree not to sell publicly or otherwise transfer or dispose of the Shares for a specified period of time (not to exceed 180 days) following the effective date of such registration statement (the "Lock-up"), provided that:

(i) all holders of more than two percent (2%) of the Common Stock then outstanding (including holders of securities convertible into or exchangeable or exercisable for shares of Common Stock) and all officers and directors of the Company enter into similar agreements; and

(ii) in the event of any discretionary waiver or termination of the Lock-up by the Company or representatives of the underwriter, the Company shall use its best efforts to obtain the waiver or termination of the Lock-up with respect to all persons subject to such Lock- up on a pro-rata basis.

The Company may impose stop-transfer instructions with respect to the Shares or such other securities subject to the Lock-up until the end of such 180day period.

(g) Legend. Each certificate representing the Shares shall bear a legend substantially in the following form:

"The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended, and may not be offered, sold or otherwise transferred, pledged or hypothecated unless and until such shares are registered under such Act or an opinion of counsel satisfactory to the Company is obtained to the effect that such registration is not required."

(h) <u>Dispositions</u>. Without in any way limiting the representations set forth above, Purchaser further agrees that Purchaser shall in no event make any disposition of all or any portion of the Shares unless and until:

(i) There is then in effect a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with said registration statement; or

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



(ii) (A) Purchaser shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of circumstances surrounding the proposed disposition, (B) Purchaser shall have furnished the Company with an opinion of Purchaser's counsel (or, at Purchaser's expense, an opinion of the Company's counsel) to the effect that such disposition will not require registration of such Shares under the Act, and (C) any opinion of counsel to Purchaser shall have been concurred in by counsel for the. Company and the Company shall have advised Purchaser of such concurrence.

### 3. Miscellaneous.

(a) <u>Successors and Assigns</u>. This Agreement shall inure to the benefit of the successors and assigns of the Company and be binding upon Purchaser and Purchaser's successors and assigns.

(b) <u>Governing Law</u>. This Agreement shall be governed by and interpreted under the laws of the Commonwealth of Massachusetts.

(c) <u>Headings</u>. Headings are for convenience only and are not deemed to be part of this Agreement.

(d) <u>Counterparts</u>. This Agreement may be executed simultaneously in any number of counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement under seal as of the day and year first above written.

#### COLEY PHARMACEUTICAL GROUP, INC.

By:	/s/ Robert L. Bratzler
Name:	Robert L. Bratzler, Ph.D.
Title:	CEO and President

## THE OTTAWA HEALTH RESEARCH INSTITUTE

By:	/s/ Robert Hanlon
Name:	Robert Hanlon
Title:	Chief Operating Officer

Portions of this Exhibit were omitted and have been filed separately with the Secretary of the Commission pursuant to the Company's application requesting confidential treatment under Rule 406 of the Securities Act.

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# <u>EXHIBIT D</u>

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

LICENSE AGREEMENT



#### **News Release**

<u>Coley Contact:</u> Susan Hager Senior Director, Investor Relations and Corporate Communications +1.781.431.9079 <u>shager@coleypharma.com</u>

<u>Media Contact:</u> Karen L. Bergman or Michelle Corral BCC Partners +1.650.575.1509 or +1.415.794.8662 <u>kbergman@bccpartners.com</u> <u>mcorral@bccpartners.com</u>

For Immediate Release



<u>Dynavax Contact:</u> Shari Annes Investor Relations Public Relations +1-650-888-0902 sannes@dynavax.com

### Coley Pharmaceutical Group Grants Dynavax License for Commercialization of HEPLISAV<sup>TM</sup>

Wellesley, MA and Berkeley, CA, June 28, 2007 – Coley Pharmaceutical Group, Inc. (Nasdaq: COLY) and Dynavax Technologies Corporation (Nasdaq: DVAX) today announced they have entered into a license agreement relating to certain TLR Therapeutics<sup>™</sup> patents from Coley.

Under the terms of the agreement, Dynavax receives a non-exclusive license under Coley's immunostimulatory oligonucleotide patent estate for the commercialization of HEPLISAV<sup>TM</sup>, a hepatitis B prophylactic vaccine, currently in Phase 3 clinical trials. Coley will receive a \$5 million up-front payment. Coley is also eligible to receive up to an additional \$5.0 million upon regulatory approvals of HEPLISAV, as well as royalty payments for any future sales of HEPLISAV.

-more-

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## About HEPLISAV and Hepatitis B

HEPLISAV is currently being evaluated in a Phase 3 clinical trial in Canada and in Europe. The multi-center trial, known as PHAST (Phase 3 HeplisAv Short-regimen Trial), is comparing a two-dose regimen of HEPLISAV administered at 0 and 1 month to the conventional three-dose regimen of Engerix-B<sup>®</sup>. The enrollment target of the study is approximately 2,000 subjects, ages 11 to 55 years. Dynavax expects to submit a BLA in 2008 for approval of the product with a database of approximately 4,000 patients

In several previous clinical studies, HEPLISAV has been shown to provide seroprotection against hepatitis B faster and with fewer doses than conventional hepatitis B vaccines. Additionally, HEPLISAV has provided 100% seroprotection in all subjects who have received the full regimen, including those who are difficult-to-immunize.

## About Coley's TLR Therapeutics<sup>™</sup>

Coley's TLR Therapeutics are a new class of investigational drug candidates that target certain immune cells through Toll-like receptors. The patents licensed today to Dynavax relate to Coley's Toll-like receptor 9 (TLR9) agonist technology that induce enhanced antigen-specific antibody and T-cell immune responses when used in combination with vaccines. Coley's TLR9 agonist drug candidate has been included in approximately 35 clinical trials of vaccines in development for use in various cancer indications, infectious diseases and biowarfare defense. The most advanced clinical program with Coley's TLR9 agonist vaccine adjuvant candidate is a forthcoming Phase III clinical trial under the direction of GlaxoSmithKline (GSK) as part of a treatment for resectable, early stage lung cancer.

### **About Coley Pharmaceutical Group**

Coley Pharmaceutical Group, Inc. is an international biopharmaceutical company, headquartered in Wellesley, Massachusetts, USA, that discovers and develops TLR Therapeutics™, a new class of investigational drug candidates that direct the human immune system to fight cancers, asthma and allergic diseases and to enhance the effectiveness of vaccines. Coley has established a pipeline of TLR Therapeutic product candidates currently advancing through clinical development with partners and has additional product candidates in preclinical development. Coley has product development, research and license agreements with Pfizer, sanofi-aventis, GSK, Novartis Vaccines, Merck and the United States government. For further information on Coley Pharmaceutical Group please visit www.coleypharma.com.

## **About Dynavax**

Dynavax Technologies Corporation discovers, develops, and intends to commercialize innovative TLR9 agonist-based products to treat and prevent infectious diseases, allergies, cancer, and chronic inflammatory diseases using versatile, proprietary approaches that alter immune system responses in highly specific ways. The company's TLR9 agonists are based on immunostimulatory sequences, or ISS, which are short DNA sequences that enhance the ability of the immune system to fight disease and control chronic inflammation. Dynavax's pipeline includes: HEPLISAV, a hepatitis B vaccine in Phase 3; TOLAMBA™, a ragweed allergy immunotherapeutic; a therapy for non-Hodgkin's lymphoma (NHL) in Phase 2 and for metastatic colorectal cancer in Phase 1; and a therapy for hepatitis B also in Phase 1. A preclinical asthma and COPD program is partnered with AstraZeneca. The National Institutes of Health (NIH) partially funds preclinical work on a vaccine for influenza; Symphony Dynamo, Inc., funds the company's colorectal cancer trials and a preclinical hepatitis C therapeutic program. While the

<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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NIH and Symphony provide program support, Dynavax has retained rights to seek strategic partners for future development and commercialization. For more information, please visit http://www.dynavax.com.

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#### Safe Harbor Statements

Certain statements in this news release concerning Coley's business are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, those relating to royalty payments for any future product sales involving HEPLISAV. Any or all of the forward-looking statements in this press release may turn out to be wrong. They can be affected by inaccurate assumptions Coley might make or by known or unknown risks and uncertainties, including, but not limited to: the early stage of product development; uncertainties as to the future success of ongoing and planned clinical trials; the risk that results from early stage clinical trials may not be indicative of results in later stage trials; the unproven safety and efficacy of products under development; intellectual property rights and litigation; competitive products; and other risks identified in Coley's filings with the Securities and Exchange Commission including, but not limited to, Coley's Annual Report on Form 10-K for the fiscal year ended December 31, 2006. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially. Coley undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise, except as required by applicable law.

This press release contains forward-looking statements concerning Dynavax that are subject to a number of risks and uncertainties, including statements about Dynavax's HEPLISAV hepatitis B vaccine and financial terms of its agreement with Coley. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in Dynavax's business, including difficulties or delays in development; achieving the objectives of collaborative and licensing efforts; and obtaining regulatory approval for HEPLISAV; the scope and validity of patent protection; possible claims based on the patent rights of others; the ability to obtain additional financing to support operations; and other risks detailed in the "Risk Factors" section of Dynavax's Quarterly Report on Form 10-Q. Dynavax undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

TLR Therapeutics is a trademark of Coley Pharmaceutical Group. HEPLISAV is a trademark of Dynavax Technologies Corporation. All other trademarks are the property of their respective holders.

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<sup>[\*] =</sup> Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## Rule 13a-14(a) Certification of Chief Executive Officer

CERTIFICATIONS

I, Dino Dina, M.D., certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the "registrant");
- 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 officer 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) and 15d-15(f)) for the registrant and 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 quarterly 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 quarterly 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 like to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2007

By: /s/ DINO DINA, M.D.

Dino Dina, M.D. President, Chief Executive Officer and Director (Principal Executive Officer)

### Rule 13a-14(a) Certification of Chief Financial Officer

CERTIFICATIONS

I, Deborah A. Smeltzer, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Dynavax Technologies Corporation (the "registrant");
- 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 officer 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) and 15d-15(f)) for the registrant and 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 quarterly 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 quarterly 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 like to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2007

By: /s/ DEBORAH A. SMELTZER

Deborah A. Smeltzer Vice President, Operations and Chief Financial Officer (Principal Financial Officer)

### Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

I, Dino Dina, M.D., hereby certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of Dynavax Technologies Corporation (the "Company"), that, to the best of my knowledge:

- (i) The Quarterly Report of the Company on Form 10-Q for the period ended June 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and
- (ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 3, 2007

By: /s/ DINO DINA, M.D. Dino Dina, M.D. President, Chief Executive Officer and Director (Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. § 1350, as adopted) has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission ("SEC") or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

### Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

I, Deborah A. Smeltzer, hereby certify, pursuant to 18 U.S.C § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, in my capacity as an officer of Dynavax Technologies Corporation (the "Company"), that, to the best of my knowledge:

- (i) The Quarterly Report of the Company on Form 10-Q for the period ended June 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities and Exchange Act of 1934; and
- (ii) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 3, 2007

## By: /s/ DEBORAH A. SMELTZER

Deborah A. Smeltzer Vice President, Operations and Chief Financial Officer (Principal Financial Officer)

A signed original of this written statement required by Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. § 1350, as adopted) has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission ("SEC") or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.