UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

Or

o TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-32587

PHARMATHENE, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

One Park Place, Suite 450, Annapolis, MD (Address of principal executive offices)

21401 (Zip Code)

20-2726770

(I.R.S. Employer Identification No.)

(410) 269-2600 (Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

Large Accelerated Filer o

Non-Accelerated Filer o (Do not check if a smaller reporting company)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: The number of shares of the registrant's Common Stock, par value \$0.0001 per share, outstanding as of November 11, 2009 was 28,435,598.

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PHARMATHENE, INC.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

PHARMATHENE, INC. UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

		September 30, 2009	December 31, 2008		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	4,188,272	\$	19,752,404	
Restricted cash				12,000,000	
Short-term investments		7,382,329		3,190,912	
Accounts receivable		5,055,107		8,890,077	
Other receivables (including unbilled receivables)		13,668,072		1,391,512	
Prepaid expenses and other current assets		1,765,758		917,125	
Total current assets		32,059,538		46,142,030	
Long-term restricted cash		—		1,250,000	
Property and equipment, net		6,207,971		5,313,219	
Patents, net		930,350		925,489	
Other long-term assets and deferred costs		423,530		257,623	
Goodwill		2,348,453		2,502,909	
Total assets	\$	41,969,842	\$	56,391,270	
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)					
Current liabilities:					
Accounts payable	\$	1,030,171	\$	3,870,871	
Accrued expenses and other current liabilities		15,252,530		14,624,757	
Convertible notes		—		13,377,505	
Current portion of derivative instruments		47,431		_	
Current portion of long-term debt				4,000,000	
		16,330,132		35,873,133	
Other long-term liabilities		446,390		626,581	
Derivative instruments		2,126,868			
Convertible notes and other long-term debt		16,579,864		928,117	
Total liabilities		35,483,254		37,427,831	
Stockholders' equity:					
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 28,091,635 and 25,890,143 shares issued and outstanding, respectively		2,809		2,589	
Additional paid-in-capital		156,242,571		142,392,163	
Accumulated other comprehensive income		879,759		386,351	
Accumulated deficit		(150,638,551)		(123,817,664)	
Total stockholders' equity		6,486,588		18,963,439	
Total liabilities and stockholders' equity	\$	41,969,842	\$	56,391,270	
Total nautrities and stockholders equity	Ф	41,709,042	φ	50,591,270	

See the accompanying notes to the condensed consolidated financial statements.

PHARMATHENE, INC. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended September 30,					Nine months ended September 30,			
		2009		2008		2009		2008	
Contract revenue	\$	6,830,399	\$	10,643,705	\$	20,423,513	\$	27,377,207	
Other revenue				32,461				53,612	
		6,830,399		10,676,166		20,423,513		27,430,819	
Operating expenses:									
Research and development		7,609,794		9,414,093		22,769,749		26,475,436	
General and administrative		6,224,868		4,803,190		15,787,115		14,655,971	
Acquired in-process research and development		—		225,000		—		16,131,002	
Depreciation and amortization		247,747		205,409		639,924		641,425	
Other expenses		274,005	_			1,158,566			
Total operating expenses		14,356,414		14,647,692		40,355,354		57,903,834	
	-								
Loss from operations		(7,526,015)		(3,971,526)		(19,931,841)		(30,473,015)	
Other income (expenses)									
Interest income		61,743		250,014		258,841		1,083,949	
Interest expense		(748,892)		(628,470)		(1,949,402)		(1,947,245)	
Loss on early extinguishment of debt		(4,690,049)		—		(4,690,049)		—	
Change in fair value of derivative instruments		(1,059,509)		7,604		(295,218)		123,148	
Total other income (expenses)		(6,436,707)		(370,852)		(6,675,828)		(740,148)	
	-								
Net loss		(13,962,722)		(4,342,378)		(26,607,669)		(31,213,163)	
Basic and diluted net loss per share	\$	(0.50)	\$	(0.20)	\$	(0.97)	\$	(1.41)	
Weighted average shares used in calculation of basic and diluted net									
loss per share		28,077,348		22,095,545		27,388,761		22,089,949	

See the accompanying notes to the condensed consolidated financial statements.

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PHARMATHENE, INC. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASHFLOWS

		Nine months ended September 30,		
		2009		2008
Operating activities	¢		<i>•</i>	
Net loss	\$	(26,607,669)	\$	(31,213,163)
Adjustments to reconcile net loss to net cash used in operating activities:				
Acquired in-process research and development				16,131,002
Loss on early extinguishment of debt		4,690,049		
Change in fair value of derivative instruments		295,218		(123,148)
Depreciation and amortization		639,924		641,425
Measurement period changes in purchase accounting estimates		154,456		
Share-based compensation		2,725,246		1,976,497
Non-cash interest expense on debt		605,265		1,292,598
Changes in operating assets and liabilities:				
Accounts receivable		3,834,970		(1,521,184)
Prepaid expenses and other assets		(12,913,132)		(124,912)
Accounts payable		(2,840,700)		(1,446,808)
Accrued expenses and other liabilities		7,453,987		5,012,542
Net cash used in operating activities		(21,962,386)		(9,375,151)
Investing activities				
Purchases of property and equipment		(1,539,537)		(455,242)
Purchase of letter of credit		—		(14,500,000)
Purchases of available-for-sale investments		(8,800,640)		(11,577,455)
Sales of available-for-sale investments		4,600,000		20,624,293
Payments for purchase business combination		(7,000,000)		(11,556,117)
Net cash used in investing activities		(12,740,177)		(17,464,521)
Financing activities				
Issuance of convertible notes		10,528,196		
Payments of long-term debt		(9,538,016)		(3,000,000)
Decrease in restricted cash requirements		13,250,000		
Other financing costs		(551,090)		(206,154)
Proceeds from issuance of common stock		4,946,710		
Net cash provided by (used in) financing activities		18,635,800		(3,206,154)
Effects of exchange rates		502,631		(395,898)
Decrease in cash and cash equivalents		(15,564,132)		(30,441,724)
Cash and cash equivalents, at beginning of period		19,752,404		40,582,643
Cash and cash equivalents, at end of period	\$	4,188,272	\$	10,140,919
Supplemental disclosure of non-cash financing activities:				
Exchange of 8% convertible debt for 10% convertible debt and warrants	\$	8,767,606	\$	_

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PHARMATHENE, INC. Notes to Condensed Consolidated Financial Statements September 30, 2009 (unaudited)

Note 1 — Organization and Business

Historically our operations were conducted by our wholly-owned subsidiary PharmAthene US Corporation. In March 2008, PharmAthene Inc., through its whollyowned subsidiary PharmAthene UK Limited, acquired substantially all the assets and liabilities related to the biodefense vaccines business (the "Avecia Acquisition") of Avecia Biologics Limited (along with its affiliates, "Avecia"). In February 2009, PharmAthene US Corporation was merged with and into PharmAthene, Inc., with PharmAthene, Inc. being the surviving corporation.

We are a biopharmaceutical company focused on developing biodefense countermeasure applications. We are subject to those risks associated with any biopharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change and are largely dependent on the services and expertise of our employees, consultants and other third parties.

Note 2 — Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of PharmAthene, Inc. and its wholly-owned subsidiaries, PharmAthene U.S. Corporation, PharmAthene Canada, Inc., and PharmAthene UK Limited, collectively referred to herein as "PharmAthene", "we", "us", "our" or the "Company". All significant intercompany transactions and balances have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The condensed consolidated balance sheet at December 31, 2008 has been derived from audited consolidated financial statements at that date. These condensed statements should be read in conjunction with the Consolidated Financial Statements and Notes included in our Annual Report on Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission.

We currently operate in one business segment.

Use of Estimates

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

Comprehensive Loss

Comprehensive loss includes the total of our net loss and all other changes in equity other than transactions with owners, including (i) changes in equity for cumulative translation adjustments resulting from the consolidation of foreign subsidiaries as the financial statements of the subsidiaries located outside of the United States are accounted for using the local currency as the functional currency, and (ii) unrealized gains

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and losses on short term available-for-sale investments. Comprehensive loss for the three month periods ended September 30, 2009 and 2008 was approximately \$12.7 million and \$4.5 million, respectively. Comprehensive loss for the nine month periods ended September 30, 2009 and 2008 was approximately \$26.1 million and \$31.6 million, respectively.

Basic and Diluted Net Loss Per Share

Basic loss per share is computed by dividing consolidated net loss by the weighted average number of common shares outstanding during the period, excluding unvested restricted stock. For the periods presented in the accompanying condensed consolidated statements of operations, diluted loss per share is calculated similarly because the impact of all potentially dilutive securities is anti-dilutive due to our net loss each period. At September 30, 2009 and 2008 we had total potential dilutive securities outstanding of approximately 19.3 million shares and 16.2 million shares, respectively (related to outstanding stock options, outstanding stock purchase warrants, shares underlying our convertible notes, and unvested restricted stock) that we excluded from the calculation of diluted net loss per share since their inclusion would be anti-dilutive.

Fair Value of Financial Instruments

Our financial instruments primarily include cash and cash equivalents, accounts receivable, short-term investments and other current assets, accounts payable, accrued and other liabilities, convertible notes and long-term debt. Due to the short-term nature of the cash and cash equivalents, accounts receivable, short-term investments and other current assets, accounts payable and accrued and other liabilities (including derivative instruments), the carrying amounts of these assets and liabilities approximate their fair value. The carrying values of our convertible notes and other long term debt approximate their fair values, based on our current incremental borrowing rates.

Short-term investments consist of investment grade government agency and corporate debt securities due within one year. All investments are classified as available-forsale and are recorded at market value. Unrealized gains and losses are reflected in other comprehensive loss. The estimated fair value of the available-for-sale securities is determined based on quoted market prices or rates. Management reviews our investment portfolio on a regular basis and seeks guidance from our professional portfolio manager related to U.S. and global market conditions. We assess the risk of impairment related to securities held in our investment portfolio on a regular basis and identified no permanent or "other-than-temporary" impairment during the quarter and nine months ended September 30, 2009. Refer to Note 3.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk are primarily cash and cash equivalents, investments and accounts receivable. We maintain our cash and cash equivalents and investment balances in the form of money market accounts, corporate and government debt securities and overnight deposits with financial institutions that management believes are creditworthy. Our accounts receivables are primarily from agencies within the U.S. government, including the U.S. Department of Defense (the "DoD"), the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority ("BARDA"), and the National Institute of Health ("NIH").

Intangible Assets

Patents are carried at cost less accumulated amortization which is calculated on a straight line basis over the estimated useful lives of the patents, currently estimated to be 11 years. Goodwill represents the excess of purchase price over the fair value of net identifiable assets associated with the Avecia Acquisition. We review the carrying value of our intangible assets for impairment annually during the fourth quarter or more frequently if impairment indicators exist. Evaluating for impairment requires management judgment, including the estimation of future cash flows, future growth rates and profitability and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in

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market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of the intangible asset over its estimated fair value. For the three and nine month periods ended September 30, 2009, we determined that there was no impairment of our intangible assets.

Revenue Recognition

Our contracts may include multiple elements, including one or more of up-front license fees, research payments, and milestone payments. In these situations, we allocate the total contract price to the multiple elements based on their relative fair values and recognize revenue for each element according to its characteristics. We generate our revenue from two different types of contractual arrangements: cost-plus-fee contracts and cost reimbursable grants. Revenues on cost-plus-fee contracts are recognized to the extent of costs incurred plus an estimate of the applicable fees earned. We consider fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. We analyze each cost reimbursable grant to determine whether we should report such reimbursements as revenue or as an offset to our expenses incurred. For the three months ended September 30, 2009 and 2008, the Company recorded approximately \$0.2 million and \$0.9 million, respectively, of costs reimbursed by the government as an offset to research and development expenses. For the nine months ended September 30, 2009 and 2008, the Company recorded approximately \$1.4 million and \$1.7 million, respectively, of costs reimbursed by the government as an offset to research and development expenses.

As revenue is recognized in accordance with the terms of our contracts, related amounts are recorded as unbilled receivables, the primary component of "Other receivables (including unbilled receivables)". As specific contract invoices are generated and sent to our government customer, invoiced amounts are transferred out of unbilled receivables and into accounts receivable.

Collaborative Arrangements

We are an active participant with exposure to significant risks and rewards of commercialization relating to the development of several of our pipeline products. For costs incurred and revenues generated from third parties where we are deemed to be the principal participant, we recognize revenues and costs using the gross basis of accounting; otherwise, we use the net basis of accounting.

Research and Development

Research and development costs are expensed as incurred; advance payments are deferred and expensed as performance occurs. Research and development costs include salaries, facilities expense, overhead expenses, material and supplies, pre-clinical expense, clinical trials and related clinical manufacturing expenses, stock-based compensation expense, contract services and other outside services.

Share-Based Compensation

We expense the estimated fair value of share-based awards granted to our employees under our stock-based compensation plans. Share-based compensation cost is determined at the grant date using an option pricing model. The value of the award that is ultimately expected to vest is recognized as expense on a straight line basis over the employee's requisite service period. We have estimated the fair value of each award using the Black-Scholes option pricing model. The Black-Scholes model considers, among other factors, the expected life of the award and the expected volatility of the Company's stock price; we have not made any significant changes to these factors during 2009.

Employee share-based compensation expense recognized for the three and nine months ended September 30, 2009 and 2008 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures at a rate of approximately 17% for both stock options and restricted shares, based on our historical forfeitures. Share-based compensation expense for the three and nine months ended September 30, 2009 and 2008, respectively, was:

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	Three months ended Nine months September 30, September						i
	2009 20			2008		2009	2008
Research and development	\$	179,559	\$	124,038	\$	646,028	\$ 317,967
General and administrative		806,112		784,030		2,079,218	1,658,530
Total share-based compensation expense	\$	985,671	\$	908,068	\$	2,725,246	\$ 1,976,497

During the nine months ended September 30, 2009, we granted 1,507,350 options to employees and non-employee directors, and made restricted stock grants of 258,633. At September 30, 2009, we have total unrecognized stock based compensation expense related to unvested awards of approximately \$6.7 million that we expect will be recognized over the next three years.

Income Taxes

We account for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are recorded for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a tax rate change on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. We record valuation allowances to reduce net deferred tax assets to the amount considered more likely than not to be realized. Changes in estimates of future taxable income can materially change the amount of such valuation allowances. As of September 30, 2009, we had recognized a valuation allowance to the full extent of our net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold. We believe that any uncertain tax position taken in the past would not result in an adjustment to our effective income tax rate because adjustments to deferred tax assets and liabilities would be offset by adjustments to recorded valuation allowances. We file a U.S. federal income tax return as well as returns for various state and foreign jurisdictions. The Company's income taxes have not been examined by any tax jurisdiction since our inception.

Recent Accounting Pronouncements

In August 2009, the Financial Accounting Standards Board issued Accounting Standards Update 2009-05, "Fair Value Measurements and Disclosures (Topic 820) Measuring Liabilities at Fair Value ("ASU 2009-05"). ASU 2009-05 clarifies that in circumstances in which a quoted market price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one of several acceptable valuation techniques. ASU 2009-05 also clarifies (i) that when estimating the fair value of a liability, a reporting entity is not required to include a separate input or adjustments to other inputs relating the existence of a restriction that prevents the transfer of the liability, and (ii) that both a "quoted price in an active market for the identical liability at the measurement date" and the "quoted price for the identical liability when traded as an asset in a active market when no adjustments to the quoted price of the asset are required" are Level 1 fair value measurements. ASU 2009-05 is effective in the fourth quarter of 2009. The Company has not yet determined the impact of the adoption of ASU 2009-05 on its financial statements.

In October 2009, the Financial Accounting Standards Board issued Accounting Standards Update 2009-13, "Revenue Recognition (Topic 605) Multiple-Deliverable Revenue Arrangements, a consensus of the FASB Emerging Issues Task Force ("ASU 2009-13"). ASU 2009-13 amends existing accounting guidance for separating consideration in multiple-deliverable arrangements. ASU 2009-13 establishes a selling price hierarchy for determining the selling price of a deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence if available, third-party evidence if vendor-specific evidence is not available, or estimated selling price if neither vendor-specific evidence nor third-party evidence is available. ASU 2009-13 eliminates residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the "relative selling price method."

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The relative selling price method allocates any discount in the arrangement proportionately to each deliverable on the basis of each deliverable's selling price. ASU 2009-13 requires that a vendor determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a stand-alone basis. ASU 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier adoption permitted. The Company has not yet determined the impact of the adoption of ASU 2009-13 on its financial statements.

Note 3 — Fair Value Measurements

We define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. We report our assets and liabilities that are measured at fair value using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- · Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices
- for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
 Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.
- An asset's or liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, we perform a detailed analysis of our assets and liabilities that are measured at fair value. All assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

We have segregated our financial assets and liabilities that are measured at fair value into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below. We have no non-financial assets and liabilities that are measured at fair value.

	as of September 30, 2009										
	 Level 1		Level 2		Level 3	Balance					
Assets											
Available-for-sale securities	\$ 7,328,329	\$		\$		\$	7,382,329				
Liabilities											
Stock purchase warrants	\$ _	\$		\$	2,174,299	\$	2,174,299				
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The following table sets forth a summary of changes in the fair value of our Level 3 liabilities for the nine months ended September 30, 2009:

			Cumulative Effect				Balance
		alance at Dec. 31,	f Adoption of w Accounting	New Liabilities	Unrealized (Gains)	s	as of eptember 30,
Description	_	2008	 Guidance	 In 2009	 Losses		2009
Embedded conversion option	\$	6,405	\$ _	\$ _	\$ (6,405)	\$	_
Stock purchase warrants	\$		\$ 636,609	\$ 1,236,067	\$ 301,623	\$	2,174,299

The unrealized losses on the derivative instruments are classified in other expenses as the change in derivative instruments in our condensed consolidated statement of operations. The fair value of our stock purchase warrants and conversion option is determined based on the Black-Scholes option pricing model.

Note 4 - Short-Term Investments — Available-for-Sale Securities

The amortized cost, gross unrealized gains, gross unrealized losses and estimated fair value of available-for-sale short-term investments by security classification as of September 30, 2009 were as follows:

September 30, 2009	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Values
Corporate debt securities	\$ 4,769,207	\$ 8,591	\$ (1,685)	\$ 4,776,113
Government debt securities	\$ 2,605,661	\$ 561	\$ (6)	\$ 2,606,216
Total securities	\$ 7,374,868	\$ 9,152	\$ (1,691)	\$ 7,382,329

During the nine months ended September 30, 2009, we had no realized gains or losses on sales of available-for-sale securities. Gains and losses on available-for-sale securities are based on the specific identification method.

Note 5 — Debt

Convertible Notes

Our 8% senior unsecured convertible notes accrued interest at an interest rate of 8% per annum and were to mature on August 3, 2009 (the "Old Notes"). The principal amount of the Old Notes and any accrued interest were convertible into shares of PharmAthene common stock at the option of the holder at any time based upon a conversion rate of \$10.00 per share. In July 2009, we cancelled a portion of the Old Notes, and issued new convertible notes and stock purchase warrants to holders of the cancelled notes as well as to certain new note investors in a private placement (the "July 2009 Private Placement"). Specifically, in connection with the July 2009 Private Placement, we:

- exchanged a portion of our Old Notes in the aggregate principal amount plus accrued interest totaling \$8.8 million for new two-year 10% unsecured senior convertible notes, convertible into common shares at a conversion price of approximately \$2.54 per share (the "New Convertible Notes") and cancelled the corresponding Old Notes;
- · issued additional New Convertible Notes in the aggregate principal amount of \$10.5 million to new note investors;
- issued to the recipients of the New Convertible Notes stock purchase warrants to purchase up to 2,572,775 shares of common stock at \$2.50 per share, which warrants are exercisable from January 28, 2010 through January 28, 2015; and
- used the proceeds from the sale of the New Convertible Notes to repay \$5.5 million of our Old Notes that were not exchanged for the New Convertible Notes and warrants and repaid all outstanding amounts and fees under our existing credit facility.

The New Convertible Notes issued in exchange for the Old Notes were accounted for as an early extinguishment of debt, resulting in a loss on extinguishment of the Old Notes of approximately \$4.7 million. This portion of the New Convertible Notes and the related stock purchase warrants were recorded

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at their fair values, resulting in an increase to additional paid-in capital for the premium associated with the New Convertible Notes and the value attributed to the warrants.

The New Convertible Notes and related stock purchase warrants issued to new note investors were initially recorded at their relative fair values. As a result of this relative fair value allocation, the total value allocated to the New Convertible Notes issued to new note investors was \$7.3 million. In combination with the \$8.8 million of New Convertible Notes issued to the Old Note holders, the total initial value ascribed to the New Convertible Notes was approximately \$16.1 million. The initial value of \$16.1 million will be accreted up to the total aggregate principal amount of \$19.3 million over the life of the notes by the recognition of additional interest expense. The total value of the New Convertible Notes, including accretion from additional interest expense, as of September 30, 2009, was approximately \$16.6 million.

Financing costs incurred in connection with the July 2009 Private Placement were allocated to the various components of consideration based on their relative fair values.

Credit Facility

In March 2007, we entered into a \$10 million credit facility with Silicon Valley Bank and Oxford Finance Corporation (together, the "Lenders"). In July 2009, we repaid all outstanding amounts due under the credit facility along with certain prepayment fees. In connection with the credit facility, we issued to the Lenders certain stock purchase warrants, which expire on March 30, 2017, to purchase an aggregate of 100,778 shares of the Company's common stock at \$3.97 per share.

Note 6 — Avecia Acquisition

Avecia Settlement Agreement

In June 2009, PharmAthene and Avecia entered into a settlement agreement (i) to resolve certain issues related to the wind down and cancellation of work related to our rPA vaccine program being conducted at Avecia pursuant to a master services agreement ("MSA") between our two organizations, and (ii) to accelerate the payment of certain deferred consideration related to the Avecia Acquisition. Under the settlement agreement:

- we paid Avecia \$7.0 million of the remaining deferred purchase price consideration under the Avecia Acquisition, and as a result our existing letter of credit that
 had supported the deferred consideration (and the related requirement to maintain restricted cash as collateral for the letter of credit) was terminated in
 June 2009:
- we agreed to pay Avecia approximately \$1.8 million related to past performance and raw materials under the MSA subject to certain remaining performance obligations by Avecia related to, among other things, the technology transfer effort to a new U.S.-based bulk drug substance manufacturer; and
- we agreed to pay Avecia approximately \$3.0 million in cancellation fees no later than January 5, 2010 (and earlier if certain other conditions are met).

In June 2009, the Company expensed as allowable costs under its government contract the \$1.8 million payment for past contract performance and recognized related contract revenues. The Company also expensed the \$3.0 million cancellation fee in June 2009.

Contemplated Exit Activities

In the second quarter 2009, our existing research and development contract for SparVaxTM was transferred from NIAID to BARDA. In the third quarter 2009 BARDA and PharmAthene modified the existing statement of work to include, among other things, the completion of on-going stability studies and development of potency assays along with certain manufacturing scale-up and technology transfer activities to a U.S.-based manufacturer for the bulk drug substance for SparVaxTM. We then entered into a corresponding subcontract with our U.S.-based manufacturer.

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As a result of the transfer of the contract and modification of the statement of work, we have been transitioning development and manufacturing activities as well as other general and administrative functions from the UK to the U.S. In connection with this transition, we anticipate relocating our UK operations, including terminating our UK workforce, by June 30, 2010. In the third quarter of 2009 we incurred expenses associated with these exit activities of approximately \$1.6 million.

License Agreements

In connection with the Avecia Acquisition, we acquired license agreements with The Defence Science and Technology Laboratory of the United Kingdom Ministry of Defence ("DSTL") for the rights to certain technologies. These agreements allow for the licensing of specified patents and technology necessary to perform development of the rPA and rYP programs as required under our contracts with NIAID and BARDA. Upon commercialization, the license agreements require us to make royalty payments equal to a specified percentage of future sales of products for both government procurement and commercial markets. No payments on these licenses have been incurred. In February 2009, both of these licenses were amended and restated to broaden the scope of exclusivity and address other general business issues.

Note 7 — Common Stock

Common Stock

In March 2009, the Company completed a public sale of 2,116,055 newly issued shares of its common stock at \$2.60 per share and warrants to purchase 705,354 shares of its common stock at an exercise price of \$3.00 per share, generating gross proceeds of \$5.5 million. The warrants became exercisable on September 27, 2009 and will expire on September 27, 2014.

Share-Based Awards

Prior to 2007, we granted share-based awards pursuant to our 2002 Long-Term Incentive Plan (the "2002 Plan"). In connection with the merger between the subsidiary of Healthcare Acquisition Corp. ("HAQ") and PharmAthene, Inc. on August 3, 2007 (the "Merger"), we assumed all outstanding awards that had been initially granted under the 2002 Plan. No further grants are being made under the 2002 Plan. On August 3, 2007, our stockholders approved the 2007 Long Term Incentive Plan (the "2007 Plan") which provides for the granting of incentive and non-qualified stock options, stock appreciation rights, performance units, restricted common awards and performance bonuses (collectively "awards") to our officers and employees. Additionally, the 2007 Plan authorizes the granting of non-qualified stock options and restricted stock awards to our directors and to independent consultants.

At that time, we reserved 3,500,000 shares of common stock in connection with awards to be granted under the 2007 Plan, including those awards that had originally been made under the 2002 Plan. In 2008, our shareholders approved amendments to the 2007 Plan, increasing from 3,500,000 shares to 4,600,000 shares the maximum number of shares authorized for issuance under the plan and adding an evergreen provision pursuant to which the number of shares authorized for issuance under the plan will increase automatically in each year, beginning in 2009 and continuing through 2015, according to certain limits set forth in the 2007 Plan. The Board of Directors in conjunction with management determines who receives awards, the vesting conditions, which are generally four years, and the exercise price. Options may have a maximum term of ten years.

Unit Purchase Option

In connection with the initial public offering of HAQ in 2005, the underwriters paid \$100 for an option to purchase up to a total of 225,000 units. The units issuable upon exercise of this option are identical to those offered in the initial public offering (i.e. each unit consists of one share of common stock and one warrant) except that the associated warrants have a higher exercise price (see below). The unit purchase option became exercisable at \$10.00 per unit on August 3, 2007, and expires on July 27, 2010 (except that the warrant included in such option expired unexercised on July 27, 2009). The exercise price and number

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of units issuable upon the exercise of the option may be adjusted in certain circumstances including in the event of a stock dividend, or recapitalization, reorganization, merger or consolidation. We are not obligated to pay cash or other consideration to the holders of the unit purchase option or "net-cash settle" the obligation of HAQ under the unit purchase option.

Stock Purchase Warrants

In connection with HAQ's initial public offering in 2005, HAQ sold warrants to acquire approximately 9.4 million shares of common stock at an exercise price of \$6.00 per share; the warrants expired unexercised on July 27, 2009. HAQ also issued to the representative of the underwriters an option to purchase up to a total of 225,000 units (as discussed above). Underlying the units are 225,000 shares of common stock and warrants to acquire 225,000 shares of common stock at an exercise price of \$7.50 per share. All warrants expired unexercised on July 27, 2009.

Pursuant to the terms of our credit facility (all outstanding amounts under which were repaid in full in July 2009), we issued to the Lenders 100,778 common stock warrants with an exercise price of \$3.97 per share. The warrants expire in 2017, and are classified in equity.

In connection with a stock purchase by Kelisia Holdings Ltd. in 2008, we issued a warrant to purchase up to 2,745,098 additional shares of our common stock at an exercise price of \$5.10 per share. This warrant expired unexercised on October 10, 2009.

Prior to our adoption on January 1, 2009 of new accounting guidance related to the determination of derivative liabilities, we classified our stock purchase warrants as equity in our consolidated balance sheets. As a result of our adoption of the new accounting guidance, we considered the warrant issued to Kelisia Holdings Ltd. to be a derivative liability and reclassified the warrant to reflect it as a liability in our consolidated balance sheets. The impact of adopting this new guidance resulted in an increase in our retained deficit and a decrease to our additional paid in capital at January 1, 2009 of approximately \$213,000 and \$423,000, respectively, along with an increase in our reported liabilities of approximately \$637,000.

In connection with the March 27, 2009 public offering of approximately 2.1 million shares, we issued warrants to purchase an aggregate of 705,354 shares of our common stock at an exercise price of \$3.00 per share. The warrants became exercisable on September 27, 2009 and will expire on September 27, 2014. We consider these warrants to be a derivative liability and as such reflect the liability at fair value in our condensed consolidated balance sheets. The fair value of this derivative liability will be re-measured at the end of every reporting period and the change in fair value will be reported in the consolidated statement of operations as other income (expense).

In connection with the July 2009 Private Placement, we issued warrants to purchase an aggregate of 2,572,775 shares of our common stock at an exercise price of \$2.50 per share. The warrants will be exercisable beginning January 28, 2010 and will expire on January 28, 2015, and classified in equity.

Note 8 — Commitments and Contingencies

In December 2006, the Company filed a complaint against Siga Technologies, Inc. ("SIGA") in the Delaware Chancery Court. The complaint alleges, among other things, that the Company has the right to license exclusively development and marketing rights for SIGA's drug candidate, SIGA-246, pursuant to a merger agreement between the parties (the "Merger Agreement") that was terminated in October 2006. The complaint also alleges that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement.

The Company is seeking alternatively a judgment requiring SIGA to enter into an exclusive license agreement with the Company for SIGA-246 in accordance with the terms of the term sheet attached to the merger agreement or monetary damages. In January 2008, the Delaware Chancery Court issued a ruling denying a motion by SIGA to dismiss the complaint. SIGA has filed a counterclaim against the Company

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alleging that the Company breached its duty to engage in good-faith negotiations by, among other things, presenting SIGA with a bad-faith initial proposal for a license agreement that did not contain all necessary terms, demanding SIGA prepare a complete draft of a partnership agreement and then unreasonably rejecting that agreement, and unreasonably refusing to consider economic terms that differed from those set forth in the license agreement term sheet attached to the Merger Agreement. SIGA is seeking recovery of its reliance damages from this alleged breach.

Fact discovery in the case is now complete, and the parties are engaged in expert witness discovery, which the Company believes will be complete in February 2010. Following that, if neither party files motions for summary judgment, the Company believes the case could proceed to trial in March or April 2010, subject to the court's docket and schedule. If one or both of the parties files motions for summary judgment, the Company believes a trial in the case is unlikely to occur before the end of the third quarter 2010, depending on the timing and outcome of the court's ruling on the motions for summary judgment and the court's docket and schedule at that time.

The Company entered into a Registration Rights Agreement with the investors who participated in the July 2009 Private Placement. The Company subsequently filed a registration statement on Form S-3 with the Securities and Exchange Commission to register shares underlying the New Convertible Notes and related warrants. This registration statement has not yet been declared effective. The Registration Rights Agreement requires the Company to cause the registration statement to be declared effective by November 25, 2009 and thereafter to continuously keep such registration statement effective.

Under the terms of the New Convertible Notes, if the registration statement is not declared effective by November 25, 2009 ("Effectiveness Failure"), or after the effective date of the registration statement, after the 2nd consecutive business day (other than during an allowable blackout period) on which sales of all of the securities required to be included on the registration statement cannot be made pursuant to the registration statement (a "Maintenance Failure"), we will be required to pay to each selling stockholder a one-time payment of 1.0% of the aggregate principal amount of the New Convertible Notes relating to the affected shares on: (i) the day of an Effectiveness Failure and (ii) the initial day of a Maintenance Failure.

Following an Effectiveness Failure or Maintenance Failure, we will also be required to make to each selling stockholder monthly payments of 1.0% of the aggregate principal amount of the New Convertible Notes relating to the affected shares on each of the following dates: (i) on every 30th day after the initial day of an Effectiveness Failure and (ii) on every 30th day after the initial day of a Maintenance Failure, in each case prorated for shorter periods and until the failure is cured.

Note 9 — Subsequent Events

Management performed an evaluation of Company activity through November 11, 2009, the date the unaudited condensed consolidated financial statements were issued. The Company concluded that there are no other significant subsequent events requiring disclosure.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. This information may involve known and unknown risks, uncertainties and other factors that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risk associated with the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of the Company's product candidates, unexpected funding delays and/or reductions or elimination of U.S. government funding for one or more of the Company's development programs, including without limitation our bid related to SparVaxTM under the DHHS Request for Proposals for an Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile, the award of government contracts to our competitors, unforeseen safety issues, challenges related to the development, technology transfer, scale-up, and/or process validation of manufacturing processes for our product candidates, unexpected determinations that these product candidates prove not to be effective and/or capable of being marketed as products, as well as risks detailed from time to time in PharmAthene's Forms 10-Q under the caption "Risk Factors" and in its other reports filed with the U.S. Securities and egnerally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," "project," "potential" or "plan" or the negative of these words or other variations on these words or comparable terminology. Such statements include, but are not limited to, statements about potential future government contract or grant awards, potential governets

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looking statements are based on assumptions that may be incorrect, and we cannot assure you that the projections included in the forward-looking statements will come to pass.

We have based the forward-looking statements included in this Quarterly Report on Form 10-Q on information available to us on the date of this Quarterly Report, and we assume no obligation to update any such forward-looking statements, other than as required by law. Although we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise, you are advised to consult any additional disclosures that we may make directly to you or through reports that we, in the future, may file with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

The following discussion should be read in conjunction with the our condensed consolidated financial statements which present our results of operations for the three and nine months ended September 30, 2009 and 2008 as well as our financial positions at September 30, 2009 and December 31, 2008, contained elsewhere in this Quarterly Report on Form 10-Q. The following discussion should also be read in conjunction with the Annual Report on Form 10-K for the year ended December 31, 2008 filed on March 31, 2009 and as amended on April 30, 2009, including the consolidated financial statements contained therein.

Overview

We are a biodefense company engaged in the development and commercialization of medical countermeasures against biological and chemical weapons. We currently have five product candidates in various stages of development:

- · SparVax[™], a second generation recombinant protective antigen ("rPA") anthrax vaccine,
- Valortim®, a fully human monoclonal antibody (an identical population of highly specific antibodies produced from a single clone) for the prevention and treatment of anthrax infection,
- Protexia®, which mimics a natural bioscavenger for the treatment or prevention of nerve agent poisoning by organophosphate compounds, including nerve
 gases and pesticides,
- · a third generation rPA anthrax vaccine, and
- · RypVax[™], a recombinant dual antigen vaccine for pneumonic and bubonic plague ("rYP").

In August 2009 we began a Phase I clinical trial of our Valortim® anthrax anti-toxin fully human monoclonal antibody in combination with the antibiotic ciprofloxacin. During the course of the study, there were two adverse reactions in the four subjects dosed, one of which was characterized by the clinical investigators as a serious adverse event. While both adverse reactions resolved after cessation of the administration of Valortim® and appropriate medical treatment, and neither of the subjects appears to have experienced any further or lasting adverse consequences, we temporarily halted the trial per the requirements of the clinical trial protocol and informed the U.S Food and Drug Administration ("FDA") and the National Institute of Allergy and Infectious Diseases (NIAID) of these developments. The FDA has placed the Valortim®/ciprofloxacin study on partial clinical hold pending the outcome of an investigation. This clinical hold does not pertain to other Valortim® related development efforts under the existing investigational new drug (IND) application, and adverse reactions like those seen in this trial have been observed before with the administration of other marketed monoclonal antibodies.

The Biomedical Advanced Research and Development Authority ("BARDA") has also informed us that they will

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not make an award with respect to our submission for additional advanced development funding for Valortim® under BAA-BARDA-09-34 until satisfactory resolution of this issue and the clinical hold is lifted, at which point we expect they will promptly re-commence the negotiation process. The antibiotic interaction study is not on the critical development path for FDA licensure for the product, and at this point the Company does not believe the delay to this trial will impact the overall Valortim® development timeline. However, it is unclear at this time how long it will take us to complete our investigation, if and when we will be in a position to recommence negotiations with BARDA with respect to a potential award under the BAA, and how any delay in potential future funding of the program could affect the overall Valortim® development timeline.

Critical Accounting Policies

Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. We base our estimates and assumptions on historical experience and various other factors that are believed to be reasonable under the circumstances. Actual results could differ from our estimates and assumptions. We believe the following are our critical accounting policies, i.e., they affect our more significant estimates and assumptions and require the use of difficult, subjective and complex judgment in their application.

Share-Based Payments

We expense all share-based awards to employees, including grants of employee stock options, based on their estimated fair value at date of grant. Costs of all sharebased payments are recognized over the requisite service period that an employee must provide to earn the award (i.e. usually the vesting period) and charged to the functional operating expense associated with that employee.

Revenue Recognition

Our revenue-generating contracts may include multiple elements, including one or more of up-front license fees, research payments, and milestone payments. In these situations, we allocate the total contract price to the multiple elements based on their relative fair values and recognize revenue for each element according to its characteristics. We generate our revenue from two different types of contractual arrangements: cost-plus-fee contracts and cost reimbursable grants. Revenues on cost-plus-fee contracts are recognized to the extent of costs incurred plus an estimate of the applicable fees earned. We consider fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. We analyze each cost reimbursable grant to determine whether we should report such reimbursements as revenue or as an offset to our expenses incurred. As revenue is recognized in accordance with the terms of our contracts, related amounts are recorded as unbilled receivables, the primary component of "Other receivables (including unbilled receivables)". As specific contract invoices are generated and sent to our government customer, invoiced amounts are transferred out of unbilled receivables and into accounts receivable.

Research and Development Expenses

Research and development costs are expensed as incurred; advance payments are deferred and expensed as performance occurs. Research and development costs include salaries, facilities expense, overhead expenses, material and supplies, pre-clinical expense, clinical trials and related clinical manufacturing expenses, stock-based compensation expense, contract services and other outside services.

Intangible Assets

Because of the nature of pharmaceutical research, and particularly because of the difficulties associated with efficacy studies in humans related to the bioterrorist products with which we work and the government's related funding provisions, factors that affect the estimate of the life of an asset are often more uncertain than with respect to other non-bioterrorist pharmaceutical research. On an annual basis, we assess recoverability of intangible assets from future operations, using undiscounted future cash flows

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derived from the intangible assets. Any impairment would be recognized in operating results to the extent the carrying value exceeds the fair value, which is determined based on the net present value of estimated future cash flows; in certain situations, where the carrying value is dependent upon the outcome of a single study and that study is unsuccessful, that impairment may be significant in amount and immediate in timing.

Results of Operations for the Three and Nine Months ended September 30, 2009 and 2008

Revenue

We recognized revenue of \$6.8 million and \$10.7 million during the three months ended September 30, 2009 and 2008, respectively. We recognized revenue of \$20.4 million and \$27.4 million during the nine months ended September 30, 2009 and 2008, respectively.

Our revenue consisted primarily of contract funding from the U.S. government for the development of $Protexia^{\text{®}}$, $SparVax^{TM}$ and $Valortim^{\text{®}}$. Our revenue in each of the three and nine months ended September 30, 2009 changed from the comparable periods of 2008 due to the following:

- Under the September 2006 contract with the U.S. Department of Defense ("DoD") for the advanced development of Protexia[®], we recognized \$1.5 million and \$4.9 million of revenue for the three months ended September 30, 2009 and 2008, respectively. We recognized \$6.8 million and \$17.6 million of revenue for the nine months ended September 30, 2009 and 2008, respectively. The significant decline in revenue in 2009 is primarily attributable to the shift of our Protexia[®] program from broad pre-clinical development efforts, including manufacturing, to a focus on clinical evaluation as well as the completion, during the third quarter of 2009, of all work and related funding under the initial phase of the contract with the DoD. We believe that the DoD will make a decision regarding funding for the next phase of the development work for Protexia[®] during the first quarter of 2010. Consequently, during the fourth quarter of 2009 and until a funding decision is made, we do not expect to recognize revenues under this contract during that period.
- Under our contract for the development of SparVaxTM, acquired as part of the Avecia Acquisition in April 2008, we recognized approximately \$2.4 million and \$3.8 million of revenue for the three months ended September 30, 2009 and 2008, respectively. We recognized \$7.3 million and \$6.0 million of revenue for the nine months ended September 30, 2009 and 2008, respectively. The nine month period in 2008 only includes revenue recognized from and after April 2, 2008, the closing date of the Avecia Acquisition. The rate of revenues (and corresponding costs) recognized in the 2009 periods associated with work on this development contract declined as compared to the same periods in 2008 as we stopped our development work at Avecia, revised our development plan, and commenced our efforts to transfer technology from Avecia to a US-based bulk drug substance manufacturer. For the nine month period, this decline was partially offset by revenue attributable to our June 2009 settlement agreement with Avecia, which included \$1.8 million related to past performance and raw materials under our master services agreement with Avecia.
- Under the September 2007 contract for the advanced development of Valortim[®], we recognized \$2.0 million and \$0.5 million of revenue for the three months ended September 30, 2009 and 2008, respectively. We recognized \$4.2 million and \$1.0 million of revenue for the nine months ended September 30, 2009 and 2008, respectively. The increase in revenue for both the three and nine month periods is primarily attributable to the reimbursement of higher costs related to pre-clinical studies as well other development work in the 2009 periods as we prepared for and commenced human clinical trials. For reasons discussed previously, we expect that revenues for the rest of 2009 and into 2010 will not continue to increase at this rate.
- Under our contract for the advanced development of our plague vaccine, RypVaxTM, acquired as part of the Avecia Acquisition in April 2008, we recognized approximately \$0.7 million and \$1.6 million of revenue for the three months ended September 30, 2009 and 2008, respectively.

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We recognized \$1.5 million and \$2.9 million of revenue for the nine months ended September 30, 2009 and 2008, respectively. We and the U.S. government have agreed to a reduction to the scope of work under our current contract that will result in early wind down of all activities under that contract, likely no later than the end of the first half of 2010. As such, we expect revenues and related costs under that contract will decline over the wind down period.

Under our September 2008 contract award for the additional development work on our third generation rPA anthrax vaccine, we recognized approximately \$0.2 million and \$0.6 million of revenue for the three and nine months ended September 30, 2009, respectively, and none in the corresponding periods of 2008, as we began work under this contract in 2009.

Research and Development Expenses

Our research and development expenses were \$7.6 million and \$9.4 million for the three months ended September 30, 2009 and 2008, respectively, and were \$22.8 million and \$26.5 million for the nine months ended September 30, 2009 and 2008, respectively. These expenses resulted from research and development activities related to programs for Valortim[®] and Protexia[®], as well as from activities related to the SparVaxTM, RypVaxTM and third generation anthrax vaccine programs. Our research and development expenses are primarily funded through U.S. government contracts and grant awards. We incurred both direct expenses, which included salaries and other costs of personnel, raw materials and supplies, and an allocation of indirect expenses. We also incurred third-party costs, such as contract research, consulting and clinical development costs for individual projects. Research and development expenses for the three and nine months ended September 30, 2009 were net of cost reimbursements under certain of our government grants of \$0.2 million and \$1.4 million, respectively. Research and development expenses for the three and nine months ended September 30, 2008 were net of cost reimbursements under certain of our government grants of \$0.9 million and \$1.7 million, respectively.

Research and development expenses for the three and nine months ended September 30, 2009 and 2008 were attributable to research programs as follows:

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Recombinant dual antigen plague vaccine	.6	2.0	1.5	4.1
Internal research and development		0.2	0.2	0.5
Total research and development expenses	\$ 7.6	\$ 9.4	\$ 22.8	\$ 26.5

For the three and nine months ended September 30, 2009 and 2008, research and development expenses decreased \$1.8 million and \$3.7 million, respectively, primarily attributable to a reduction in pre-clinical development costs for our chemical nerve agent protectants program as we progress in our clinical evaluation phase, and a reduction in development costs for our plague vaccine program, partially offset by increased pre-clinical development associated with our anthrax-related therapeutics and vaccines programs. The decrease in development expenses related to the clinical nerve agent protectants program resulted from reduced process development and manufacturing activities as the program moved from the development stage to the Phase I clinical trial. Expenses in connection with the anthrax therapeutics and vaccines programs increased primarily as a result of increased pre-clinical development activity in 2009 as we prepared for and started Phase I human clinical trials, along with increased costs incurred in connection with our June 2009 settlement agreement with Avecia. As we note above, we and the U.S. government have agreed to a reduction to the scope of work under our current contract for RypVax[™] and expect revenues and related costs under that contract will decline over the wind down period. We also anticipate that costs under our chemical nerve agent protectants program will increase in future periods as that program progresses through human clinical trials.

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General and Administrative Expenses

General and administrative functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal, and compliance. For each function, we may incur direct expenses such as salaries, supplies and third-party consulting and other external costs and non-cash expenditures such as expense related to stock option and restricted share awards. An allocation of indirect costs such as facilities, utilities and other administrative overhead is also included in general and administrative expenses.

Expenses associated with general and administrative functions were \$6.2 million and \$4.8 million for the three months ended September 30, 2009 and 2008, and were \$15.8 million and \$14.7 million for the nine months ended September 30, 2009 and 2008, respectively.

General and administrative expenses increased \$1.4 million and \$1.1 million for the three and nine months ended September 30, 2009, respectively, as compared to the comparable 2008 periods. The increases were primarily due to the costs associated with the transitioning of our development and manufacturing activities as well as other general and administrative functions from the UK to the U.S., and with preparing and submitting various bids and proposals, along with increased stock-based compensation costs during the nine-month period.

Depreciation and Intangible Amortization

Depreciation and amortization expenses were \$0.2 million for both the three months ended September 30, 2009 and 2008, respectively, and were \$0.6 million for both the nine month periods. These expenses relate primarily to the depreciation and amortization of farm building improvements, leasehold improvements and laboratory equipment, and patents acquired as part of a 2005 business combination.

Other Income and Expenses

Other income and expenses primarily consists of income on our investments, interest expense on our debt and other financial obligations, changes in market value of our derivative financial instruments, loss on early extinguishment of debt, and foreign currency transaction gains or losses. For the three months ended September 30, 2009 and 2008, we recognized interest income of \$0.1 million and \$0.3 million, respectively. For the nine months ended September 30, 2009 and 2008, we recognized interest income of \$0.3 million, respectively. The decrease in interest income during the periods is primarily attributable to the reduced average balances of our investments and cash balances as we continue to use cash to support our operations, along with lower prevailing interest rates.

We incurred interest expense of \$0.7 million and \$0.6 million for the three months ended September 30, 2009 and 2008, respectively, and \$1.9 million in both nine month periods. Interest expense relates primarily to our outstanding convertible notes (including the amortization of debt discount related to the (i) allocation of fair value to the stock purchase warrants and (ii) beneficial conversion feature) and our senior secured credit facility, which facility we repaid in full in July 2009.

The change in the fair value of our derivative instruments (various stock purchase warrants and the embedded conversion option in the Old Notes) was \$1.1 million and \$0.3 million for the three and nine months ended September 30, 2009, respectively. We measure the fair value of these derivative instruments using the Black-Scholes option pricing model. As discussed in Note 7 to our condensed consolidated financial statements, we adopted new accounting guidance in the first quarter of 2009 related to the accounting for warrants we issued in October 2008 (which expired unexercised in October 2009). The new guidance was adopted using the cumulative catch-up method. Accordingly, there was no change in the fair value of the warrants in 2008 prior to adoption.

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Liquidity and Capital Resources

Overview

Our primary cash requirements through the end of 2010 are to fund our research and development programs and support our general and administrative activities. Our future capital requirements will depend on many factors, including, but not limited to, the progress of our research and development programs; the progress of pre-clinical and clinical testing; the time and cost involved in obtaining regulatory approval; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; changes in our existing research relationships, competing technological and marketing developments; our ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and any future change in our business strategy. These cash requirements could change materially as a result of shifts in our business and strategy.

Since our inception, we have not generated positive cash flows from operations. To bridge the gap between payments made to us under our government contracts and grants and our operating and capital needs, we have had to rely on a variety of financing sources, including the issuance of equity securities and convertible notes, proceeds from loans and other borrowings, and the trust funds obtained in the Merger. For the foreseeable future, we will continue to need these types of financing vehicles and potentially others to help fund our future operating and capital requirements. We believe that the funds obtained from the July 2009 Private Placement, existing cash resources, along with cash receipts from contract receivables (a substantial portion of which was unbilled at September 30, 2009) generated under our contracts, will be sufficient to enable us to fund our existing research and development programs and support our currently anticipated general and administrative

activities at least through the end of 2010. We have based this projection on our current and anticipated operations, which do not take into account any potential future government contracts that may be awarded to the Company, merger and acquisition or corporate partnering activities, or unexpected financial obligations.

The continuing turmoil affecting the banking system and financial markets and the possibility that financial institutions may consolidate or cease operations has resulted in a tightening in the credit markets, a low level of liquidity in many financial markets, and extreme volatility in fixed income, credit, currency and equity markets. As a result, there can be no assurance that future funding will be available to us on reasonably acceptable terms, or at all. In addition, due to the United States government's substantial efforts to stabilize the economy, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government contract awards, the likelihood that the government will exercise its right to extend any of its existing contracts with us and/or the likelihood that the government would procure products from us. Finally, the note and warrant purchase agreement entered into in connection with the July 2009 Private Placement limits us from incurring senior indebtedness (other than trade payables) in excess of \$10 million without the prior written approval of no less than a majority of the aggregate principal amount of the debt then outstanding.

We have incurred cumulative net losses and expect to incur additional losses in conducting further research and development activities. We do not have commercial products and, given the substantial costs relating to the development of pharmaceutical products, have relatively limited existing capital resources. Our plans with regard to these matters include continued development of our products as well as seeking additional funds to support our research and development efforts. Although we continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient future financing on commercially reasonable terms or at all or that we will be able to secure additional funding through government contracts and grants. Our condensed consolidated financial statements have been prepared on a basis which assumes that we will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business and do not include any adjustments that might result if the carrying amount of recorded assets and liabilities are not realized.

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Sources and Uses of Cash

Cash, cash equivalents and short-term available-for-sale investments were \$11.6 million and \$22.9 million at September 30, 2009 and December 31, 2008, respectively. The \$11.3 million decrease in the first nine months of 2009 primarily was attributable to the funding of our operations and capital expenditures (of approximately \$23.5 million) and the payment of deferred consideration related to the Avecia Acquisition (of \$7.0 million), offset in part by the March 2009 public sale of common stock (for net proceeds of approximately \$4.9 million) and the July 2009 Private Placement (for net proceeds after repayment of debt, of approximately \$2.5 million), along with the associated reduction in our requirement to maintain restricted cash of \$13.3 million.

In March 2009, we closed on the public sale of 2,116,055 newly issued shares of our common stock at \$2.60 per share and warrants to purchase 705,354 shares of our common stock at an exercise price of \$3.00 per share, resulting in net proceeds of approximately \$4.9 million. The warrants became exercisable on September 27, 2009 and will expire on September 27, 2014. We intend to use the net proceeds for general corporate purposes, including the satisfaction of existing obligations.

Upon the closing of the Avecia Acquisition, in addition to certain initial consideration paid at that time, we also provided a letter of credit in the amount of \$7 million as security for deferred consideration in that same amount. Pursuant to the settlement agreement with Avecia entered into as of June 17, 2009, we paid the \$7 million deferred consideration to Avecia during the second quarter 2009 (in connection with which the letter of credit securing such amount was terminated and the required cash restrictions eliminated).

In July 2009, we closed on the private sale of approximately \$19.3 million of newly issued two-year 10 % unsecured senior convertible notes, convertible immediately into common shares at a conversion price of approximately \$2.54 per share (the "New Convertible Notes"), and warrants to purchase 2,572,775 shares of common stock at \$2.50 per share. The warrants become exercisable beginning on January 28, 2010 and will expire on January 28, 2015. As part of this sale we exchanged a portion of our then-outstanding 8% unsecured senior convertible notes, originally issued on August 3, 2007 and due August 3, 2009 (the "Old Notes"), in the aggregate principal amount plus accrued interest of \$8.8 million for New Convertible Notes, cancelled the corresponding Old Notes, issued additional New Convertible Notes in the aggregate principal amount of \$10.5 million to new note investors, and issued to the recipients of the New Convertible Notes the stock purchase warrants described above. In connection with the exchange, we recognized a loss on the early extinguishment of the Old Notes of approximately \$4.7 million. We used the proceeds from the sale of the New Convertible Notes to repay \$5.5 million of our Old Notes that were not exchanged for the New Convertible Notes and warrants and repaid all outstanding amounts and fees under our existing senior secured credit facility.

Operating Activities

Net cash used in operating activities was \$22.0 million and \$9.4 million for the nine months ended September 30, 2009 and 2008, respectively. Net cash used in operations during the nine months ended September 30, 2009 reflects our net loss of \$26.6 million, adjusted for certain non-cash items, including share-based compensation (of \$2.7 million), non-cash interest expense (of \$0.6 million), a decrease in accounts receivable (of \$3.8 million), an increase in other assets (the increase in other assets of \$12.9 million primarily relates to an increase in unbilled receivables related to government contracts), and an increase in accrued expenses and accounts payable (of \$4.6 million).

Net cash used in operations during the nine months ended September 30, 2008 reflects our net loss of \$31.2 million, adjusted for certain non-cash items, including acquired in-process research and development related to the Avecia Acquisition (of \$16.1 million), share-based compensation (of \$2.0 million), non-cash interest expense (of \$1.3 million), an increase in accounts receivable (of \$1.5 million), and an increase in accounts payable (of \$3.6 million).

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Investing Activities

Net cash used in investing activities was \$12.7 million for the nine months ended September 30, 2009, compared to \$17.5 million for the nine months ended September 30, 2008. Investing activities for the first nine months of 2009 related primarily to the payment in June of \$7.0 million of deferred purchase consideration to Avecia, purchases, net of sales, of available for sale securities of \$4.2 million and approximately \$1.5 million of capital expenditures.

In the first nine months of 2008 and in connection with the Avecia Acquisition, we paid \$10.0 million to Avecia and funded a \$7.0 million letter of credit. In order to fund the transaction and the restricted cash obligations pursuant to the loan modification agreement under our senior secured credit facility, approximately \$20.6 million of available-for-sale securities were sold. Additionally, during the first nine months of 2008, the Company incurred approximately \$1.6 million related to transactions costs incurred as a result of the Avecia Acquisition.

Net cash provided by financing activities was \$18.6 million for the nine months ended September 30, 2009 as compared to net cash used by financing activities of \$3.2 million for the nine months ended September 30, 2008. In March 2009, we raised net proceeds of approximately \$4.9 million as a result of the public sale of shares of our common stock and warrants. We raised \$10.5 million in the July 2009 Private Placement, and used \$9.5 million of those proceeds to repay our existing convertible notes and all amounts outstanding under our credit facility. We exchanged and cancelled \$8.8 million of our then-outstanding 8% convertible notes for our newly issued 10% convertible notes and stock purchase warrants. Additionally, pursuant to the payment to Avecia of the deferred purchase consideration and the repayment of all amounts due under our credit facility, we eliminated all of our restricted cash obligations (approximately \$13.3 million).

Net cash used by financing activities was \$3.2 million for the nine month period ended September 30, 2008. We made principal repayments of \$3.0 million under outstanding credit facilities for the nine months ended September 30, 2008.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

The following are contractual commitments at September 30, 2009 associated with leases, research and development arrangements, collaborative development obligations and long term debt:

		Less than 1]	More than
Contractual Obligations (\$ in thousands) (1)	 Total	 Year	 1-3 Years	 3-5 Years		5 years
Operating facility leases	\$ 6,301	\$ 993	\$ 2,263	\$ 2,434	\$	611
Research and development agreements	12,594	9,294	3,300	—		—
Notes payable, including interest	23,209		23,209	—		—
Total contractual obligations	\$ 42,104	\$ 10,287	\$ 28,772	\$ 2,434	\$	611

(1) This table does not include any royalty payments of future sales of products subject to license agreements the Company has entered into in relation to its in-licensed technology, as the timing and likelihood of such payments are not known.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

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Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control Over Financial Reporting

Management has identified several changes in our internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during 2009 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting, including (i) the resignation of our financial reporting manager during the second quarter 2009, (ii) our reliance on external financial consultants to provide a significant portion of our internal accounting and financial reporting functions; and (iii) our implementation of a new financial accounting system. We are in the process of completing but have not yet completed our internal documentation of all the changes in our internal controls over financial reporting.

To specifically address the changes identified in our internal controls over financial reporting, we developed and performed additional analytical and substantive procedures during our quarter closing process. Management believes that these additional procedures provide reasonable assurance that our condensed consolidated financial statements as of and for the three and nine months ended September 30, 2009, are fairly stated in all material respects in accordance with generally accepted accounting principles in the United States.

Inherent Limitations on Disclosure Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

In December 2006, the Company filed a complaint against Siga Technologies, Inc. ("SIGA") in the Delaware Chancery Court. The complaint alleges, among other things, that the Company has the right to license exclusively development and marketing rights for SIGA's drug candidate, SIGA-246, pursuant to a merger agreement between the parties (the "Merger Agreement") that was terminated in October 2006. The complaint also alleges that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement.

The Company is seeking alternatively a judgment requiring SIGA to enter into an exclusive license agreement with the Company for SIGA-246 in accordance with the terms of the term sheet attached to the merger agreement or monetary damages. In January 2008, the Delaware Chancery Court issued a ruling denying a motion by SIGA to dismiss the complaint. SIGA has filed a counterclaim against the Company alleging that the Company breached its duty to engage in good-faith negotiations by, among other things, presenting SIGA with a bad-faith initial proposal for a license agreement that did not contain all necessary terms, demanding SIGA prepare a complete draft of a partnership agreement and then unreasonably rejecting that agreement, and unreasonably refusing to consider economic terms that differed from those set forth in the license agreement term sheet attached to the Merger Agreement. SIGA is seeking recovery of its reliance damages from this alleged breach.

Fact discovery in the case is now complete, and the parties are engaged in expert witness discovery, which the Company believes will be complete in February 2010. Following that, if neither party files motions for summary judgment, the Company believes the case could proceed to trial in March or April 2010, subject to the court's docket and schedule. If one or both of the parties files motions for summary judgment, the Company believes a trial in the case is unlikely to occur before the end of the third quarter 2010, depending on the timing and outcome of the court's ruling on the motions for summary judgment and the court's docket and schedule at that time.

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Item 1A. Risk Factors

Investing in our securities involves risks. In addition to the other information in this quarterly report on Form 10-Q, stockholders and potential investors should carefully consider the risks described below relating to investment in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition and/or results of operations could be materially adversely affected, the trading price of our common stock could decline and a stockholder could lose all or part of his or her investment.

Risk Related to Request for Proposal RFP-BARDA-08-15

If we do not receive the award by the U.S. Department of Health and Human Services (the "DHHS") for an rPA anthrax vaccine, we likely will need to curtail our operations significantly and we may be placed at a competitive disadvantage in the biodefense industry.

On February 29, 2008, the DHHS issued a formal Request for Proposal (RFP-BARDA-08-15) for an "Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile," which includes a requisition for 25 million doses of an rPA anthrax vaccine. We submitted a response to this solicitation on July 31, 2008. While the original solicitation indicated that an award would be made by September 26, 2008, which was later extended to December 31, 2008, DHHS subsequently delayed the award date further because, among other things, of a protest filed by a bidder that had been eliminated from further consideration under the solicitation. The U.S. General Accounting Office (the "GAO") subsequently denied that protest. On April 15, 2009, DHHS issued an amendment to the RFP requiring that each bidder submit by April 30, 2009 a comprehensive plan to the FDA outlining the bidder's regulatory strategy for the rPA anthrax vaccine to be developed under a contract should one be awarded under the solicitation. Pursuant to an amendment dated April 22, 2009, DHHS further extended the submission deadline to June 15, 2009. On July 9, 2009, the Company announced that the FDA completed its review of the Company's proposed development plan for SparVaxTM, and the Company has shared the FDA's feedback with BARDA as required by these two amendments. Timing for an award under this solicitation remains uncertain. There can be no assurance that DHHS will not again extend the timeline for issuing an award, add other requirements, or that the Company will be awarded a contract under that solicitation.

We are currently aware of at least one other bidder for the award with substantially greater financial and other resources, manufacturing capabilities and commercialization capabilities than we have. Because the U.S. government is currently the only customer for our product candidates, if we fail to receive the award for the rPA anthrax vaccine, we could be forced to abandon or severely curtail our efforts with respect to our lead product candidate, SparVaxTM, which, in turn, could place us at a competitive disadvantage. We have been engaged in discussions with DHHS with respect to our ability to satisfy the requirements of the RFP. DHHS has requested additional information that, if not determined by them to be satisfactory, could result in our elimination from consideration for procurement. No assurances can be given that DHHS will make an award to us or that if made, it will not include substantial conditions, that we can satisfy all of these conditions or that we can begin to receive any proceeds from any such award within any specific period of time. In any event, we still have not completed development of SparVaxTM and our ability to recognize any meaningful proceeds from the sale of SparVaxTM will still depend upon our completing the development and testing of such product.

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Risks Related to Our Financial Condition

We have a history of losses and negative cash flow, anticipate future losses and negative cash flow, and cannot provide assurances that we will achieve profitability.

We have incurred significant losses since we commenced operations. For the three and nine months ended September 30, 2009, we incurred operating losses of approximately \$14.0 million and \$26.6 million respectively and had an accumulated deficit of approximately \$150.6 million at September 30, 2009. Our losses to date have resulted principally from research and development costs related to the development of our product candidates, general and administrative costs related to operations, and costs related to the Avecia Acquisition.

Our likelihood for achieving profitability will depend on numerous factors, including success in:

- · developing our existing products and developing and testing new product candidates;
- · receiving regulatory approvals;
- · carrying out our intellectual property strategy;
- establishing our competitive position;
- pursuing third-party collaborations;
- · acquiring or in-licensing products;
- manufacturing and marketing products; and
- · continuing to receive government funding and identifying new government funding opportunities.

Many of these factors will depend on circumstances beyond our control. We cannot guarantee that we will achieve sufficient revenues for profitability. Even if we do achieve profitability, we cannot guarantee that we can sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than we anticipate, or if operating expenses exceed our expectations or cannot be adjusted accordingly, then our business, results of operations, financial condition and cash flows will be materially and adversely affected. Because our strategy might include acquisitions of other businesses, acquisition expenses and any cash used to make these

acquisitions will reduce our available cash. While we believe that our existing cash resources, along with cash receipts from contract receivables (some of which were unbilled at September 30, 2009) generated under our contracts, will be sufficient to enable us to fund our existing research and development programs and support our currently anticipated general and administrative activities at least through the end of 2010, there can be no assurance that unexpected financial obligations or other activities that increase our use of cash will not result in our depleting our cash resources quicker than presently anticipated. Furthermore, if we receive the award from DHHS for advanced development and procurement of SparVaxTM, we would be obligated to make \$10 million in milestone payments to Avecia within 90 days of the receipt of such award.

The continuing turmoil affecting the banking system and financial markets and the possibility that financial institutions may consolidate or cease operations has resulted in a tightening in the credit markets, a low level of liquidity in many financial markets and extreme volatility in fixed income, credit, currency and equity markets. As a result, there can be no assurances that we will be successful in obtaining sufficient financing on commercially reasonable terms or at all. Our requirements for additional capital may be substantial and will be dependent on many factors, including the success of our research and development efforts, our ability to commercialize and market products, our ability to successfully pursue our licensing and collaboration strategy, the receipt of continued government funding, competing technological and marketing developments, costs associated with the protection of our intellectual property and any future change in our business strategy.

To the extent that we raise additional capital through the sale of securities, as we did recently with the July 2009 Private Placement, the issuance of those securities or shares underlying such securities would result in dilution that could be substantial to our stockholders. In addition, if we incur additional debt financing, a

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substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities.

If adequate funds are not available, we may be required to curtail significantly our development and commercialization activities. This would have a material adverse effect on our business, financial condition and/or results of operations.

Risks Related to Product Development and Commercialization

We have not commercialized any products or recognized any revenues from sales. All of our product candidates are still under development, and there can be no assurance of successful commercialization of any of our products.

We have not commercialized any products or recognized any revenues from product sales. In general, our research and development programs are at early stages. There can be no assurances that one or more of our future product candidates will not fail to meet safety standards in human testing, even if those product candidates are found to be effective in animal studies. To develop and commercialize biodefense treatment and prophylactic product candidates, we must provide the U.S. Food and Drug Administration (the "FDA") and foreign regulatory authorities with human clinical and non-clinical animal data that demonstrate adequate safety and effectiveness. To generate these data, we will have to subject our product candidates to significant additional research and development efforts, including extensive non-clinical studies and clinical testing. We cannot be sure that our approach to drug discovery will be effective or will result in the development of any drug. Even if our product candidates are successful when tested in animals, such success would not be a guarantee of the safety or effectiveness of such product candidates in humans.

Research and development efforts in the biodefense industry are time-consuming and subject to delays. Even if we initially receive positive early-stage pre-clinical or clinical results, such results may not be indicative of results that could be anticipated in the later stages of drug development. Delays in obtaining results in our non-clinical studies and clinical testing can occur for a variety of reasons, such as slower than anticipated enrollment by volunteers in the trials, adverse events related to the products, failure to comply with Good Clinical Practices, unforeseen safety issues, unsatisfactory results in trials, perceived defects in the design of clinical trials, changes in regulatory policy as well as for reasons detailed in *"Risk Factors—Necessary Reliance on the Animal Rule in Conducting Trials is Time-Consuming and Expensive."*

Any delay or adverse clinical event arising during any of our clinical trials could force us to conduct additional clinical trials in order to obtain approval from the FDA and other regulatory bodies. Our development costs will increase substantially if we experience material delays in any clinical trials or if we need to conduct more or larger trials than planned.

If delays are significant, or if any of our products do not prove to be safe, pure, and potent (including efficacy) or do not receive required regulatory approvals, we may have to abandon the product altogether and will be unable to recognize revenues from the sale of that product. In addition, our collaborative partners may not be able to conduct clinical testing or obtain necessary approvals from the FDA or other regulatory authorities for any product candidates jointly developed by us and our partners. If we fail to obtain required governmental approvals, we and our collaborative partners will experience delays in, or be precluded from, marketing products developed through them or, as applicable, their research.

Necessary Reliance on the Animal Rule in Conducting Trials is Time-Consuming and Expensive.

As described in "Business—U.S. Government Regulatory Pathway—General", to obtain FDA approval for our biological warfare defense products under current FDA regulations, we are required to utilize animal model studies for efficacy and provide animal and human safety data under the "Animal Rule." For many of the biological and chemical threats, animal models are not yet available, and as such we are developing, or will have to develop, appropriate animal models, which is a time-consuming and expensive research effort. Further, we may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these corollaries are difficult to establish and are often unclear. The FDA may decide that our

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data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Further, other countries do not, at this time, have established criteria for review and approval of these types of products outside their normal review process; i.e., there is no "Animal Rule" equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

Additionally, few facilities in the U.S. and internationally have the capability to test animals with anthrax, plague, nerve agents, or other lethal biotoxins or chemical agents or otherwise assist us in qualifying the requisite animal models. We have to compete with other biodefense companies for access to this limited pool of highly specialized resources. We therefore may not be able to secure contracts to conduct the testing in a predictable timeframe or at all.

Even if we succeed in commercializing our product candidates, they may not become profitable and manufacturing problems or side effects discovered at later stages can further increase costs of commercialization.

We cannot assure you that any drugs resulting from our research and development efforts will become commercially available. Even if we succeed in developing and commercializing our product candidates, we may never generate sufficient or sustainable revenues to enable us to be profitable. Even if effective, a product that reaches market may be subject to additional clinical trials, changes to or re-approvals of our manufacturing facilities or a change in labeling if we or others identify side effects or manufacturing problems after a product is on the market. This could harm sales of the affected products and could increase the cost and expenses of commercializing and marketing them. It could also lead to the suspension or revocation of regulatory approval for the products.

We and our contract manufacturers ("CMOs") will also be required to comply with the applicable FDA current Good Manufacturing Practice ("cGMP") regulations. These regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved to supply licensed products to the commercial marketplace. We and our contract manufacturers may not be able to comply with the applicable cGMP requirements and other FDA regulatory requirements. Should we or our contract manufacturers fail to comply, we could be subject to fines or other sanctions or could be precluded from marketing our products.

In particular, as part of the transfer of our existing contract with NIAID for the development of SparVaxTM to BARDA on April 1, 2009, the terms of that contract were modified to provide for the transfer of the manufacturing process for the bulk drug substance for SparVaxTM from Avecia Biologics in the U.K. to a U.S.-based contract manufacturing organization. We believe that if we are awarded a contract under RFP-BARDA-08-15 for the advanced development and procurement of 25 million doses of SparVaxTM, the U.S. government will require that such new CMO manufacture the bulk drug substance for SparVaxTM. This contract manufacturer has not manufactured that bulk drug substance before, and there can be no assurance we will be successful in our technology transfer efforts or that this new contract manufacturer will ever be able to manufacture sufficient amounts of cGMP quality bulk drug substance necessary for us to meet our obligations under any such advanced development and procurement contract.

We may fail to fully realize the potential of Valortim[®] and of our co-development arrangement with Medarex, our partner in the development of Valortim[®], which would have an adverse effect upon our business. We have completed only one Phase I clinical trial for Valortim[®] with our development partner, Medarex, at this point. As discussed in "*—Risks Related to Our Dependence on U.S. Government Contracts—Most of our immediately foreseeable future revenues are contingent upon grants and contracts from the U.S. government and we may not achieve sufficient revenues from these agreements to attain profitability"*, in the fourth quarter of 2009, the FDA placed our Phase I clinical trial of Valortim[®] and ciprofloxacin on clinical hold, pending the results of our investigation of the potential causes for adverse reactions observed in two subjects dosed in the trial. BARDA has advised us that until satisfactory resolution of this issue and the clinical hold is lifted it will not act on our request for additional advanced development funding for Valortim[®] under BAA-BARDA-09-34.

Before we may begin selling any doses of Valortim[®], we will need to conduct more comprehensive safety trials in a significantly larger group of human subjects. We will be required to expend a significant amount to finalize manufacturing capability through a contract manufacture to provide material to conduct the pivotal safety and efficacy trials. If our contract manufacturer is unable to produce sufficient quantities at a reasonable cost, or has any other obstacles to production, such as volatile manufacturing, then we will be unable to commence these required clinical trials and studies. Even after we expend sufficient funds to complete the development of Valortim[®] and if and when we enter into an

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agreement to supply Valortim[®] to the U.S. government, we will be required to share any and all profits from the sale of products with our partner in accordance with a pre-determined formula.

If we cannot maintain successful licensing arrangements and collaborations, enter into new licensing arrangements and collaborations, or effectively accomplish strategic acquisitions, our ability to develop and commercialize a diverse product portfolio could be limited and our ability to compete may be harmed.

A key component of our business strategy is the in-licensing of compounds and products developed by other pharmaceutical and biotechnology companies or academic research laboratories.

For example, we have an agreement with Medarex to develop Valortim[®], a fully human monoclonal antibody product designed to protect against and treat inhalation anthrax. Under the agreement with Medarex, we will be entitled to a variable percentage of profits derived from sales of Valortim[®], if any, depending, in part, on the amount of our investment. In addition, we have entered into licensing and research and development agreements with a number of other parties and collaborators. There can be no assurances that the research and development conducted pursuant to these agreements will result in revenue generating product candidates. If our suppliers, vendors, licensors, or other collaboration partners experience financial difficulties as a result of the continuing credit crisis and further weakening of the global economy, or if they are acquired as part of the current wave of consolidations in the pharmaceutical industry (such as, for example, with the recent acquisition of Medarex by Bristol Myers Squibb), their priorities or our working relationship with them might change. As a result, they might shift resources away from the research, development and/or manufacturing efforts intended to benefit our products, which could lead to significant delays in our development programs and potential future sales. Finally, our current licensing, research and development, and supply agreements may expire and may not be renewable or could be terminated if we do not meet our obligations. For example, our license agreement from DSTL for certain technology related to RypVaxTM requires that we diligently pursue development of RypVaxTM, which is on an accelerated wind-down schedule, we may decide not to continue with development efforts at a level necessary to meet this requirement.

If we are not able to identify new licensing opportunities or enter into other licensing arrangements on acceptable terms, we may be unable to develop a diverse portfolio of products. For our future collaboration efforts to be successful, we must first identify partners whose capabilities complement and integrate well with ours. We face, and will continue to face, significant competition in seeking appropriate collaborators. Collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other similar arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us. Furthermore, technologies to which we gain access may prove ineffective or unsafe or our partners may prove difficult to work with or less skilled than we originally expected. In addition, any past collaborative successes are no indication of potential future success.

We may also pursue strategic acquisitions to further our development and commercialization efforts. To achieve the anticipated benefits of an acquisition, we must integrate the acquired company's business, technology and employees in an efficient and effective manner. The successful combination of companies in a rapidly changing biodefense industry may be more difficult to accomplish than in other industries. The combination of two companies requires, among other things, integration of the companies' respective technologies and research and development efforts. We cannot assure you that any integration will be accomplished smoothly or successfully. The difficulties of integration are increased by the need to coordinate geographically separated organizations and address possible differences in corporate cultures and management philosophies. The integration of certain operations will require the dedication of management resources that may temporarily distract attention from the day-to-day operations of the combined companies. The business of the combined companies may also be disrupted by employee retention uncertainty and lack of focus during integration. The inability of management to integrate successfully the operations of the two companies, in particular, to integrate and retain key scientific

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personnel, or the inability to integrate successfully two technology platforms, could have a material adverse effect on our business, results of operations and financial condition.

We may become subject to product liability claims, which could reduce demand for our product candidates or result in damages that exceed our insurance coverage.

We face an inherent risk of exposure to product liability suits in connection with our product candidates being tested in human clinical trials or sold commercially. We may become subject to a product liability suit if any product we develop causes injury, or if treated individuals subsequently become infected or suffer adverse effects from our products. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to our reputation, withdrawal of clinical trial volunteers, and loss of revenues.

In addition, if a product liability claim is brought against us, the cost of defending the claim could be significant and any adverse determination may result in liabilities in excess of our insurance coverage. Although our anthrax countermeasures are covered under the general immunity provisions of the U.S. Public Readiness and Emergency Preparedness Act (the "Public Readiness Act"), there can be no assurance that the U.S. Secretary of Health and Human Services will make other declarations in the future that cover any of our other product candidates or that the U.S. Congress will not act in the future to reduce coverage under the Public Readiness Act or to repeal it altogether. For further discussion of that act, see "Risk Factors - *Legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and we cannot be certain that any such protection will apply to our products or if applied what the scope of any such coverage will be"* below. Additionally, we are considering applying for indemnification under the U.S. Support Anti-terrorism by Fostering Effective Technologies (SAFETY) Act of 2002 which preempts and modifies tort laws so as to limit the claims and damages potentially faced by companies who provide certain "qualified" anti-terrorism products. However, we cannot be certain that we will be able to obtain or maintain coverage under the SAFETY Act or adequate insurance coverage on acceptable terms, if at all.

Risks Related to Our Dependence on U.S. Government Contracts

Most of our immediately foreseeable future revenues are contingent upon grants and contracts from the U.S. government and we may not achieve sufficient revenues from these agreements to attain profitability.

For the foreseeable future, we believe our main customer will be national governments, primarily the U.S. government. Substantially all of our revenues to date have been derived from grants and U.S. government contracts. There can be no assurances that existing government contracts will be renewed or that we can enter into new contracts or receive new grants. The process of obtaining government contracts is lengthy and uncertain and we will have to compete with other companies for each contract. For example, while RFP-BARDA-08-15 for an rPA vaccine for the SNS initially indicated that the government would make an award by September 26, 2008 (later extended multiple times), as of the date this quarterly report on Form 10-Q is filed, the government has still not issued an award under that solicitation. There can be no assurances that we will be awarded any contracts to supply the U.S. or other governments with our products as such awards may be made, in whole or in part, to our competitors. If the U.S. government makes significant future contract awards for the supply to the U.S. emergency stockpile of a competing product, our business will be harmed and it is unlikely that we will ultimately be able to supply that particular treatment or product to foreign governments or other third parties. Further, changes in government budgets and agendas, cost overruns in our programs, or advances by our competitors, we are developing. For example, the U.S. government will provide additional funding in the future for or procure RypVaxTM. Furthermore, given the limited future prospects for RypVaxTM at this time, we and the U.S. government will provide additional funding in the future for or procure RypVaxTM. Furthermore, given the limited future prospects for RypVaxTM at this time, we and the U.S. government have agreed to a reduction to the scope of work that will result in early wind down of all activities under that contract, likely no later than the end of the first half of 2010. Previously, the contract was expec

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Under the terms of our 2006 contract with the U.S. Department of Defense regarding Protexia[®], the Department of Defense may elect not to continue development assistance of this nerve agent countermeasure after the final payment under the initial funding of \$41 million has been received (which decision we anticipate may occur in the first quarter of 2010), or, if the Department of Defense does so elect to continue funding and we meet all development milestones, it may nevertheless choose not to procure any doses of Protexia[®].

In the fourth quarter of 2009, the FDA placed our phase I clinical trial of Valortim® and ciprofloxacin on clinical hold, pending the results of our investigation of the potential causes for adverse reactions observed in two subjects dosed in the trial. BARDA has advised us that until satisfactory resolution of this issue and the clinical hold is lifted it will not act on our request for additional advanced development funding for Valortim® under BAA-BARDA-09-34. It is unclear at this time how long it will take us to complete our investigation, if and when we will be in a position to recommence negotiations with BARDA with respect to a potential award under the BAA, and how any delay in potential future funding of the program could affect the overall Valortim® development timeline.

Due to the current economic downturn, the accompanying fall in tax revenues and the U.S. government's efforts to stabilize the economy, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government contract awards or that the government would procure products from us.

U.S. government agencies have special contracting requirements that give them the ability to unilaterally control our contracts.

U.S. government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. These risks include the ability of the U.S. government unilaterally to:

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our contracts, including if funds become unavailable to the applicable governmental agency;
- reduce the scope and value of our contracts;
- · audit and object to our contract-related costs and fees, including allocated indirect costs;
- · control and potentially prohibit the export of our products; and
- · change certain terms and conditions in our contracts.

The U.S. government will be able to terminate any of its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed, settlement expenses, and profit on the work completed prior to termination. Termination-for-default provisions do not permit these recoveries and would make us liable for excess costs incurred by the U.S. government in procuring undelivered items from another source.

Due to the current economic downturn, the accompanying fall in tax revenues, and the U.S. government's efforts to stabilize the economy, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government contract awards, the likelihood that the government will exercise its right to extend any of its existing contracts with us and/or the likelihood that the government would procure products from us.

The U.S. government's determination to award any contracts may be challenged by an interested party, such as another bidder, at the GAO or in federal court. If such a challenge is successful, a contract may be terminated.

The laws and regulations governing the procurement of goods and services by the U.S. government provide procedures by which other bidders and other interested parties may challenge the award of a government

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contract. If we are awarded a government contract, such challenges or protests could be filed even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of goods and services and payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate our contract and reselect bids. The government could even be directed to award a potential contract to one of the other bidders. An example is the protest filed by a third-party bidder with the GAO challenging the decision of the DHHS to eliminate that bidder from further consideration under the solicitation for an rPA vaccine for the Strategic National Stockpile (RFP-BARDA-08-15), a result of which was a delay to the contract award date under this solicitation.

Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.

U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- · termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- \cdot suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under these contracts. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations, or FAR, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting
 of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Foreign governments typically also have laws and regulations governing contracts with their respective agencies. These foreign laws and regulations affect how we and our customers conduct business and, in

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some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

Risks Related to Dependence on or Competition From Third Parties

Because we depend on clinical research centers and other contractors for clinical and non-clinical testing, including testing under the Animal Rule, and for certain research and development activities, the results of our clinical trial, non-clinical animal efficacy studies, and research and development activities are largely beyond our control.

The nature of clinical trials and our business strategy of outsourcing substantially all of our research and development and manufacturing work require that we rely on clinical research centers and other contractors to assist us with research and development, clinical and non-clinical testing (including animal efficacy studies under the Animal Rule), patient enrollment and other activities. As a result, our success depends largely on the success of these third parties in performing their responsibilities. Although we prequalify our contractors and believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Furthermore, we have to compete with other biodefense companies for access to this limited pool of highly specialized resources. If our contractors do not perform their obligations in an adequate and timely manner or we are unable to enter into contracts with them because of prior commitments to our competitors, the pace of clinical or non-clinical development, regulatory approval and commercialization of our product candidates could be significantly delayed and our prospects could be adversely affected.

We depend on third parties to manufacture, package and distribute compounds for our product candidates and key components for our product candidates. The failure of these third parties to perform successfully could harm our business.

We do not have any of our own manufacturing facilities. We have therefore utilized, and intend to continue utilizing, third parties to manufacture, package and distribute our product candidates and key components of our product candidates. Any material disruption in manufacturing could cause a delay in our development programs and potential future sales. Furthermore, certain compounds, media, or other raw materials used to manufacture our drug candidates are available from any one or a limited number of sources. Any delays or difficulties in obtaining key components for our product candidates or in manufacturing, packaging or distributing our product candidates could delay clinical trials and further development of these potential products. Additionally, the third parties we rely on for manufacturing and packaging are subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities.

We were notified by the contract manufacturer who supplies the pegylation reagent for our Protexia[®] product candidate that it intends to cease its contract manufacturing operations to focus exclusively on developing its own proprietary product candidates. We are now in the process of searching for an alternative supplier. As part of this process, we will need to negotiate and execute a license to certain intellectual property from our current supplier related to the pegylation process and to engage in a technology transfer process to a new supplier. If we are not successful in these endeavors, our Protexia[®] development program will be adversely affected.

Finally, third-party manufacturers, suppliers and distributors, like most companies, have been adversely affected by the current credit crisis and weakening of the global economy and as such may be more susceptible to being acquired as part of the current wave of consolidations in the pharmaceutical industry. It has, for example, become increasingly challenging for companies to secure debt capital to fund their

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operations as financial institutions have significantly curtailed their lending activities. If our third-party suppliers continue to experience financial difficulties as a result of weakening demand for their products or for other reasons and are unable to obtain the capital necessary to continue their present level of operations or are acquired by others, they may have to reduce their activities and/or their priorities or our working relationship with them might change. A material deterioration in their ability or willingness to meet their obligations to us could cause a delay in our development programs and potential future sales and jeopardize our ability to meet our obligations under our contracts with the government or other third parties.

We face, and likely will continue to face, competition from companies with greater financial, personnel and research and development resources. Our commercial opportunities will be reduced or eliminated if our competitors are more successful in the development and marketing of their products.

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. There are many organizations, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these organizations have substantially greater financial, technical, intellectual property, research and development, and human resources than we have. Competitors may develop products or other technologies that are more effective than any that we are developing or may obtain FDA approval for products more rapidly. As noted above in "- *Most of our immediately foreseeable future revenues are contingent upon grants and contracts from the U.S. government and we may not achieve sufficient revenues from these agreements to attain profitability,*" the U.S. government has selected a plague vaccine product candidate from a competitor for advanced development funding. We and the U.S. government have agreed to a reduction to the scope of work that will result in early wind down of all activities under that contract, likely no later than the end of the first half of 2010.

If we commence commercial sales of products, we still must compete in the manufacturing and marketing of such products, areas in which we have limited experience. Many of these organizations also have manufacturing facilities and established marketing capabilities that would enable such companies to market competing products through existing channels of distribution. Our commercial opportunities will be reduced or eliminated if our competitors develop and market products that:

- · are more effective;
- have fewer or less severe adverse side effects;
- \cdot $\;$ are more adaptable to various modes of dosing;
- · obtain orphan drug exclusivity that blocks the approval of our application for seven years;
- are easier to administer; or
- · are less expensive than the products or product candidates that we are, or in the future will be, developing.

While the regulatory climate for generic versions of biological products approved under a Biologics License Application (or a BLA) in the United States remains uncertain, and currently there is no formalized mechanism by which the FDA can approve a generic version of an approved biological product, Federal legislation has been introduced to establish a legal pathway for the approval of generic versions of approved biological products. If enacted, the legislation will impact the revenue projections for our products.

Even if we are successful in developing effective products, and obtain FDA and other regulatory approvals necessary for commercializing them, our products may not compete effectively with other successful products. Our competitors may succeed in developing and marketing products either that are more effective than those that we may develop, alone or with our collaborators, making our products obsolete, or that are marketed before any products that we develop are marketed.

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Risks Related to Political and Social Factors

Political or social factors may delay or impair our ability to market our products and our business may be materially adversely affected.

Products developed to treat diseases caused by, or to combat the threat of, bioterrorism will be subject to changing political and social environments. The political and social responses to bioterrorism have been unpredictable. Political or social pressures may delay or cause resistance to bringing our products to market or limit pricing of our products, which would harm our business.

Risks Related to Intellectual Property

Our commercial success will be affected significantly by our ability (i) to obtain and maintain protection for our proprietary technology and that of our licensors and collaborators and (ii) not to infringe on patents and proprietary rights of third parties.

The patent position of biotechnology firms generally is highly uncertain and involves complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. We currently hold two U.S. patents, have five pending U.S. patent applications, and have a limited number of foreign patents and pending international and foreign patents applications. In addition, we have rights under numerous other patents and patent applications pursuant to exclusive and non-exclusive license arrangements with licensors and collaborators. However, there can be no assurance that patent applications owned or licensed by us will result in patents being issued or that the patents, whether existing or issued in the future, will afford protection against competitors with similar technology. Any conflicts resulting from third-party patent applications and patents could significantly reduce the coverage of the patents owned, optioned by or licensed to us or our collaborators and limit our ability or that of our collaborators to obtain meaningful patent protection.

Further, our commercial success will depend significantly on our ability to operate without infringing the patents and proprietary rights of third parties. We are aware of one U.S. patent covering recombinant production of an antibody and a license may be required under such patent with respect to Valortim[®], which is a monoclonal antibody and uses recombinant reproduction of antibodies. Although the patent owner has granted licenses under such patent, we cannot provide any assurances that we will be able to obtain such a license or that the terms thereof will be reasonable. If we do not obtain such a license and if a legal action based on such patent was to be brought against us or our distributors, licensees or collaborators, we cannot provide any assurances that we or our distributors, licensees or collaborators would prevail or that we have sufficient funds or resources to defend such claims.

We are also aware of pending applications directed to pegylated butyrylcholinesterase. Protexia[®] incorporates butyrylcholinesterase. If patents are issued to third parties that cover Protexia[®] or other products, we may be required to obtain a license under such patents or obtain alternative technology. We cannot provide any assurances that such licenses will be available or that the terms thereof will be reasonable or that we will be able to develop alternative technologies. If we do not obtain such a license and if a legal action based on such patent was to be brought against us or our distributors, licensees or collaborators, we cannot provide any assurances that we or our distributors, licensees or collaborators would prevail or that we have sufficient funds or resources to defend such claims.

The costs associated with establishing the validity of patents, of defending against patent infringement claims of others and of asserting infringement claims against others is expensive and time consuming, even if the ultimate outcome is favorable. An outcome of any patent prosecution or litigation that is unfavorable to us or one of our licensees or collaborators may have a material adverse effect on us. The expense of a protracted infringement suit, even if ultimately favorable, would also have a material adverse effect on us.

We furthermore rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information; however, these measures may not provide

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adequate protection to us. We have sought to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

Risks Related to Regulatory Approvals and Legislation

Our use of hazardous materials and chemicals requires us to comply with regulatory requirements which may result in significant costs and expose us to potential liabilities.

Our research and development involves the controlled use of hazardous materials and chemicals. We are subject to federal, state, local and foreign laws governing the use, manufacture, storage, handling and disposal of such materials. We will not be able to eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be forced to pay significant damages or fines, and these damages could exceed our resources and any applicable insurance coverage. In addition, we may be required to incur significant costs to comply with regulatory requirements in the future.

Legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and we cannot be certain that any such protection will apply to our products or if applied what the scope of any such coverage will be.

The U.S. Public Readiness Act was signed into law in December 2005 and creates general immunity for manufacturers of countermeasures, including security countermeasures (as defined in Section 319F-2(c)(1)(B) of that act), when the U.S. Secretary of Health and Human Services issues a declaration for their manufacture, administration or use. The declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. Manufacturers are excluded from this protection in cases of willful misconduct. Although our anthrax countermeasures have been covered under the general immunity provisions of the Public Readiness Act since October 1, 2008, there can be no assurance that the Secretary of Health and Human Services will make other declarations in the future that would cover any of our other product candidates or that the U.S. Congress will not act in the future to reduce coverage under the Public Readiness Act or to repeal it altogether.

Upon a declaration by the Secretary of Health and Human Services, a compensation fund would be created to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." The "covered injuries" to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. A willful misconduct action could be brought against us if an individual(s) has exhausted their remedies under the compensation program which thereby could expose us to liability. Furthermore, there is no assurance that the Secretary of Health and Human Services will issue under this act a declaration to establish a compensation fund. We may also become subject to standard product liability suits and other third party claims if products we develop which fall outside of the Public Readiness Act cause injury or if treated individuals subsequently become infected or otherwise suffer adverse effects from such products.

We are required to comply with certain export control laws, which may limit our ability to sell our products to non-U.S. persons and may subject us to regulatory requirements that may delay or limit our ability to develop and commercialize our products.

Our product candidates are subject to the Export Administration Regulations ("EAR") administered by the U.S. Department of Commerce and are, in certain instances (such as regarding aspects of our Protexia® product candidate) subject to the International Traffic in Arms Regulations ("ITAR") administered by the U.S. Department of State. EAR restricts the export of dual-use products and technical data to certain

countries, while ITAR restricts the export of defense products, technical data and defense services. The U.S. government agencies responsible for administering EAR and ITAR have significant discretion in the interpretation and enforcement of these regulations. Failure to comply with these regulations can result in criminal and civil penalties and may harm our ability to enter into contracts with the U.S. government. It is also possible that these regulations could adversely affect our ability to sell our products to non-U.S. customers.

Risks Related to Personnel

We depend on our key technical and management personnel, and the loss of these personnel could impair the development of our products.

We rely, and will continue to rely, on our key management and scientific staff, all of whom are employed at-will. The loss of key personnel or the failure to recruit necessary additional qualified personnel could have a material adverse effect on our business and results of operations. There is intense competition from other companies, research and academic institutions and other organizations for qualified personnel. We may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. If we do not succeed in retaining and recruiting necessary personnel or developing this expertise, our business could suffer significantly.

In particular, as noted above in "*Even if we succeed in commercializing our product candidates, they may not become profitable and manufacturing problems or side effects discovered at later stages can further increase costs of commercialization,*" we are transferring the manufacturing process for the bulk rPA drug substance from Avecia in the United Kingdom to a U.S.-based contract manufacture. In connection with that transfer, we also anticipate moving our U.K.-based operations to the United States by June 30, 2010. There can be no assurance that we will be able to recruit and hire the necessary staff in the U.S. to complete the transfer of activities in a timely and cost effective manner.

Biotechnology companies often become subject to claims that they or their employees wrongfully used or disclosed alleged trade secrets of the employees' former employers. Such litigation could result in substantial costs and be a distraction to our management.

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including at competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and distract management.

Risks Related to our Common Stock

Shares that we may issue in the future in connection with certain capital-raising transactions and shares available for future issuance upon conversion and exercise of convertible notes, warrants and options could dilute our shareholders and depress the market price of our common stock.

We will likely seek to raise additional capital and may do so at any time through various financing alternatives, including potentially selling shares of common or preferred stock, notes and/or warrants convertible into, or exercisable for, shares of common or preferred stock. We could again rely upon the shelf registration statement on Form S-3, which was declared effective on February 12, 2009, in connection with a sale from time to time of common stock, preferred stock or warrants or any combination of those securities, either individually or in units, in one or more offerings for up to \$50,000,000 (inclusive of the gross proceeds from our recent public offering of \$5.5 million and the \$2.1 million we would receive if all of the warrants issued in that offering were exercised). Raising capital in this manner or any other manner may depress the market price of our stock, and any such financing(s) will dilute our existing shareholders.

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In addition, as of September 30, 2009, we had outstanding options to purchase approximately 5.2 million shares of common stock. Additional shares are reserved for issuance under our 2007 Long-Term Incentive Compensation Plan. Our stock options are generally exercisable for ten years, with a significant portion exercisable either immediately or beginning one year after the date of the grant. Furthermore, the senior unsecured convertible notes in the aggregate principal amount of \$19.3 million issued in July 2009 are convertible at approximately \$2.54 per share into approximately 7.6 million shares of our common stock, and the accompanying warrants are exercisable beginning on January 28, 2010 for up to approximately 2.6 million shares of common stock at \$2.50 per share. Finally, as of November 6, 2009, the Company had issued and outstanding additional warrants to purchase up to an additional approximately 3.5 million shares of common stock. The issuance or even the expected issuance of a large number of shares of our common stock upon conversion or exercise of the securities described above could depress the market price of our stock and the issuance of such shares will dilute the stock ownership of our existing shareholders.

If we are unable to continue to satisfy the listing requirements of NYSE Amex, our securities could be delisted from trading which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Our common stock and certain warrants are listed on the NYSE Amex (formerly the NYSE Alternext US or American Stock Exchange), a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to satisfy one or more of the requirements, such as the policy that issuers that have had losses in their five most recent fiscal years have stockholders' equity of at least \$6,000,000, that issuers have more than 300 public shareholders, or that the aggregate market value of shares publicly held be more than \$1,000,000, the NYSE Amex may decide to delist our common stock. If the NYSE Amex delists our securities from trading on its exchange and we are not able to list our securities on another exchange or to have them quoted on Nasdaq, our securities could be quoted on the OTC Bulletin Board or on the "pink sheets". As a result, we could face significant adverse consequences including:

- · a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We can make no assurances that we will ever pay dividends.

We have not paid any dividends on our common stock in 2007, 2008, and the first nine months of 2009 and do not intend to declare any dividends in the foreseeable future. While subject to periodic review, our current policy is to retain all earnings, if any, primarily to finance our future growth. We make no assurances that we will ever pay dividends, cash or otherwise. Whether we pay any dividends in the future will depend on our financial condition, results of operations, and other factors that we will consider.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On July 28, 2009, we closed on the private sale of approximately \$19.3 million of newly issued two-year 10% unsecured senior convertible notes, convertible immediately into common shares at a conversion price of approximately \$2.54 per share (the "New Convertible Notes"), and warrants to purchase 2,572,775 shares of

common stock at \$2.50 per share. The warrants become exercisable beginning on January 28, 2010 and will expire on January 28, 2015. The conversion price of the New Convertible Notes and the exercise price of the warrants are subject to customary anti-dilution adjustments, including in the event of a stock dividend, stock split or stock combination, recapitalization or reorganization, merger or consolidation, sale of all or substantially all of our assets, distribution of debt or assets to our stockholders and in connection with certain other dilutive equity issuances.

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An aggregate of up to 11,704,010 shares of our common stock is issuable upon conversion of the New Convertible Notes and exercise of the related warrants, including (i) up to 9,131,235 shares of common stock issuable upon conversion of all of the New Convertible Notes and (ii) 2,572,775 shares of our common stock issuable upon exercise of all of the related warrants. Of the 9,131,235 shares of common stock issuable upon conversion of the New Convertible Notes, up to 7,591,790 shares are issuable in respect of the aggregate principal amount of the notes and up to 1,539,455 shares are issuable in respect of interest that accrues on the notes, assuming conversion of all of the notes on the date of maturity.

As part of this sale we exchanged a portion of our then-outstanding 8% unsecured senior convertible notes, originally issued on August 3, 2007 and due August 3, 2009 (the "Old Notes"), in the aggregate principal amount plus accrued interest of \$8.8 million for New Convertible Notes, cancelled the corresponding Old Notes, issued additional New Convertible Notes in the aggregate principal amount of \$10.5 million to new note investors, and issued to the recipients of the New Convertible Notes the stock purchase warrants described above. We used the proceeds from the sale of the New Convertible Notes to repay \$5.5 million of our Old Notes that were not exchanged for the New Convertible Notes and warrants and repay all outstanding amounts and fees under our existing senior secured credit facility.

The New Convertible Notes and related warrants were issued in reliance on the exemption from registration provided by 4(2) of the Securities Act of 1933, as amended, as they were issued in a transaction by us not involving a public offering. We are currently in the process of registering with the Securities and Exchange Commission for resale the shares of common stock underlying the New Convertible Notes and related warrants.

Item 5. Other Information

The descriptions contained in Item 3.03 "Material Modification to Rights of Security Holders" in our Current Report on Form 8-K, filed on November 4, 2009, and in "Proposal 2" in our Definitive Proxy Statement on Schedule 14A, filed on September 29, 2009, are incorporated herein by reference.

Item 6. Exhibits.

No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended on October 29, 2009 *
4.9	Form of 10% Unsecured Senior Convertible Note**
4.10	Form of Warrant to Purchase Common Stock**
10.45.1	Modification (Amendment) 16 to the Contract with the National Institutes of Health for the Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine (#N01-AI-30052) ***
10.50	Form of Note and Warrant Purchase Agreement, dated as of July 24, 2009, by and among PharmAthene, Inc. and the investors signatories thereto, as amended by Amendment No. 1 to Note and Warrant Purchase Agreement, dated as of July 26, 2009 and Amendment No. 2 to Note and Warrant Purchase Agreement, dated as of July 28, 2009**
10.51	Form of Registration Rights Agreement, dated as of July 28, 2009 by and among PharmAthene, Inc. and the investors signatories thereto**
10.52	Technology Transfer and Development Services Subcontract, dated as of September 17, 2009, by and between Diosynth RTP Inc. and PharmAthene, Inc. ***
31.1	Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
31.2	Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350

* Incorporated by reference to the corresponding exhibit to the Company's current report on Form 8-K filed on November 4, 2009.

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** Incorporated by reference to the corresponding exhibit to amendment no. 1 to the Company's current report on Form 8-K filed on *August 3, 2009.* *** Certain confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

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SIGNATURES

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Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused the report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHARMATHENE, INC.

By: /s/ David P. Wright David P. Wright Chief Executive Officer

Dated: November 13, 2009

By: /s/ Charles A. Reinhart III

Charles A. Reinhart III Chief Financial Officer

PharmAthene, Inc. Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission

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1	TEM ONLY APPLIES	O AMENDMENTS O	OF SOL	ICITATIONS			
The above numbered solicitation is amone	led at set l	both In Item 14. The hour	and date specified for m	ecelpt of	Offers [] is extended	lr not ex	tended,
fors must acknowledge receipt of this amon	denost pelo	r to the hour and date spec	filled in the solicitation	or na An	nended by one of the A	lowing anoth	hods:
By completing frem 8 and 15, and return offer submitted; or (a) By separate fatter on KNOWLEDOMENT TO BE RECEIVED SULT IN RERECTION OF YOUR OFFER er, provided each telegreun or letter anakes ACCOUNTEND AND APPROPRIATION	AT THE I AT THE I . If by vict reference i	which includes a reference I.ACB DESIGNATED FC we of this amendment you the solicitation and this o	to the solicitation and	smeinder OPFER	tent numbers, PAILUR S PRIOR TO THE HO	ROF YOUR	TH SPECIFIED MAY
AN: Appropria	ation :		O.C.		Obligation		
		APPLIES ONLY TO M					
A. THIS CHANGE ORDER IS ISSUED NO. IN ITEM 10A.						ADS IN TH	B CONTRACT ORDE
B. THE ABOVE NUMBERED CONTR oppropriation date, etc.) SET FORTH in	ACT/ORD	BR IS MODIFIED TO RE PURSUANT TO THE A	RUBCT THE ADMIN UTHORITY OF PAR	ISTRAT 43.103 (TVILCHANGES (and b).	at changer	he paying office.
C. THIS SUPPLEMENTAL AORHUME FAR 1.602-1, 52,243-2 Changes Cost)P:			
D. OTHER (Specify type of modification	and antha	ity)					
1							
	nr 🖾	is required to sign this d		٤			
DESCRIPTION OF AMENDMENT/MOD e purpose of this modification is t changed at \$32,458,052. Period of	o reduce Perform	the Scope of Work	performed under t	his co	nirnet. The total of	atimated t	fesible, o completo remeia
or to this MOD:			otal				
vised Totel Inect Paded through date: 2/31/2011.		\$11	7,736,200.00				
ept as provided infretor all terms and condition			16A. NAMB AND	TITLE (OF CONTRACTING		ill force and affect.
CONTRACTORIONPEROR HRE TO PHER C. CAMON HE MESIDENT		E ARESIDEN T SIGNED W/9/09	Danick A. Bast	THE OI	PANIBRICA		IGC. DATE SIONED
(Signature of parson authorized to a 7540-01-152-8070 ious Edition Unusable	dgət)	16/4/04	1 Cister	estione ad	Contracting Officer) STAND/RED	FORM 30 (I	10/9/09 (EV. 10-83) 48 CFR) 53.243

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SECTION B - SUPPLIES OR SERVICES AND PRICE/COSTS

ARTICLE B.2. ESTIMATED COST AND FIXED FEE has been modified to read as follows.

- a. The estimated cost for this contract is
- b. The Fixed fee for this contract is \$ The fixed fee shall be paid in installments based on the negotiated milestones set forth in ARTICLE B.4.h. and subject to the withholdings provisions of the ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, Article 1.1 of this contract. Payment of fixed fee shall not be made in less than monthly increments.
- c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee is \$117,736,200.
- d. Total funds currently available for payment and allotted to this contract modification are **contract** of which **contract** represents the estimated costs, and of which **contract** is this fixed fcc. These funds cover the start dates for Milestones 1, 2, 3, 4, 5, 6, Program Management and EVMS. For further provision on funding, see the LIMITATIONS OF COSTS clause referenced in PART II, ARTICLE I.2. Authorized Substitutions of Clauses.
- It is estimated that the amount currently allotted will cover performance of contract through June 30 of 2011.

ARTICLE B.4. ADVANCE UNDERSTANDINGS, in accordance FAR 52.244-2 (approval of subcontractor) paragraph a, b, c, d, e, f, Subcontracts have been deleted in it entirety and replaced with the following. Any future subcontract awards or modification to existing subcontracts that fall within the requirements of FAR Section 52.244-2 shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation and the draft subcontract as required by the Subcontract clause in this contract. After written approval of the Subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

a.

A firm-fixed price subcontract between PharmAthene and amount not to exceed **Comparison** for an amount not to exceed **Comparison** for continued development of rPA vaccine is hereby approved by the Contracting Officer. The period of performance is (04/01/2009 to 12/31/2010). This approval includes the following scope of work:

- MS1; BDS Stability HPPS Analysis, On-going Stability Lot B2272/008, Time Points T=24 and T=36 months (WBS 1.1.1) FDP Stability CD, SDS-PAGE, Fluorescence Analysis, On-going Stability Lot 907616, Time Points 18, 21, 24, 27, 30, 33, and 36 months (WBS 1.2.1)
- MS4; Reference standard Lot B2272-007, 2009 re-qualification HPPS assay (WBS 4.1.5)

Reference standard Lot B2272-012, 2009 Qualification HPPS assay (WBS 4.1.5)

Reference standard Lot B2272-012, 2010 re-qualification HPPS assay (WBS 4.1.5)

- MS6; Support for technology transfer of BDS and assays to Diosynth (WBS 6.10) Shipment and disposal (WBS 6.1)
- MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

b.
 A firm-fixed price subcontract between PharmAthene and amount not to exceed the between PharmAthene and contracting Officer. The period of performance is (04/01/2009 to 12/31/2010). 'This approval encompasses the following scope of work:
 MS2; Immunopotency development studies (WBS 2.2.2)

- MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (RVMS)



A firm-fixed price subcontract between PharmAthene and the period of an amount not to exceed the period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work:

- MS1; Shipping (WBS 1.2.10)
- MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)



A firm-fixed price subcontract between PharmAthene and amount not to exceed **Contracting** officer. The period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work:

MS1; Storage (WBS 1.2.9)

MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

Rada an Court

A firm-fixed price subcontract between PharmAthene and the contracting Officer. The period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work:

MS1; FDP stability sterility testing, time point 24 and 36 months (WBS 1.2.1) FDP CTM 100ug dose stability sterility testing, time point 12 months (WBS 1.2.2)

PDP CTM 50ug dose stability sterility testing, time point 12 months (WBS 1.2.3)

High phosphate diluent CTM stability sterility testing, time point 12 months (WBS 1.2.6)

Sample storage (WBS 1.2.11)

MS3; FDP CTM 100ug dose GMP documents, media fiil, raw material procurement & release, development, lot manufacture, lot testing, and release (WBS 3.1)
 FDP CTM 50ug dose GMP documents, raw material procurement & release, development, lot manufacture, lot testing, and release (WBS 3.2)
 High phosphate diluent CTM lot manufacture, lot testing, and release (WBS 3.4)
 FDP VMP (WBS 3.6)
 Storage (WBS 3.7)

MS4; FDP Phosphate Analysis Development and Validation (WBS 4.2.2)

MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

f. .

A firm-fixed price subcontract between PharmAthene and for an amount not to exceed the price subcontract between PharmAthene and for an amount not to exceed the period of performance is (04/01/2009 to 12/31/2009). This approval encompasses the following scope of work:

MS3; Order and ship Alhydrogel (WBS 3.5)

exceed	ice subcontract between PharmAthene and for an amount not to is hereby approved by the Contracting Officer. The period of performance is [2/31/2010]. This approval encompasses the following scope of work:
MS3;	Mixing Study Protocol(s) (WBS 3.5.3)
	Process Solution Protocol(s) (WBS 3.5.4)
	Demonstration Batch Protocol(s) (WBS 3.5.10)
	FDP Master Validation Plan (WBS 3.6.2)
	FDP Draft Process Validation Protocol (WBS 3.6.3)
	FDP Leachables/Extractables Studies (WBS 3.6.7)
MS6;	BDS Master Validation Plan (WBS 6.6)
	Support technology transfer to Diosynth (WBS 6.11)
and a	

A firm-fixed price subcontract between PharmAthene and for an amount not to exceed for an amount not to contracting Officer. The period of performance is (04/01/2009 to 9/30/2009). This approval encompasses the following scope of work:

MS3; Test and release Alhydrogel for 2009, provide CoA (WBS 3.5)

i. (an and the second
not to ex	xceed a	ce subcontract between PharinAthene and the Officer. The period of performance of 3/31/2010). This approval encompasses the following scope of work:
	MS2;	MCLA 2nd degraded material study, analysis and report on data from HPA (WBS 2.1.1) MCLA iustallation at HPA (WBS 2.1.1) MCLA operation efficiency studies, analysis and report on data from HPA (WBS 2.1.1) MCLA validation protocol (WBS 2.1.1) MCLA validation protocol (WBS 2.1.1) MCLA interim specification DOE settings to HPA, analysis and report on data from HPA (WBS 2.1.1) MCLA validation studies, analysis and report of results (WBS 2.1.1)
	MS7;	Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)
j.		
amount	not to e	ce subcontract between PharmAthene and Contracting Officer. The period of an acced a subcontracting officer. The period of 04/01/2009 to 12/31/2010). This approval encompasses the following scope of
	MS4;	consulting services for assay development
	MS6;	consulting services for process transfer to Diosynth
	MS7;	Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)
k.		
amount r	not to ea	cc subcontract between PharmAthene and Contracting Officer. The period of xcced (Contracting Officer. The period of 04/01/2009 to 12/31/2010). This approval encompasses the following scope of
	MS1;	BDS stability physical and chemical testing, Lot B2272/008, Storage, Appearance, pH, SDSPAGE, IBF, TVC, Time Points T=24 and 36 months (WBS 1.1.1)

(WBS 1.1.1) FDP stability physical and chemical testing, Lot 907616, Storage, Appearance, pH, UBA, Osmolality, Time Points T=18 and 21 months (WBS 1.2.1) FDP stability physical and chemical testing, Lot 907616, Storage, Appearance, pH, UBA, Osmolality, SDS Des, Time Points T=24, 27, 30, 33 and 36 months (WBS 1.2.1)

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FDP CTM 100ug dose stability physical and chemical testing. Storage, Appearance, pH, UBA, Osmolality, SDS Des, Time Points T=0, 3, 6, 9 and 12 months (WBS 1.2.2)

FDP CTM 50ug dose stability physical and chemical testing, Storage, Appearance, pH, UBA, Osmolality, SDS Des, Time Points T=0, 3, 6, 9 and 12 months (WBS 1.2.3)

High phosphate diluent CTM stability physical and chemical testing, Storage, Appearance, pH, Osmolality, Time Points T=0, 3, 6, 9 and 12 months (WBS 1.2.6)

Sample storage (WBS 1.2.10)

MS4; BDS stability appearance, A280, SDS-PAGE, TVC, and IEF assay validation (WBS 4.2.2) Reference action of the P2272 007 2000 an evel (Section (WDS 4.1.5))

Reference standard Lot B2272-007, 2009 re-qualification (WBS 4.1.5) Reference standard Lot B2272-012, 2009 Qualification (WBS 4.1.5) Reference standard Lot B2272-012, 2010 re-qualification (WBS 4.1.5)

MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

A firm-fixed price subcontract between PharmAthene and for an amount not to exceed the subcontracting officer. The period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work:

- MS2; MCLA installation at HPA (WBS 2.1.1) MCLA HPA software validation protocol, execution, and report (WBS 2.1.1)
- MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (BVMS)

A firm-fixed price subcontract between PharmAthene and the subcontract by for an amount not to exceed the subcontract between PharmAthene and the contracting Officer. The period of performance is (10/01/2009 to 3/31/2011). Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation and the draft subcontract as required by the Subcontracts clause of the General Clauses incorporated in this contract. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be proved to the Contracting Officer. This approval will encompass the following scope of work:

MS4; HPPS release and stability assay validation (WBS 4.1.3) LC-MS/MS Method Development and validation Activities (WBS 4.1.4)

MS6; Upstream process transfer and development (WBS 6.5) Downstream process transfer and development (WBS 6.5) Transfer of Analytical method (WBS 6.4) Transfer of validated assays (WBS 6.4) 140L demonstration batches (WBS 6.5) Scale-up, pre-production, and 3000L run (WBS 6.7) 3000L GMP run (WBS 6.8) Validation master plan (WBS 6.6) Analytical method validation (WBS 6.4)

Small Scale Process Characterization (6.12)

Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS) MS7;

A firm-fixed price subcontract between PharmAthene and for an amount not to exceed the price subcontracting officer. The period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work: MS1; BDS stability challenge potency testing, Lot B2272/008, Time Points T=24 and 36 months (WBS 1.1.1) FDP stability challenge potency testing, Lot 907616, Time Points T=18, 21, 24, 27, 30, 33 and 36 months (WBS 1.2.1) FDP CTM 100ug dose stability challenge potency testing, Time Points T=0, 3, 6, 9 and 12 months (WBS 1.2.2) FDP CTM 50ug dose stability challenge potency testing, Time Points T=0, 3, 6, 9 and 12 months (WBS 1.2.3) MS2; FDP Mouse Challenge Potency Assay Development Plan and Studies (WBS 2.2.1) MS3; FDP CTM 100ug dose mouse challenge potency testing, Time Point T=0 months (WBS 3.1) FDP CTM 50ug dose mouse challenge potency testing, Time Point T=0 months (WBS 3.2) MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS) 0. A time-tixed price subcontract between PharmAthene and the subcontract between PharmAt MS6; MSDS (WBS 6.5) MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS) A firm-fixed price subcontract between PharmAthene and the price subcontract between PharmAthene and the price of the period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work: MS2; Immunopotency development studies (WBS 2.2.2) MS3; FDP CTM 100ug dose general safety testing (WBS 3.1) FDP CTM 50ug dose general safety testing (WBS 3.2) MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

A firm-fixed price subcontract between PharmAthene and amount not to exceed the price subcontract between PharmAthene and price subcontracting officer. The period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work: MS1: BDS stability MCLA testing, Lot B2272/008, Time Point T=36 months (WBS 1.1.1) MS2; MCLA Assay development and validation (WBS 2.1.1) MS4; Reference standard re-qualification (WBS 4.1.5) MS6; Operation of Process at Intermediate Scale, MCLA testing (WBS 6.5) Process Scale up Campaign (3 runs), MCLA testing (WBS 6.7) MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (BVMS) A firm-fixed price subcontract between PharmAthene and and for an amount not to exceed is hereby approved by the Contracting Officer. The period of performance is (04/01/2009 This approval encompasses the following scope of work: BDS stability physical and chemical testing, Lot B2272/008, Time Points T=24 to 12/31/2010). MS1; and 36 months (WBS 1.1.1) FDP stability physical and chemical testing, Lot 907616, Time Points T=18, 21, 24, 27, 30, 33 and 36 months (WBS 1.2.1) FDP CTM 100ug does stability physical and chemical testing, Time Points T=0, 3, 6, 9 and 12 months (WBS 1.2.2) FDP CTM 50ug dose stability physical and chemical testing, Time Points T=0, 3, 6, 9 and 12 months (WBS 1.2.3) MS4; Reference standard re-qualification (WBS 4.1.5) MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS) s. A firm-fixed price subcontract between PharmAthene and the period of performance is (04/01/2009 to the period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work: MS4; Reference standard re-qualification (WBS 4.1.5) MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

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A firm-fixed price subcontract between PharmAthene and contractions for an amount not to exceed the shereby approved by the Contracting Officer. The period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work:

- MS6; Office space for PTN RTP support team
- MS7: Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

A firm-fixed price subcontract between PharmAthene and the period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work: MS1; BDS stability challenge potency statistics, Lot B2272/008, Time Points T=24

and 36 months (WBS 1.1.1)

PDP stability challenge potency statistics, Lot 907616, Time Points T=18, 21, 24, 27, 30, 33 and 36 months (WBS 1.2.1)

FDP CTM 100ug dose stability challenge potency statistics, Time Points T=0, 3, 6,9 and 12 months (WBS 1.2.2)
 FDP CTM 50ug dose stability challenge potency statistics, Time Points T=0, 3,

6, 9 and 12 months (WBS 1.2.3)

MS2; MCLA validation study statistics (WBS 2.1.1) FDP Mouse Challenge Potency Assay Development Plan and Study statistics (WBS 2.2.1)

- FDP CTM 100ug dose mouse challenge potency statistics (WBS 3.1) FDP CTM 50ug dose mouse challenge potency statistics (WBS 3.2) MS3:
- MS7: Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)



A firm-fixed price subcontract between PharmAthene and the price for an amount not to exceed is hereby approved by the Contracting Officer. The period of performance is (04/01/2009 to 12/31/2010). This approval encompasses the following scope of work:

- MS1; BDS, FDP and sample storage (WBS 1.2.11)
- MS7; Report activity progress to timeline and impact of variances to schedule at the milestone level (EVMS)

ARTICLE B.4. ADVANCE UNDERSTANDINGS, paragraph h Milestones have been modified to reflect the current change in the scope of work.

The Contractor's Technical Proposal dated March 24, 2009, as amended by MOD 0016. submitted in response to this change is hereby incorporated into the contract by reference. The Contractor shall perform the remaining work substantially as set forth in this technical proposal. In the event of a conflict between Section C, and the Contractor's Technical Proposal, Section C will take precedence.

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The Contractor shall complete the work in accordance with the Statement of Work and the contract milestones set forth below. Contractor shall submit all Milestone-associated documents in draft form, subject to BARDA review and approval before finalization and acceptance. The distribution of the fixed fee shall be paid in milestone based installments and payment of this fee shall be determined by the Project Officer's written certification that the milestone has been satisfactory performed and that the technical requirements have been met regarding the completion of the following milestones. Upon notification that the Milestone and all of its subparts have been satisfactorily completed, the Contractor may bill fee as cost incurred. If the Contractor meets the milestones earlier than the dates set forth below, then the fee will be paid at the earlier date after completion of the milestone.

Milestone	WBS	Brief Description	Deliverable Date	Deliverable	Estimated Cost	Fixed Fee	Total CPFF
		BDS Stability					2
	1.1.1	Ongoing BDS	07/31/2010	BDS B2272- 008 T=36 months			
		Stability	0115112010	Certificate of Analysis			
	1.2.1 Stabil	Ongoing FDP	11/30/2010	FDP 907616, Up to T=36 months			
		Stability	1030/2010	Certificate of Analysis			
·	1.2.2	I.2.2 Clinical Batch I (2009) 100ug/dose	12/31/2010	FDP, up to T=12 months Certificate of Analysis			
	I.2.3 Clinical Batch 2 (2009) 50ug/dose	12/31/2010	FDP, up to T=12 months Certificate of Analysis				
	1.2.5	Ongoing Diluent Stability	11/15/2009	Diluent lot 803634, Final Study Report			
	1.2.7	Clinical diluent stability	11/30/2010	Diluent, up to T=12 months Certificate of Analysis			

					Estimated Cost	Fixed Fce	Total CPFF
Milestone		Potency Assay	Deliverable Date	Dellverable			
2	2.1.1	MCLA Assay development and validation	03/31/2010	MCLA assay Validation Report			

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2.2.1	Challenge Assay	8/31/2010	Challenge Assay Development Report (work to date)
2.2.2	Immunopotency	12/31/2010	Immunopotency Assay Development Report (work to date)

					Estimated Cost	Fixed Fee	Total CPFF
Milestone		FDP Manufacture	Deliverable Date	Deliverable			
	3.1	Clinical Batch I (100ug/dose)	11/30/2009	Certificate of Analysis and Disposition Cert for each Batch			
3	3.2	Clinical Batch 2 (50ug/dose)	12/15/2009	Certificate of Analysis and Disposition Cert for each Batch	4 2 7		
	3.4	30L High Phosphate Diluent Manufacture	11/15/2009	Certificate of Analysis and Disposition Certificate			

					Estimated Cost	Fixed Fee	Total CPFF
Milestone		Assay Development and Validation	Deliverable Date	Deliverable			
4	4.1.3	BDS stability assay validation for Appentance, A280, SDS- PAGE, TVC, [EF	4/30/2010	Approved validation report for all assays combined or approved validation reports for each assay			

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	4.2.1	FDP Phosphate release and stability method development and validation	02/15/2010	Approved validation report			
	4.2.2	FDP characterization method development	10/31/2010	Approved method development report(s)			
					Estimated Cost	Fixed Fee	Total CPFF
Milestone		Regulatory	Deliverable Date	Deliverable			-
5	5.1.2	Submission 2 - CMC update	12/31/2009	Submission package to FDA			
	5.2	2009 Annual Report	08/30/2009	Annual Report Submitted to FDA			
							Total
					Estimated Cost	Fixed Fee	CPFF
Milestone		Tech Transfer	Deliverable Date	Deliverable	Estimated Cost	Fixed Fee	CPFF
Milestone 6	6.5	Tech Transfer Process Transfer Initiated	Deliverable Date	Deliverable Contract signed	Estimated Cost	Fixed Fee	CPFF
	6.5 6.5	Process Transfer			Estimated Cost	Fixed Fee	CPFF
		Process Transfer Initiated Process Transfer mid-	11/1/2009	Contract signed 2 months from	Estimated Cost	Fixed Fee	CPFF
	6.5	Process Transfer Initiated Process Transfer mid- point Fermentation Process Transfer	11/1/2009	Contract signed 2 months from contract signed 4 months from	Estimated Cost	Fixed Fee	CPFF
	6.5	Process Transfer Initiated Process Transfer mid- point Fermentation Process Transfer Complete Purification Process Transfer and Development	11/1/2009 12/31/2009 2/28/2010	Contract signed 2 months from contract signed 4 months from contract signed Demonstration	Estimated Cost	Fixed Fee	CPFF
	6.5 6.5 6.5	Process Transfer Initiated Process Transfer mid- point Fermentation Process Transfer Complete Purification Process Transfer and Development Complete Analytical method transfer	11/1/2009 12/31/2009 2/28/2010 3/31/2010	Contract signed 2 months from contract signed 4 months from contract signed Demonstration run vial crack		Fixed Fee	CPFF

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	validated assays initiated		
6.4	Transfer of validated assays complete	05/31/2010	Vial crack for 3 rd demonstration run
6.5	Demonstration run #1 complete	04/30/2010	bulk fill complete
6.5	Demonstration run #2 complete	05/31/2010	bulk fill complete
6.5	Demonstration run #3 complete	05/31/2010	bulk fill complete
6.7	cGMP pre- production started	04/30/2010	3 months before planned start of engineering run
6.7	Pre-production and facility set- up complete	07/31/2010	Engineering run vial crack
6.7	Start of 1st. engineering run	07/31/2010	Vial crack
6.7	Completion of 1 st engineering run	30 days after start	Bulk fill complete
6.7	Start of 2 rd engineering run	08/30/2010	Vial crack
6.7	Completion of 2 nd engineering run	30 days after start	Bulk fill complete
6.8	Start of cGMP run	10/31/2010	Vial crack
6.8	Completion of cGMP run	30 days after start	Bulk fill complete
6.8	cGMP run tested	12/31/2010	CoA
6.6	Validation master plan work initiated	10/31/2010	Bulk fill complete cGMP run
6.6	Validation master plan complete	02/28/2011	Validation master plan approved
6.4	Start Analytical - method validation	08/30/2010	initiated
6.4	Complete Analytical method validation	02/28/2011	Reports approved
	Small Scale	. 3/31/11	Reports

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Other Cost Areas			
	Estimated Cost	Fixed Fee	Total Cost
Program Management			
General Program Management			\$906,928
	\$499,105	\$0.0	\$499,105
Earaed Value Management	Estimated Cost	Fixed Fee	Total Cost
Estimated Program Cost	\$25,250,793	\$3,687,259	\$28,938,052
Estimated incurred Cost in Performance (NIAID Contract N01-AI-30052) prior to April 1, 2009 that were not previously billed	Estimated Cost	Fixed Fee	Total Cost
			\$3,520,000
Estimated Contract PRICE			\$32,458,052

ARTICLE B.4 –Advance Understanding is hereby modified to add paragraph (p) (q), (r), (s), and (t),

p. Site Visits and Inspections

At the discretion of the USG and independent of activities conducted by the Contractor, with ten (10) business days notice to the Contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and key intermediates held by the Contractor, or sub-contractors. In the case of subcontractor visits and inspections that are independent of activities conducted by the Contractor, the USG shall demonstrate cause for such visit and/or inspection. These site visits shall be coordinated through the Prime Gontractor. Under time-sensitive or critical situations, the USG reserves the right to suspend the 10 day notice to the Contractor. The areas covered under the site visits and audits could include, but are not limited to: security, regulatory and quality systems, and cGMP/GLP/GCP compliance.

The USG will conduct cGMP inspections of all manufacturing facilities (including sub-contractor facilities) under this contract within six (6) months of contract award. Formal cGMP inspections will occur on an annual basis, or as needed, if cause dictates. The Contractor shall provide a written response including appropriate corrective actions within twenty (20) business days after receipt of audit or inspection report, or request for information and clarification from the USG.

q. People in Plant

For a duration of its choosing, the USG may place, one or more persons in the Contractor's or Subcontractor's facility (PIP) with a seven (7) days advance notice to the Contractor. In the case of subcontractor visits, the USG shall coordinate these activities through the Contractor. The People in Plant (PIP) will have necessary training prior to being placed in the Contractor's facility. The PIP are restricted to observing, verifying, and surveying the Contractor's or subcontractor's performance and work environment, in adherence to the applicable regulations and the Scope of Work under this contract.

r. Subject Matter Experts

The Contractor shall acquire the services of qualified Subject Matter Experts (SMEs), as needed, for additional oversight to achieve compliance with FDA regulations in the areas of quality assurance and related to activities in areas of manufacturing, clinical, non-clinical, assay development, storage and distribution, and other relevant aspects within the Scope of Work under this contract. These SMEs shall be approved by the Contracting Officer prior to being hired.

s. Material Transport and Delivery

The USG must pre-approve all plans and Standard Operating Procedures (SOPs) related to the distribution, transport, delivery and acceptance of vaccine materials including but not limited to cell banks (master and or working), BDS, FDP and critical reagents. Pre-approvals shall be based on generally accepted and current industry best practices. Documents for pre-approval include, but are not limited to: qualification and validation plans for temperature-controlled packaging of said materials; qualification of vehicles and shipping procedures, instructions, choice of temperature recording methods (and associated limits) and procedures for handling deviations and excursions, and communication plans.

- t. Access to Documentation
 - a. The Contractor shall provide the USG with access, as requested, to documentation and data generated during this contract in accordance with

the SOW, including but not limited to: Contractor efforts; communications and correspondence with regulatory agencies and bodies to include audit observations, inspection reports, and Contractor's commitments and responses; Subcontractor documentation including protocols for preapproval and, QA reviewed raw data from studies and final technical reports. The Contractor shall provide this documentation within a reasonable amount of time. The Contractor shall provide BARDA with a minimum of 5 business days to provide feedback. In the case of lengthy or complex submissions, BARDA reserves the right to require additional time for review. The Contractor shall review and approve any request for information generated outside of this contract under previous USG-funded efforts.

U. Program Management

a. Condition of Payment for Risk Mitigation Management Activities.

During the course of this development effort, if the Contractor perceives a risk that is likely or will cause a negative consequence to the development effort, the Contractor shall notify the Project Officer and Contracting Officer. The Contractor shall present a risk mitigation plan that contains the following elements.

- Statement of the problem: This should be based on the risk assessment and should indicate the source of the problem.
- Indicate the impact cost and schedule. A statement, of the additional funds or other unprogrammed resources required to accomplish the plan. If no additional resources are required, so state. If known or projected, indicate the source(s) of these funds/resources.
- Selected Approach: A clear statement of which option (or options) was selected and why. This could include the results of a trade off study if appropriate. It should also include any additional description of that option necessary to make the selected approach clear.
- Present an updated project schedule: chart which shows start and end dates for each action

Before commencing, the project plan must be approved by the Contractor Officer.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK. Paragraph a, has been modified as set forth below:

Independently and not as an agent of the USG, the Contractor shall furnish all the necessary services, qualified personnel, material equipment, and facilities, not otherwise provided by the USG as needed to accomplish the tasks and milestones in the Statement of Work, Section J, Attachment 1, attached hereto and made a part of this contract modification . Performance and expenditures under this modification shall be consistent with the work plans schedule and budget described in the Contractor's March 24, 2009 Scope of Work, as amended by MOD 0016 as amended by this contract modification 0016, which would include answers provided in response to Technical and Administrative Questions.

All work included in Section J, Attachment 1, dated September 30, 2003 and any amendments thereto through Modification 0016 associated with process development and validation, engineering runs sufficient to ensure production of at least 3 cGMP consistency lots suitable for Phase 3 trials, initial Phase 2 clinical trials and such other efforts that are not included in the above Statement of Work has been terminated and/or deleted at the request of the USG.

ARTICLE C.2. REPORTING REQUIREMENTS. Paragraph b is hereby deleted in its entirety and replaced with the following:

a. Monthly Technical Progress Reports.

On the tenth of each month, the Contractor shall submit a Monthly Technical Progress Report for the previous calendar month, to the Project Officer and the Contracting Officer. The Contractor shall submit one copy of the Monthly Technical Progress Report electronically via e-mail. Report documents sent by e-mail shall be submitted in MSWord, MSExcel, MSProject, or compatible versions. Such reports shall include the following specific information: The contractor's name and address, the author(s), and the date of submission. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and provide the following information in no more than 15 pages:

(1) The Monthly Technical Progress report shall address each of the below items and be cross-referenced to the WBS in the Gantt chart and Project Plan.

· An Executive Summary in MS PowerPoint format, highlighting the progress,

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issues, and relevant activities in manufacturing, non-clinical, regulatory, and security. The Executive summary should be limited to 2-3 slides and highlight only critical issues for that reporting period and resolution approach.

- Progress in meeting contract milestones- broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned progress and actual progress during the period covered, explaining occurrences of any differences between the two, and the corrective steps and actions are planned, if behind schedule.
- The reports shall also include a three month rolling forecast of key planned activities, referencing the WBS/Project Plan.
- The project's plans and schedule must reflect up to date FDA regulatory requirements and guidance.
- Estimated and Actual Expenses (applicable until the EVMS reports are submitted)
 - a. This report shall also contain a narrative statement as to whether there is any discrepancy at this time between the % of work completed and the cumulative costs incurred to date. Section IV of this report shall also contain estimates for the Subcontractors' expenses from the Contract No. HHSO100200900103C previous month if the Subcontractor did not submit a bill in the previous month. These shall be listed for each Subcontractor. If the Subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors

(2) Earned Value Management

- a. In lieu of a formal Integrated Baseline Review, 60 days after contract modification Contractor shall deliver a submission to include: a description of the work scope through Work Authorization Documents (WADs); Integrated Master Schedule (IMS) with the inclusion of agreed major milestones and control account plans (CAP) for all control accounts; baseline revision documentation and program log(s); and risk register. BARDA will review documentation and provide written comments and questions to Contractor, who shall provide a written response back to BARDA within 20 days.
- b. The Contractor shall deliver the Integrated Master Schedule statused with performance data and should include actual start/finish and projected start/finish dates. The statused schedule should be delivered 10 days after reporting month end. Contractor shall deliver a program level Integrated Master Schedule that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks.

c. The Contractor shall deliver an Earned Value Contract Performance Report (EV-CPR) on a monthly basis per the instruction in DI-MGMT-81466A (see http://www.acq.osd.mil/pm/). Contractor shall provide preliminary EV-CPR, Format 1,on the 15th day after end of Contractor reporting period and final EV-CPR and Format 5 on the 20th day after end of Contractor reporting period. The USG shall use best efforts to respond within 5 business days.

(3) Milestone Reports

As specified in Section B.4.h, the Contractor shall provide a Milestone Report with final versions of key project documentation, after the completion of each Milestone unless otherwise agreed upon by the Project Officer and the Contracting Officer. All documents related to Milestone deliverables shall be submitted to BARDA in draft form for review and comments prior to submittal in final form in the final Milestone Report. Milestone reports and monthly reports may be combined if agreed by the Project Officer and the Contracting Officer.

(4) Annual Report

The Contractor shall be required to submit to the Project Officer and Contracting officer an annual technical progress report within 15 days after the anniversary of the contract award date.

(5) Weekly teleconferences

The Contractor shall participate in weekly teleconferences with BARDA to discuss the performance of the contract. The Contractor shall record, maintain and provide draft meeting minutes to the Project Officer for approval within 3 days after teleconference. The Project Officer will approve the final version. The Contractor shall distribute final approved version within 3 business days after receipt of BARDA approval.

(6) Interactions with Regulatory Agencies

- b. The Contractor shall notify the Project Officer and Contracting officer of all site visits/audits by any regulatory agency, within 24 hours of receipt of notice. In the event of an FDA inspection which occurs as a result of this contract and for this product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor will provide the USG with an exact copy of the FDA Form-482, Form 483, and the Establishment Inspection report (EIR) within 24 hours of receipt.
- c. The Contractor shall include BARDA representatives in all scheduled meetings and teleconferences with any regulatory agency. The Contractor shall provide both the meeting minutes and finalized meeting minutes related to any meeting with regulatory agencies.

d. The Contractor shall provide BARDA the opportunity to review and comment upon any documents required to be submitted to regulatory agencies. These shall include documents that are generated as result of this contract or documents that have the reasonable potential to impact the performance of this contract. The Contractor shall provide BARDA with a minimum of 5 business days to provide feedback comments. In the case of lengthy or complex submissions, BARDA reserves the right to require additional time for review.

(7) Final Report

The Contractor shall submit five (5) copies of a comprehensive Final Report, with four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved under all milestones.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES OR PERFORMANCE, paragraph b is modified to read as follows:

The items specified below as described in Section C, ARTICLE 2 will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-45.

Addressee	Deliverable Item	Delivery Time	Quantity
Andre Early Contracting Officer US Department of Health and Human Services	Monthly Progress Reports Milestone Reports (after completion) EVMS	10 th of EA Month 10 th of EA Month	l original l original
Assistant Secretary for Preparedness and Response Biomedical Advance Research &	Initial documentation for PMB	w/in 60 days of Contract Mod	I original
Development Authority 330 Independence Avenue, SW	Integrated Master Schedule	10 th of EA Month (after reporting Month end	l original
Room O640 Washington, DC 20201 Email: <u>darrick.carly@hhs.gov</u>	• BV-CPR	Preliminary by 15 th day, final by the 20 th day after reporting month end	Ioriginal
	Milestone Report	By 10 th day after completion of Milestone	1 original
	Annual Report	W/in 15 business days of Anniversary of contract nward	I original
	Draft Weekly Teleconference Meeting Minutes	W/in 3 business days following teleconference	IorigInal
1	Final Weekly Teleconference Meeting Minutes	Win 3 business days following receipt of BARDA Comments	l original
	Final Report	By the Expiration of the Contract	loriginal
	Interaction with Regulatory Agencies	In accordance with Section C.2.6	I original
	Government Furnished Property Report	W/in 15 days of Anniversary date of contract award	loriginal
Jucy Mac Gabhann	Monthly Progress Reports	10 th of BA Month	I original
Project Officer US Department of Health and Human Services	Milestone Reports (after completion)	10 th of BA Month	I original
Assistant Secretary for Preparedness and Response Biomedical Advance Research &	EVMS Initial documentation for PMB	win 60 days of Contract Mod	l original
Development Authority 30 Independence Avenue, SW Room G640 Vashington, DC 20201	Integrated Master Schedule	10 th of EA Month (after reporting Month end	l original
Smail: Jucy.macgabhann@hhs.gov	• EV-CPR	Preliminary by 15th day, final by the 20th day after reporting month and	loriginal
	Milestone Report	By 10 th day after completion of Milestone	l original
	Annual Report	W/in 15 business days of Anniversary of contract award	I original
	Draft Weekly Teleconference Meeting	Win 3 business days following teleconference	Ioriginal

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Minutes		
Final Weekly Teleconference meeting Minutes	W/in 3 business days following receipt of BARDA comments	l original
Pinal Report	By the Expiration of the Contract	4 original
Interaction with Regulatory Agencies	In accordance with Section C.2.6	t original
Government Furnished Property Report	W/in 15 business days of Anniversary date of contract award	1 original

V9-Final

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SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER is hereby modified to read as follows:

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

FROM: Gopa Raychaudhuri, Project Officer, NIH/NIAID TO: Lucy G. Mac Gabhann, Project Officer, BARDA

Performance of the work hereunder shall be subject to the technical directions of the designated Project Officer for this contract.

As used herein, technical directions are directions to the Contractor, which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor feels that full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer in a letter separate of any required report(s) within two (2) weeks of the date of receipt of the technical direction exceeds the scope of the contract, then it shall be contract rails to provide the required notification within the said two (2) week period that any technical direction exceeds the scope of the contract, then it shall be deemed for purposes of this contract that the technical direction was within the scope. No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government Project Officer is not authorized to change any of the terms and conditions of this contract. Changes shall be made only by the Contracting Officer by properly written modification(s) to the contract. Any changes in Project Officer delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

(End of Clause)

ARTICLE G.2. KEY PERSONNEL is hereby modified to read as follows:

The personnel specified in this contract modification are considered to be essential to the work being performed hereunder and that the Government recognizes that some of the named individuals may or may not charge directly to this Program. Prior to removing any of the specified individuals to other programs on a full time basis, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No changes shall be made by the Contractor without the written consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer.

required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.

Senior Vice-President of Operations
Vice President of Regulatory Affairs and Quality
Chief Scientific Officer
Vice President of Manufacturing and Supply Chain
Program Director
Senior Director of Operations: Research Triangle
Park Site
Medical Director
Head of Operations
Head of Quality
Senior Director of Final Drug Product
Head of Vaccines Quality
Director of Vaccines Technical Development
VP of Bioanalysis

ARTICLE G.4 - INDIRECT RATES, is hereby modified to read as follows:

- (a) Subject to the provisions of the clause entitled "Allowable cost and Payment" in Section I, Contract Clauses, allowable indirect cost under this contract shall be obtained by applying the approved DCAA and/or negotiated indirect cost rates below to the base,
- (b) The Contractor shall be reimbursed for allowable indirect rates as the following rate(s)

Туре	Calendar Year 2009	Calendar Year 2010	Base
Fringe (US)			
Fringe (UK)			1
Overhead (US)			1
Overhead (UK)			
G & A			
Fee			1.52

SECTION H- SPECIAL CONTRACT REQUIREMENTS

ARTICLE H. 10. ANIMAL WELFARE is hereby deleted in its entirety and replaced with the following:

Information on Compliance with Animal Care Requirements

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. The USDA office contact information is available at <u>http://www.aphis.usda.gov/ac/acorg.html</u>. They are responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), <u>http://www.nal.usda.gov/awic/legislat/awa.htm</u>.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) <u>http://grants2.nih.gov/grants/olaw/olaw.htm</u>. An essential requirement of the PHS Policy <u>http://grants2.nih.gov/grants/olaw/references/phspol.htm</u> is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* <u>http://www.nap.edu/readingroom/books/labrats/</u> and that they comply with the regulations (9 CFR, Subchapter A) <u>http://www.nal.usda.gov/awic/legislat/usdaleg1.htm</u> issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) <u>http://www.aaalac.org</u> is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the Accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the *Guide* as their primary evaluation tool. They also use the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*. It is published by the Federated of Animal Science Societies <u>http://www.fass.org</u>.

ARTICLE H. 14. PRESS RELEASES deleted in its entirety and replaced with the following:

a. **Press Releases** -Pursuant to Public Law(s) cited in paragraph (2), below, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: the percentage of the total costs of the program or project which will be financed with Federal money; the dollar amount of Federal funds for the project or program; and the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V, section 506, as Directed by P.L. 110-5, Div. B, title I, Section 104.	2009	10/1/08 - 9/30/09

ARTICLE H.15. Reporting Matters Involving Fraud, Waste, and Abuse, has been deleted in its entirety and replaced with the following:

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

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

ARTICLE H. 16. ANTI-LOBBYING, has been deleted in its entirety are placed with the following:

Prohibition on the Use of Appropriated Funds for Lobbying Activities HHSAR 352.270-10 Anti – Lobbying (Jan 2006)

The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 31, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits

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from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself as stated in P.L. 109-149, Title V, section 503(a), as directed by P.L. 110-5, Div. B, Title I, section 104.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature as stated in P.L. 109-149, Title V, section 503(b), as directed by P.L. 110-5, Div. B, Title I, section 104.

(End of Clause)

ARTICLE 22 - DISSEMINATION OF INFORMATION, is hereby added and shall read as follows:

After the execution of Modification 16, information first produced under this contract shall not be released or publicized without the prior written consent of the Contracting Officer, which approval shall not be unreasonably withheld, conditioned, or delayed; provided, however, that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

(End of Clause)

ARTICLE 23- IDENTIFICATION AND DISPOSITION OF DATA, is hereby added and shall read as follows:

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). The Contractor shall consent to USG review of data produced outside of this contract. The data must be deemed relevant to this contract and statement of work. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

SECTION I- CONTRACT CLAUSES

The following contract clause has been incorporated into this contract.

FAR Clause No.	Date	Title
52.245-1	JUN 2007	Government Property
52.245-9	June 2007	Use and Charges

SECTION J - LIST OF ATTACHMENTS

ATTACHMENT 1 - Statement of Work, is deleted in its entirety and replaced as follows. All other milestones are no longer required.

Independently and not as an agent of the USG, the Contractor shall furnish all the necessary services, qualified personnel, material equipment, and facilities, not otherwise provided by the USG as needed to accomplish the tasks and milestones in the Statement of Work, Section J, Attachment 1,attached hereto and made a part of this contract. Performance and expenditures under this modification shall be consistent with the work plans schedule and budget described in the Contractor's March 24, 2009 Scope of Work as amended by MOD 0016, which would include answers provided in response to Technical and Administrative Questions.

- a. Execute a stability testing program to ensure the safety, sterility, potency and integrity of the vaccine used in clinical trials and non-clinical studies, to support all regulatory requirements including: IND amendments; data to support the product's use under Emergency Use Authorization (EUA), BLA submission and product licensure and post-licensure tasks as appropriate.
- b. Develop, qualify and validate product release and stability indicating assays including potency assays; in-process assays (as appropriate); product characterization methods; and reagents for use in clinical and pivotal studies that shall ultimately support the product's use under EUA, BLA submission and product licensure.
- c. Manufacture, fill and finish the Final Drug Product and companion diluents to be used in clinical trials and non-clinical studies to support the product's use under EUA, BLA submission and product licensure. Contractor shall ensure all relevant data, including that from the subcontractor, is submitted to the FDA in accordance with the licensure strategy.
- d. Plan and execute a Technology Transfer of Bulk Drug Substance production, including, but not limited to, relevant knowledge of the process including batch records, test records and other documentation, analytical methods, raw material information and master and seed stocks, to a qualified cGMP compliant Contract Manufacturing Organization (CMO) with experience producing FDA-licensed vaccines and biologics. Execute scale-up and production of at least one cGMP lot at full-scale.
- e. Execute a Performance Measurement System that meets the Seven Principles of Earned Value Management. The Seven Principles are:
 - I. Plan all work scope for the program to completion.
 - II. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

- III. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control Changes to the baseline.
- Use actual cost incurred and recorded in accomplishing the work performed.
- V. Objectively assess accomplishments at the work performance level.
- VI. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.
- VII. Use Performance Measurement System information in the company's management processes.
- f. The Contractor shall structure their Performance Measurement and Earned Value Management Systems using a discernable and consistent deliverable-based Work Breakdown Structure consistent with the rPA Work Breakdown Structure format provided by BARDA.
- g. The Contractor and BARDA shall mutually agree upon cost, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract.

MILESTONES

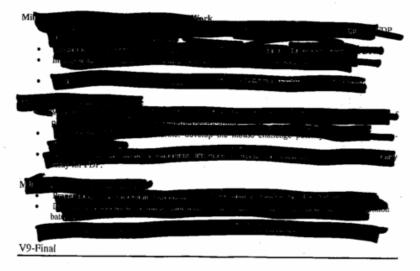
Consistent with the requirements described in the SOW above, the Contractor will submit a proposed plan, and execute this plan to accomplish the following milestones. Unless otherwise agreed, all milestones will conclude with delivery of an acceptable final milestone report to BARDA. The report shall document the details and data completed under each milestone, including all pertinent final technical reports related to work accomplished

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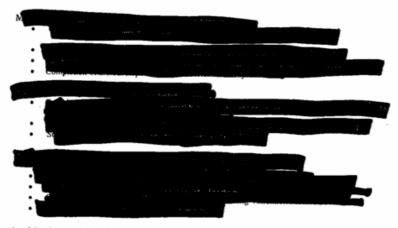
New MS P	Previous MS #	Previous Milestone Title	Scope of previous millastone
1	16	Develop and manage e stability plan for Drug Substance and Drug Product	Work carried out under this Milestone has included all BDS and FDP stability program activities
2	4	Assay development, qualification and velidation	Recent work carried out under this milestone has included assay development of BDS and FDP potency assays i.e. MCLA, challenge potency and immunopotency
3	6, 11	Milestone 6: Final Drug product - process technology transfer, development and pre-validation	Work under Milestone 6 has included FDP manufature for clinical studies and pre process validation activities
		Milestone 11: Fill 750,000 doses as part of a process validation compaign and fill 750,000 doses as part of a consistency campaign	Work under Milestone 11 to date has included some preparatory activities for the FOP process validation campaign including Raw Material purchases and supplier Audits.
4	12	Release of 3 process validation cGMP lots, deliver or store 750,000 doses	This milestone included a Sub-milestone relating to establishment of assays, therefore all activities relating to release, stability and characterisation assay development and validation have been allocated to this Milestone
5	15	Complete Regulatory Plan	Work allocated to this Milestone has included preparation and review of regulatory submissions
6	None	associated with a specific NIH Miles	s are new activities and have not been previously stone. Previously all BDS menufacturing activities IPA buik drug substance menufacture for process scilon.

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The following Work Plan describes the remaining activities associated with contract HHSO100200900103C, this updated Plan reflects the activities that have been selected to be undertaken under this contract.



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h. Meetings and Conferences:

In accordance with the responsibilities to oversee the contract effort, the Project Officer, shall direct the need for meetings and conferences. The Contractor shall coordinate and participate in regular meetings and conference and include all relevant Contractors and subcontractor personnel. Such meetings may cover areas, but are not limited to, the technical, regulatory and ethical aspects of the program, preclinical and clinical study designs, assay development and validation. The meeting may involve BARDA technical consultants and Subject Matter Experts to discuss technical data provided by the Contractor.

TECHNOLOGY TRANSFER AND DEVELOPMENT SERVICES SUBCONTRACT

THIS TECHNOLOGY TRANSFER AND DEVELOPMENT SERVICES SUBCONTRACT (the "Subcontract") is made as of September 17, 2009 (the "Effective Date") by and between Diosynth RTP Inc., a Delaware corporation, located at 101 J. Morris Commons Lane, Morrisville, North Carolina 27560 ("Diosynth"), and PharmAthene, Inc., a Delaware corporation, located at One Park Place, Suite 450, Annapolis, MD 21401 ("PharmAthene"). Each of Diosynth and PharmAthene may be referred to herein separately as a "Party" and collectively as the "Parties."

WHEREAS, PharmAthene owns rights to a recombinant protective antigen for anthrax vaccine (rPA) product (the "Product");

WHEREAS, PharmAthene has been awarded a prime contract in respect of the development of an anthrax vaccine, numbered NO-A1-30052 with the National Institutes of Health ("NIH"), an agency of the U.S. Government, which contract was recently transferred from NIH to the Biomedical Advanced Research and Development Authority ("BARDA") within the Department of Health and Human Services (as amended from time to time, and together with any successor or replacement contract(s), collectively the "Prime Contract");

WHEREAS, PharmAthene anticipates further funding of its development of recombinant protective antigen (rPA) for anthrax (rPA);

WHEREAS, Diosynth is a contract manufacturing organization ("CMO") providing a range of services related to the development and manufacture of biopharmaceutical products;

WHEREAS, prior to the date hereof, another CMO provided certain development and manufacturing services to PharmAthene related to the supply of the bulk drug substance for the Product ("Drug Substance");

WHEREAS, PharmAthene desires to transfer the technology related to, among other things, the development, scale-up and manufacture of the Drug Substance from the prior CMO to Diosynth (the "Technology Transfer");

WHEREAS, Diosynth desires to assist PharmAthene with the Technology Transfer to its organization and facilities and to begin development work related to the manufacturing process for the Drug Substance in support of the Prime Contract (all of the foregoing, including the Technology Transfer and all other services included in the Scope, collectively, the "CMO Services");

WHEREAS, PharmAthene and Diosynth may in the future decide to amend this Subcontract to add additional development services and provisions relating to the Drug Substance, including without limitation validation, verification and conformance manufacturing; WHEREAS, PharmAthene and Diosynth are also in discussions regarding entering into a separate subcontract (a "Development and Supply Subcontract") under which Diosynth would supply Drug Substance in support of any future prime contract awarded to PharmAthene for the advanced development and procurement of the Product; and

WHEREAS, Diosynth wishes to be hired by PharmAthene and to assist PharmAthene with the CMO Services (collectively the "Program") under the terms of this Subcontract.

NOW, THEREFORE, in consideration of the foregoing premises and the promises, benefits, rights and obligations set forth below, the Parties agree as follows:

CMO Services.

1.1 Statement of Work.

(a) Diosynth shall perform the CMO Services described in the Statement of Work attached hereto as <u>Exhibit A</u> (the "Scope"), in accordance with the terms and conditions of this Subcontract and all exhibits attached hereto, including without limitation the Quality Agreement, all of which are incorporated herein by reference. In exchange, PharmAthene shall pay Diosynth the fixed prices specified in the Program Price and Payment Schedule attached hereto as <u>Exhibit B</u> ("Program Price"). In addition, Process Consumables (as defined in the Scope), Raw Materials (as defined in the Scope) and Third Party Analytical Testing (as defined in the Scope) purchased for the CMO Services will be invoiced separately as pass-through costs as such costs are incurred by Diosynth (such pass-through costs and the Program Price, collectively the "Total Program Price"). PharmAthene agrees to pay Diosynth's actual cost (inclusive of necessary testing) for the Process Consumables, Third Party Analytical Testing and Raw Materials (collectively, the "Pass-Through Costs") purchased for the CMO Services that such mark-up represents its mark-up on Process Consumables, Third Party Analytical Testing and Raw

Raw Materials, customarily offered to Diosynth's customers. Amounts payable for Process Consumables, Third Party Analytical Testing and Raw Materials will be invoiced as they are incurred by Diosynth, but in no event shall Diosynth invoice PharmAthene more than once monthly. Subject to the accuracy of applicable Assumptions, the total price (including mark-up) charged to PharmAthene for the Pass-Through Costs shall not exceed the "not to exceed" price for such items set forth in the Scope.

(b) PharmAthene shall perform its obligations as set forth in this Subcontract, the Scope and the Quality Agreement, and shall support and cooperate with Diosynth in its performance of the CMO Services. However, the foregoing shall not require PharmAthene to incur any material burden, cost or obligation not its responsibility under this Subcontract.

Sponsor Deliverables.

(a) As further set forth in the Scope, PharmAthene will timely provide Diosynth with Sponsor Deliverables (as defined in the Scope). A failure by PharmAthene to provide Sponsor Deliverables within the timeframes set forth in the Scope or as otherwise agreed to by the Parties in writing that delays performance of the CMO Services could result in additional charges to PharmAthene and a delay in meeting the objectives of this Subcontract. Claims for any such charges and delays must be pursued in accordance with Section 2.2 hereof.

(b) Title to Sponsor Deliverables shall remain with PharmAthene. Diosynth shall not sell, pledge, hypothecate, dispose of, or otherwise transfer any interest in Sponsor Deliverables except as otherwise provided in this Subcontract, and shall use Sponsor Deliverables solely for purposes of performing the CMO Services. Diosynth shall provide safe and secure storage conditions for Sponsor Deliverables while they are at Diosynth's Facility.

1.3 <u>Entire Agreement; Conflicts</u>. This Subcontract (together with the exhibits attached hereto), the Quality Agreement, and the Scope collectively constitute the Parties' entire agreement for the CMO Services. Terms defined in this Subcontract shall have same meaning when used in the Scope or the Quality Agreement except as otherwise provided. In the event of any conflict among the components of this Subcontract, the following order of precedence shall apply: (i) "flow down" requirements of the Prime Contract attached hereto as <u>Exhibit C;</u> (ii) the terms set forth in this Subcontract; (iii) the Quality Agreement; and (iv) the Scope. References to this Subcontract herein shall, unless the context clearly indicates otherwise, be deemed to include the Scope, the exhibits, and Change Orders.

1.4 <u>Facility</u>. Diosynth shall perform the CMO Services at Diosynth's manufacturing facilities in Morrisville, North Carolina, or at such other place(s) as are mutually agreed upon by the Parties (the "Facility" or "Facilities").

1.5 <u>Shipping and Packaging</u>. The delivery point for all items to be delivered by Diosynth under this Subcontract shall be FCA, Diosynth's Facility. Diosynth shall package for shipment and ship all items at PharmAthene's expense and in accordance with PharmAthene's written instructions, with PharmAthene bearing all packaging, shipping and insurance charges during transit. Diosynth shall retain representative samples for record keeping, testing and regulatory purposes. Diosynth shall notify PharmAthene in writing when each lot of Product Deliverables is ready to be released as described in Article 10 of the Quality Agreement, and PharmAthene shall arrange for each lot of Product Deliverables to be shipped within thirty (30) days after PharmAthene provides release documentation such as a Certificate of Conformance, or similar, as described in Article 10 of the Quality Agreement. In the event of any delay by PharmAthene in providing release documentation or shipping for one or more lots of Product Deliverables that is not the fault of Diosynth, the Parties acknowledge and agree that title and risk of loss for each such lot of Product Deliverables shall automatically transfer to (and be assumed by) PharmAthene effective upon expiration of the applicable thirty (30) day period.

1.6 <u>Additional Manufacturing Activities</u>. The Parties acknowledge that this Agreement does not currently contemplate additional production of the Drug Substance at commercial production levels beyond the one (1) cGMP manufacturing run contemplated by the Scope. At

PharmAthene's request, Diosynth agrees to negotiate in good faith the terms and conditions of an agreement to manufacture and supply additional amounts of Drug Substance, including without limitation a Development and Supply Subcontract, that provides for additional manufacturing capacity; provided however that the foregoing shall not require Diosynth to reserve or set aside additional manufacturing capacity for PharmAthene unless such reservation or set-aside is mutually agreed upon in such negotiations.

2. Performance Standards; Covenants; Changes to Scope and Other Responsibilities.

2.1 Performance Standards and Related Matters.

(a) Diosynth shall at all times perform the CMO Services in accordance with: (i) the Scope, (ii) this Subcontract, including without limitation the Quality Agreement and the "flow down" requirements of the Prime Contract attached hereto as <u>Exhibit C</u>, (iii) cGMP as defined in the Quality Agreement ("cGMP"), (iv) with respect to matters not addressed by cGMP, reasonable and professional care and in a good and workmanlike manner, and (v) all applicable federal and state laws, rules and regulations (collectively, "Applicable Law"). The Parties acknowledge that they have jointly designed the Scope to be consistent with current U.S. regulatory requirements and guidelines. Notwithstanding the foregoing, Diosynth does not warrant that compliance with the requirements of this Subcontract will satisfy the requirements of any regulatory agencies at the time of submission of the results to such agencies.

(b) Except as otherwise provided herein, all warranties in this Subcontract shall survive inspection, test and Acceptance of, and payment for, the CMO Services. All warranties shall run to PharmAthene and its successors, assigns, and customers and shall extend for a period of one (1) year after PharmAthene's final Acceptance of the CMO Services.

(c) Subject to each Party's contractual obligations under this Subcontract, PharmAthene shall have the right and responsibility for determining regulatory strategy, decision and actions to the extent relating to the Program or Product and Diosynth shall have the right and responsibility for determining regulatory strategy, decision and actions to the extent relating to (i) the Facility, or its utilities, equipment or personnel; (ii) Diosynth's quality systems; (iii) any requirement imposed on Diosynth by a Regulatory Authority or (iv) any other commitments made by Diosynth prior to the Effective Date of this Subcontract. In the event of dispute concerning the appropriate division of the foregoing rights and responsibilities, the Parties agree to negotiate in good faith to resolve such dispute and, in the event that such dispute is not resolved through negotiation, either party may submit such dispute to arbitration pursuant to Article 26.

2.2 Change Orders; Changes to the Scope.

(a) The Program Price and Payment Schedule for the CMO Services are fixed, subject to the assumptions set forth in Section 3.0 of the Scope ("Assumptions"). This Section 2.2 describes the exclusive means by which the Program Price and Payment Schedule, the

Scope, or associated Program timeline may be changed. As used herein, "Change Order" means a written document signed by both Parties describing in reasonable detail a change in the Program Price and Payment Schedule, the Scope, and/or associated Program timeline.

Change Orders must be agreed by both Parties in writing, and consent to (b) a Change Order shall not be unreasonably withheld, conditioned or delayed by either Party. Either Party may propose in writing a change to the Program Price and Payment Schedule, the Scope and/or associated Program timeline, which shall contain the terms of such proposed change in reasonable detail. In such event, Diosynth shall prepare and deliver to PharmAthene within ten (10) days a proposed Change Order which shall include a statement of all effects on the Program Price and Payment Schedule, the Scope and/or associated Program timeline. The proposed Change Order shall include (i) cost information in reasonable detail for all Pass-Through Costs and (ii) a fixed price for all other services related to the proposed change(s). Diosynth agrees that such Pass-Through Costs and fixed price quote will be commercially reasonable. Within ten (10) days thereafter, PharmAthene shall respond to Diosynth indicating whether it approves or rejects the proposed Change Order, and if the Change Order is approved the Parties shall promptly execute same, whereupon the Change Order shall be effective to modify the Program Price and Payment Schedule, the Scope and/or associated Program timeline. In the event that the Parties cannot agree on the terms of any Change Order and the Parties do not resolve same promptly through good faith negotiations, then the dispute procedures of Article 26 hereof shall apply. Unless directed otherwise by PharmAthene, Diosynth shall continue to perform all work not affected by the proposed Change Order in accordance with this Subcontract during the pendency of any dispute regarding such proposed Change Order, provided that PharmAthene shall continue to comply with its payment obligations hereunder. Notwithstanding the preceding sentence, Diosynth shall not be required to continue performance of the CMO Services during the pendency of any dispute to the extent that performance of such work would be impossible in the absence of such a Change Order. Except in the case of a stop work order as described in Section 2.3 below, each Party shall notify the other within fifteen (15) days after first becoming aware of the existence of circumstances giving rise to a Change Order.

(c) Except as otherwise provided herein, all notices to be furnished by Diosynth shall be sent to PharmAthene's Director of Contracts at the address set forth in Article 20 with a copy to PharmAthene's General Counsel at the same address.

2.3 Stop-Work Orders.

(a) PharmAthene may, at any time, by written order to Diosynth, require Diosynth to stop all, or any part, of the work called for by the Scope for a period of ninety (90) days after the order is delivered to Diosynth, and for any further period to which the Parties may agree. The order shall be specifically identified as a stop-work order issued under this Section 2.3. Upon receipt of the order, Diosynth shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work

order is delivered to Diosynth, or within any extension of that period to which the Parties shall have agreed, PharmAthene shall either: (i) cancel the stop-work order, or (ii) terminate the work covered by the order as provided in Section 4.2.

(b) If a stop-work order issued under this Section 2.3 is canceled or the period of the order or any extension thereof expires, Diosynth will use all commercially reasonable efforts to resume work as soon as possible thereafter. Diosynth may request an equitable adjustment via the Change Order process in accordance with Section 2.2, within thirty (30) days after the end of the period of work stoppage, to the extent that (i) its direct costs were, or are reasonably expected to be, increased thereby or (ii) actual delay to its ability to perform was, or is reasonably expected to be, incurred.

(c) If a stop-work order is not canceled and the work covered by the order is terminated for the convenience of PharmAthene pursuant to Section 4.2(b), PharmAthene shall pay Diosynth the amounts, if any, specified in Section 4.2(b).

2.4 <u>Allocation of Resources</u>. If delays in the agreed commencement or performance of the CMO Services occur because of (i) a stop-work order issued under Section 2.3, or (ii) PharmAthene's failure to supply Diosynth with Sponsor Deliverables as required by this Subcontract within thirty (30) days of the timeframes set forth in the Scope or as otherwise agreed to by the Parties in writing, that is not the fault of Diosynth, Diosynth may, after providing ten (10) business days' prior written notice to PharmAthene, temporarily reallocate resources being held for performance of the Scope without incurring liability to PharmAthene. In addition, in such event Diosynth's obligation to perform the CMO Services as set forth in the Scope shall be suspended to the extent that such performance has been stopped by a stopwork order, or is prevented by a failure to provide a Sponsor Deliverable, but only during and for so long as Diosynth's performance is actually stopped or prevented thereby.

2.5 Support for Regulatory Submissions.

(a) Except as otherwise provided herein or as required by Applicable Law, PharmAthene shall be the sole communicator with the Food and Drug Administration ("FDA") or other applicable regulatory authority (each a "Regulatory Authority") regarding the Drug Substance and the Product or any regulatory approvals therefor. Except as otherwise provided herein or as required by Applicable Law, Diosynth shall not initiate contact with any Regulatory Authority without PharmAthene's prior written approval.

(b) If PharmAthene is required to submit to a Regulatory Authority any information concerning the CMO Services, Diosynth will provide PharmAthene copies of such documentation, data and other information as shall be necessary or reasonably desirable for such submission to the Regulatory Authorities and such other information in such form as PharmAthene may reasonably request, provided that such assistance shall be subject to the terms of the Quality Agreement. Diosynth shall also cooperate and consult as reasonably requested by PharmAthene and/or required by the Regulatory Authorities for development of additional data or performance of studies concerning the Product beyond the Scope, and

PharmAthene shall pay Diosynth's reasonable costs therefor. Diosynth shall also provide, if required by the Regulatory Authorities, information concerning its laboratory, manufacturing, and quality control procedures with respect to the CMO Services. If requested, Diosynth shall use reasonable best efforts to provide PharmAthene all documentation, data and information referred to in this Section 2.5 reasonably in advance of their required submission to allow for PharmAthene's review and comments. Diosynth shall endeavor in good faith to satisfactorily resolve all PharmAthene comments prior to submission if such submission is to be made by PharmAthene.

2.6 <u>SAFETY Act and PREP Act Compliance</u>. The Parties acknowledge and agree that the Product is intended to prevent or deter acts of terrorism and/or to limit the harm such acts might otherwise cause and mitigate, treat, or cure a pandemic or epidemic, and to limit the harm such pandemic or epidemic might otherwise cause. Diosynth shall provide reasonable assistance to PharmAthene in its efforts to secure certification and designation of the Drug Substance and the Product as a Qualified Anti-Terrorism Technology ("QATT") under U.S. law, and specifically under the Support Anti-terrorism by Fostering Effective Technologies Act of 2002 (the "SAFETY Act"), sections 441-444 of title 6, United States Code. The Parties acknowledge and agree that the Drug Substance and/or Product is intended to qualify as a "covered counter measure" within the meaning of the Public Readiness and Emergency Preparedness Act (the "PREP Act") and that each is a "covered person" as therein defined.

2.7 <u>Quality Agreement</u>. On the Effective Date, PharmAthene and Diosynth entered into the Quality Agreement attached hereto as <u>Exhibit D</u>, which shall be used by both Parties to assign certain of the day-to-day responsibilities and manage the operations of both the PharmAthene and Diosynth Quality Assurance groups with respect to the CMO Services.

Project Manager. Each Party shall appoint a project manager for this Subcontract (the 2.8 "Project Managers"). Diosynth's project manager for this Subcontract is Dr. Bernard Adkins. The Diosynth Project Manager shall be considered a "key" employee and so long as the Diosynth Project Manager remains in the employ of or under contract with Diosynth, said person shall not be replaced in the performance of this Subcontract or have their responsibilities materially reduced or altered, unless an equally qualified replacement approved Such approval shall not be unreasonably denied. by PharmAthene is assigned. Notwithstanding the foregoing, PharmAthene shall be permitted to request the replacement of the Diosynth Project Manager at any time by written notice, whereupon Diosynth shall designate and assign a qualified replacement subject to approval by PharmAthene, such approval not to be unreasonably withheld, conditioned or delayed. In the event that the Diosynth Project Manager terminates his/her relationship with Diosynth, or is unable or unwilling, for any reason, to continue with or complete the work effort, then Diosynth may propose a new Project Manager for PharmAthene's consideration. Any increase in the cost of performing the Scope due to the addition of the new Project Manager shall be the sole responsibility of Diosynth. The Project Managers will oversee the day-to-day activities of the Parties with respect to the Program and will be the primary point of contact between the

Parties with respect to the Program. The Project Managers shall report to the Joint Steering Committee.

2.9 <u>Additional Diosynth Responsibilities</u>. Diosynth shall be responsible for all necessary education and training of its employees and contractors with respect to the Facilities, equipment and processing methods used in providing the CMO Services.

3. Invoicing and Payment.

PharmAthene shall pay Diosynth for the CMO Services provided in 3.1 Payment. accordance with this Subcontract on the terms and conditions and in the amounts set forth in the Program Price and Payment Schedule, as modified by any Change Orders, which amounts shall include all expenses, taxes and other charges whatsoever except as otherwise specified in this Section 3.1. All invoices for CMO Services shall contain all supporting data and other information required under this Subcontract and as otherwise reasonably requested by PharmAthene. PharmAthene shall pay Diosynth for Process Consumables, Raw Materials and Third Party Analytical Testing in accordance with Section 1.1(a) and for packaging, shipping and insurance charges in accordance with Section 1.5. All invoices shall contain a summary of activities completed during the invoice period, including activities completed and an indication of Process Consumables and Raw Materials purchased, cost of Third Party Analytical Testing and any packaging, shipping or insurance charges incurred. Diosynth shall invoice PharmAthene monthly not later than the fifth (5th) day of each month. Separate invoices shall be submitted according to the activities described in the Scope. Unless otherwise provided in any Scope, PharmAthene shall pay Diosynth all undisputed amounts invoiced within thirty (30) days after the date of receipt of a proper invoice for such fees and expenses provided that such invoice is received by the fifth (5th) day of the month. If such invoice is received after the fifth (5th) day of any month, such invoice shall be treated as if received before the fifth (5th) day of the month after the month in which it is actually received and shall be paid in the next payment cycle. If PharmAthene disputes the amount due, then PharmAthene shall notify Diosynth of such dispute by the payment due date provided that Diosynth has timely provided such supporting documentation as PharmAthene reasonably requests. Both parties will act in good faith to promptly resolve such dispute. Late payments are subject to an interest charge of one percent (1%) per month. Unless within thirty (30) days of the date of PharmAthene's receipt of the invoice PharmAthene has advised Diosynth in good faith and in writing of the specific basis for disputing an invoice, failure to pay an undisputed invoice within ninety (90) days from the date of invoice may, at Diosynth's election, constitute a material breach of this Subcontract.

3.2 Form of Invoice. The Parties shall mutually agree on an acceptable form of invoice, consistent with the requirements of this Subcontract, the Prime Contract and Applicable Law. No amounts set forth on an invoice shall be due and payable to Diosynth hereunder unless such invoice is accurate and complete.

3.3 Address for Invoicing. Invoices shall be submitted to PharmAthene at:

PharmAthene, Inc.

Attn: Accounts Payable One Park Place, Suite 450 Annapolis, MD 21401

and to Diosynth at:

Diosynth RTP Inc. 101 J Morris Commons Lane Morrisville, North Carolina 27560.

or to such other addresses provided to the other Party in writing in accordance with the terms of Article 20 of this Subcontract.

3.4 <u>Acceptance</u>. "Acceptance" shall mean that deliverables as set forth in the Scope conform to all applicable requirements and the agreed upon acceptance criteria for such deliverable as provided in this Subcontract.

(a) With respect to protocols, reports, study plans and reports, PharmAthene-specific analytical test methods and other written deliverables that are identified as Diosynth Deliverables in the Scope(collectively, the "Written Deliverables"), the Parties shall engage in review and revision of such deliverable in a timely manner in accordance with the principles provided in the Scope to generate a final Written Deliverable. PharmAthene shall review and, if acceptable in all reasonable respects, accept final Written Deliverables within ten (10) days after receipt, unless specified otherwise in the Quality Agreement.

(b) With respect to a shipment of Drug Substance (the "Product Deliverable"), Acceptance shall occur on the date of delivery of the Certificate of Conformance by PharmAthene in accordance with Article 10 of the Quality Agreement. Diosynth shall not deliver any Product Deliverable to PharmAthene until such deliverable has been released in accordance with Article 10 of the Quality Agreement.

(c) PharmAthene shall have the right to reject any Deviating Product in accordance with Article 9 of the Quality Agreement and this Section 3.4(c). PharmAthene shall promptly (and, in any event, no later than thirty (30) days following delivery of any Product Deliverables (pursuant to Section 3.4(b))) notify Diosynth in writing that such Product Deliverables are Deviating Product due to a suspected defect that is known to PharmAthene or that was readily ascertainable through reasonable inspection. "Deviating Product" shall mean Product Deliverables that (i) were not processed in accordance with the process set forth in the Scope; (ii) were not processed, handled or stored in accordance with cGMP, or (iii) are damaged or defective. Notwithstanding anything to the contrary contained herein, in the case of suspected defects that are not readily ascertainable through reasonable inspection, PharmAthene shall notify Diosynth of such defect within ten (10) days from the date of discovery of such defect, or earlier if required by the Quality Agreement..

(i) As soon as practicable after PharmAthene provides Diosynth with a notice of rejection, the Parties shall undertake an investigation of such Product Deliverables in accordance with Article 9 of the Quality Agreement. Upon commencement of the investigation, PharmAthene shall immediately deliver to Diosynth all potentially Deviating Product. The Parties shall cooperate in good faith during such investigation and use reasonable best efforts to complete the investigation. Diosynth shall notify PharmAthene within five (5) days of the conclusion of such investigation, whether Diosynth accepts or disputes PharmAthene's assertion(s) that certain Product Deliverables are a Deviating Product.

After the completion of such investigation (or earlier, if agreed to (ii) by the Parties), at PharmAthene's request, whether or not Diosynth accepts PharmAthene's assertion that certain Product Deliverables are Deviating Product, Diosynth shall process and deliver replacement Product Deliverables ("Replacement Product") as soon as reasonably possible, provided that Diosynth shall not be required to cease, interrupt or otherwise disturb campaigns in progress. If Diosynth disputes in writing whether the Product Deliverables are Deviating Product or whether such Deviating Product was caused by the failure of Diosynth, PharmAthene shall pay Diosynth, within thirty (30) days of such Replacement Product request: (A) for such Replacement Product in accordance with the prices set forth in the Program Price and Payment Schedule and (B) for all Pass-Through Costs purchased for such Replacement Product, plus a fee equal to seven and one half percent (7.5%) of such actual costs. Following completion of an investigation and dispute resolution if any pursuant to this Section 3.4(c), Diosynth shall reimburse PharmAthene such payment, in accordance with Section 3.4(c)(iv), to the exent such Deviating Product is agreed or determined to be caused by the failure of Diosynth.

(iii) If Diosynth disputes PharmAthene's assertion that certain Product Deliverables are Deviating Product or Diosynth believes that the Deviating Product was not caused by any failure of Diosynth, then the Parties shall work together in good faith to resolve the dispute. If the Parties are unable to resolve such a dispute through good faith negotiation, then the dispute procedures of Article 26 hereof shall apply.

(iv) If Diosynth accepts PharmAthene's assertion or if it is determined through the dispute procedures of Article 26 hereof that such Deviating Product was caused by the failure of Diosynth and PharmAthene previously paid for the Replacement Product, then Diosynth shall, within thirty (30) days of such acceptance or determination, reimburse PharmAthene for the price of the Replacement Product to the extent that such Deviating Product was caused by the failure of Diosynth

(v) If it is determined through the dispute procedures of Article 26 hereof, or if PharmAthene acknowledges the same in writing, that such Product Deliverable was not a Deviating Product or such Deviating Product was not caused by the failure of Diosynth, then Diosynth shall be entitled to retain the payment made by PharmAthene pursuant to Section 3.4(c)(ii) for such Replacement Product. Such purchase price for the Replacement Product shall be in addition to the purchase price for the original shipment of the allegedly Deviating Product. PharmAthene' liability for such Deviating Products shall be limited to that stated in this Section 3.4(c).

(d) If any CMO Services other than Written Deliverables and Product Deliverables (collectively, the "Service Deliverables") do not comply with the standards set forth in Section 2.1(a) and such failure is not the fault of PharmAthene, Diosynth shall promptly, upon notice, re-perform such Service Deliverables in accordance with the standards set forth in Section 2.1(a) for no additional costs to PharmAthene.

(e) Provided that Diosynth re-performs its obligations with respect to Deviating Product or non-conforming Service Deliverables in accordance herewith and the timeframe for cure provided in Section 4.2(a)(i)(1) or (2) as applicable, the initial failure of such Deviating Product or Service Deliverable to comply with the standards set forth herein shall not be considered a default under this Subcontract (unless such failure resulted from gross negligence, bad faith or intentional misconduct).

3.5 <u>Payment Not Acceptance</u>. Payment by PharmAthene for any CMO Services performed under this Subcontract shall not be deemed to constitute acceptance of such CMO Services nor waive any rights, warranties or remedies available to PharmAthene under this Subcontract or Applicable Law.

4. Term and Termination

4.1 Term. The term of this Subcontract shall begin on the Effective Date and continue until completion of all CMO Services and as long as reasonably necessary to settle all accounts and for such additional period thereafter as may be necessary to make any payments due and fulfill any post-termination obligations. The Parties acknowledge that PharmAthene is required to complete performance under the Prime Contract by March December 31, 2011 and Diosynth agrees to use reasonable best efforts to (i) demonstrate consistent progress towards completion of this Subcontract by December 31, 2010, and (ii) complete this Subcontract by such date, subject to the terms of this Subcontract. Diosynth will provide regular reports, as described in this Subcontract, indicating progress towards milestones in reasonable detail, and such further information as PharmAthene may reasonably request.

4.2 <u>Termination</u>. This Subcontract is terminable only as follows:

(a) <u>Default</u>.

(i) If Diosynth is in default of its material obligations under this Subcontract, then PharmAthene may notify Diosynth in writing of any such default.

Diosynth shall have a period of twenty (20) days from the (1)date of receipt of such notice within which to cure such default, and shall diligently pursue efforts to cure such default at all reasonable times. If Diosynth fails to cure within such twenty (20) day period, then PharmAthene shall have the right to immediately terminate all or any part of this Subcontract by providing written notice to Diosynth. In the event of such termination, PharmAthene shall not be liable to pay for any work not Accepted; provided however that PharmAthene's Acceptance shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Diosynth shall upon request deliver to PharmAthene any supplies and materials, manufacturing materials, and manufacturing information that Diosynth has specifically produced or acquired for this Subcontract and PharmAthene shall compensate Diosynth for the reasonable cost of such supplies, materials and/or information and any costs associated with these deliverables.

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(2) With respect to production runs or other activities that are not capable of being cured in twenty (20) days from the date of receipt of such notice, Diosynth shall initiate actions during such twenty (20) day period that are reasonably anticipated to cure the default within a reasonable period (not to exceed one hundred and fifty (150) days), and thereafter cure such default within a reasonable period (not to exceed one hundred and fifty (150) days). If Diosynth fails to cure within such period, then PharmAthene shall have the right to immediately terminate all or any part of this Subcontract by providing written notice to Diosynth in accordance with Section 4.2(a)(i)(1).

(ii) If PharmAthene is in default of its material obligations under this Subcontract, Diosynth shall promptly notify PharmAthene in writing of any such default. PharmAthene shall have a period of twenty (20) days from the date of receipt of such notice within which to cure such default provided that it diligently continues efforts to cure such default at all reasonable times. With respect to non-monetary performances that are not capable of being cured in twenty (20) days from the date of receipt of such notice, PharmAthene shall initiate actions during such twenty (20) day period that are reasonably anticipated to cure the default within a reasonable period (not to exceed sixty (60) days), and thereafter cure such default within a reasonable period (not to exceed sixty (60) days). If PharmAthene fails to so cure, then Diosynth shall have the right to immediately terminate this Subcontract by providing written notice to Diosynth.

(iii) NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE ENTITLED TO INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES ARISING IN CONNECTION WITH THE DEFAULT OR BREACH OF ANY OBLIGATION OF THE OTHER PARTY UNDER THIS SUBCONTRACT, THE SCOPE OR ANY DOCUMENTS OR APPENDICES RELATED THERETO.

(iv) EXCEPT IN THE EVENT OF GROSS NEGLIGENCE, WILFUL MISCONDUCT, OR BAD FAITH, DIOSYNTH'S MAXIMUM LIABILITY FOR DAMAGES IN CONNECTION WITH A CLAIM RELATED TO THIS SUBCONTRACT, REGARDLESS OF THE CAUSE OF ACTION, WILL NOT EXCEED THREE MILLION, THREE-HUNDRED THOUSAND DOLLARS (\$3,300,000.00).

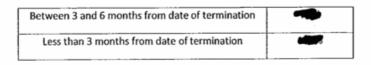
(v) If after termination by PharmAthene under Section 4.2(a)(i), it is later determined by binding arbitration pursuant to Article 26 or otherwise that Diosynth was not in default, such termination shall be deemed a termination for convenience under Section 4.2(b) hereof.

(b) <u>Termination for Convenience</u>. PharmAthene reserves the right to terminate this Subcontract, or any part hereof, for its sole convenience at any time. In the event of such termination, Diosynth shall immediately stop all work on the terminated effort hereunder and shall use all reasonable best efforts to minimize the incurrence of costs allocable to the terminated effort. Subject to the terms of this Subcontract and the Scope, in the event that PharmAthene terminates this Subcontract pursuant to this Section 4.2(b), PharmAthene shall pay Diosynth within forty (40) days after receipt of Diosynth's termination invoice, the following amounts:

(i) all amounts owed for CMO Services milestones completed (as defined by the line items in Exhibit B) but not yet invoiced and/or paid; plus

(ii) with respect to the CMO Services terminated, the percentages of unbilled amounts set forth in the Program Price and Payment Schedule for CMO Services to be performed in accordance with the following chart (but without duplication and only to the extent of CMO Services terminated under this Section 4.2(b) which result in loss of revenue to Diosynth):

Time from the date of termination until the date on which such CMO Services are scheduled to be performed as provided in the then-current Program Price and Payment Schedule	Percentage of Unbilled Amounts
More than 12 months from date of termination	
Between 6 and 12 months from date of termination	-



provided, however than in no event shall PharmAthene's liability for such termination exceed the total price set forth in the Program Price and Payment Schedule less all amounts paid to Diosynth prior to the date of termination. In no event shall PharmAthene be liable for any additional amounts, including without limitation, lost or anticipated profits or unabsorbed indirect costs or overhead. Diosynth's termination invoice shall be submitted within ninety (90) days from the effective date of the termination and must satisfy all requirements of a regular invoice. In the event of a partial termination for convenience, Diosynth shall continue all CMO Services not terminated.

(c) <u>Bankruptcy or Insolvency</u>. Either Party at its sole option may immediately terminate this Subcontract upon written notice, but without prior advance notice, to the other Party in the event that (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction, (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party, or (iii) this Subcontract is assigned by such other Party for the benefit of creditors (each, an "Insolvency Event"). Notwithstanding the foregoing, PharmAthene shall retain all rights under Section 365(n) of the Bankruptcy Code if an Insolvency Event occurs with respect to Diosynth.

4.3 <u>Winding Down and Mitigation</u>. Upon early termination of this Subcontract or any Scope for any reason, at PharmAthene's request Diosynth shall inform PharmAthene of the extent to which it expects work in progress to be completed as of the termination date and Diosynth shall (unless otherwise instructed by PharmAthene) take reasonable steps to wind down work in progress in an orderly fashion and mitigate any losses and costs. Upon early termination or expiration of any Scope, each party shall return all Confidential Information, files and other materials in its possession related to such Scope to PharmAthene. Each party shall be permitted to retain one copy of such materials solely for archival purposes to ensure compliance with the provisions of this Subcontract or with the requirements of regulatory authorities, subject to Article 5.

4.4 Technology Transfer Upon Termination.

(a) Upon expiration or sooner termination of this Subcontract for any reason Diosynth shall on an expedited basis transfer to PharmAthene any and all PharmAthene Intellectual Property Rights (as defined in Article 8), and shall provide to PharmAthene any and all Diosynth Intellectual Property Rights that may be required to manufacture the Drug Substance in accordance with the Subcontract and to support regulatory filings for the Drug Substance; provided, however, that Diosynth shall not be required to provide PharmAthene with any such Diosynth Intellectual Property Rights if PharmAthene does not possess a then current license under Section 8.4. Subject to the availability of the appropriate Diosynth

personnel, PharmAthene may request that Diosynth provide to PharmAthene reasonable consulting services related to the manufacturing, quality control, quality assurance, and the CMC (chemistry, manufacturing and control) part of the Drug Substance registration process; provided however that Diosynth shall not be required to provide consulting services under this Section 4.4 for so long as PharmAthene has not paid Diosynth amounts due to Diosynth hereunder. PharmAthene shall pay Diosynth for all reasonable expenses related to the consulting services provided under this Section 4.4, and shall compensate Diosynth at its then current rates for such consulting services. All technical assistance to be provided by Diosynth pursuant to this Section 4.4 shall be in accordance with a plan provided to Diosynth by PharmAthene and agreed upon by the Parties. To the extent transferable, Diosynth shall also transfer any license(s), permit(s), or approval(s) obtained specifically for the manufacturing of the Drug Substance. The Parties agree to work in good faith for the transfer of any information and materials related to the Drug Substance, PharmAthene's Intellectual Property Rights required under this Section 4.4(a).

Subject to the limitations set forth in Section 4.4(a), the technology (b) transfer contemplated by Section 4.4(a) shall include without limitation at least the following activities: (i) Diosynth shall provide PharmAthene access to any and all Diosynth Intellectual Property Rights (as defined in Article 8) that are used in the manufacture of the Drug Substance in accordance with the Subcontract and to support regulatory filings for the Drug Substance (including, without limitation, analytical testing methods, protocols, process descriptions, batch records, specifications and other process and manufacturing data and documentation); (ii) Diosynth shall provide PharmAthene with reasonable access to Diosynth employees with expertise in development and manufacturing the Drug Substance to answer questions related to such technology transfer; and (iii) Diosynth shall allow PharmAthene reasonable access to the Facility at reasonable times on business days for any reasonable purpose connected with such technology transfer; provided, however, that such access must be scheduled in advance with Diosynth and may not interfere with Diosynth's business operations (such training sessions, assistance, cooperation, access to Diosynth employees and access to the Facility shall be limited to (i) PharmAthene employees and (ii) any consultants hired by PharmAthene and approved by Diosynth, with such approval not to be unreasonably denied, provided each consultant signs a confidentiality agreement that consistent with the confidentiality obligations established in this Subcontract. PharmAthene shall provide Diosynth with a list of proposed visitors to the Facility at least one (1) business day in advance of such visit. PharmAthene shall pay Diosynth for all reasonable expenses related to Diosynth's provision of Facility access under this Section 4.4(b).

(c) The technology transfer contemplated in Section 4.4(a) and (b) above shall be provided promptly and in accordance with the terms of this Subcontract for the provision of CMO Services. In the event that this Subcontract is terminated (i) by Diosynth due to a default of PharmAthene under Section 4.2(a) or due to an Insolvency Event with respect to PharmAthene described in Section 4.2(c), or (ii) by PharmAthene under Section 4.2(b), PharmAthene shall pay for the technology transfer contemplated in Section 4.4(a) and (b) above at Diosynth's then-current hourly rates. If this Subcontract is terminated by

PharmAthene due to a default of Diosynth under Section 4.2(a) or due to an Insolvency Event with respect to Diosynth described in Section 4.2(c), Diosynth shall provide such technology transfer without charge to PharmAthene, except for the consulting services described in Section 4.4(a).

5. Confidential Information and Records.

5.1 <u>Disclosure</u>. During and in furtherance of this Subcontract, each of the Parties hereto may disclose certain of its Confidential Information to the other Party. "Confidential Information" shall mean a Party's non-public and/or proprietary information that is disclosed under this Subcontract by the disclosing Party to the recipient Party in writing or in other tangible form and marked "confidential," or if disclosed orally (or in some other non-tangible form), are identified as confidential to the recipient Party or reasonably should be considered confidential by the recipient Party. Such information may include technology, data, know-how, trade secrets, cell lines, specifications, drawings, designs, regulatory strategies, inventions, discoveries, methods and procedures, and all information whether technical or non-technical, including, but not limited to, financial statements, reports, pricing, secret processes, formulae, samples, proposals, SOPs, Scope, Quality Agreement, business and financial information, capacity information, etc. and any unpublished patent applications.

5.2 Use and Non-Disclosure of Confidential Information. During the term of this Subcontract and for a period of ten (10) years from the termination thereof, each of the Parties hereto agrees (a) to use the other Party's Confidential Information only in connection with the performance of this Subcontract; (b) to treat the other Party's Confidential Information as it would its own sensitive or proprietary information; and (c) to take all reasonable precautions to prevent the disclosure of the other Party's Confidential Information to any individual or entity, (except to such of its employees and contractors who reasonably require same for purposes hereof and who are bound to that Party by like obligations as to confidentiality and non-use), without the prior written consent of the other Party. The receiving Party shall be responsible for any breaches of this Subcontract by its employees, agents, board members, consultants or suppliers. In addition, a Party may disclose Confidential Information provided under this Subcontract by the other Party to any governmental authority in order to prosecute or maintain any Intellectual Property Rights or any Regulatory Authority to obtain approval to manufacture and/or market the Product or perform its obligations under the Prime Contract.

5.3 Exceptions to Confidential Information. Each Party shall be relieved of its obligations under Section 5.2 regarding Confidential Information which such Party demonstrates (a) was lawfully in the possession of such Party as evidenced by competent evidence of such Party, and which was not acquired directly or indirectly from the disclosing Party or any of the representatives or advisors to the disclosing Party, or in violation of any confidentiality agreement; (b) at the time of disclosure, was generally available to the public or which after disclosure hereunder becomes generally available to the public through no fault attributable to the receiving Party hereto; (c) is developed by the receiving Party independently of information received by it from the disclosing Party hereunder, or (d) is required to be disclosed by the law

or the rules of any applicable regulatory organization provided that the receiving Party shall apply for confidential treatment of such Confidential Information to the fullest extent permitted by law, shall provide the other Party a copy of the confidential treatment request far enough in advance of its filing, if reasonably practical or legally permitted, to give the other Party a meaningful opportunity to comment thereon, and shall use reasonable efforts to incorporate in such confidential treatment request any reasonable comments of the other Party.

5.4 <u>Return</u>. Upon the expiration or sooner termination of this Subcontract or written request, all information of the disclosing Party in the receiving Party's possession will be returned to the disclosing Party (or irretrievably destroyed by the receiving Party, with written confirmation of such destruction), and the receiving Party will make no further use thereof. Notwithstanding the foregoing, the receiving Party may retain one copy of the Confidential Information of the disclosing Party solely for archival purposes to ensure compliance with the provisions of this Article 5 or with the requirements of regulatory authorities.

5.5 Designation of Confidential Information. For purposes of this Subcontract, the Parties hereby acknowledge and agree that this Subcontract and all results, data and other information that result or are generated from the CMO Services rendered by Diosynth hereunder (other than the Diosynth Intellectual Property Rights (as defined below)) shall be considered PharmAthene's Confidential Information to the extent relating to the Drug Substance. Furthermore, any all data, information, and materials that PharmAthene transfers to Diosynth as part of the Technology Transfer shall be considered PharmAthene's Confidential Information. The Diosynth Intellectual Property Rights shall be considered Diosynth's Confidential Information.

6. Safety; Protected Health Information.

6.1 <u>Adherence to Safety Procedures</u>. Diosynth shall adhere to its internal health and safety procedures during the performance of the CMO Services, including any handling of the Drug Substance or raw materials, components, hazardous waste and other materials. Such procedures shall comply with all applicable federal, state and local laws and regulations (including without limitation federal, state and local health and safety laws and regulations).

6.2 <u>Training</u>. Diosynth shall educate and train all employees and contractors involved in the performance of the CMO Services about the potential hazards associated with the handling of the Drug Substance, raw materials, components, hazardous waste and other materials involved in the CMO Services and on the proper use of personal protective equipment, to the extent that such hazards relating to the Drug Substance have been communicated to Diosynth by PharmAthene. Diosynth shall make applicable material safety data sheets available to all affected employees and contractors to the extent that such sheets have been provided to Diosynth by PharmAthene.

6.3 <u>Disposal of Waste</u>. Diosynth shall handle, store and dispose of all Hazardous Waste in accordance with Applicable Law. For purposes of the foregoing sentence, the term "Hazardous

Waste" shall mean all hazardous waste, as defined by Applicable Law, to the extent the same arise out of Diosynth's performance of CMO Services.

6.4 <u>HIPAA Compliance</u>. The Parties recognize that the Federal Health Insurance Portability and Accountability Act of 1996 and implementing regulations ("HIPAA") require written confidentiality agreements to protect the privacy and security of protected health information (as defined under HIPAA) that may be acquired in the course of performing this Subcontract. The parties agree to comply with HIPAA and other Applicable Law governing protected health information.

7. Program Management.

7.1 Joint Steering Committee. Effective on the Effective Date, the Parties shall establish a Joint Steering Committee (the "Joint Steering Committee") comprised of three (3) representatives designated by PharmAthene and three (3) representatives designated by Diosynth, each of whom shall have experience and seniority sufficient to enable him or her to make decisions on behalf of the Party he or she represents. The Project Managers may not be appointed to the Joint Steering Committee.

7.2 <u>Replacement of Joint Steering Committee Representatives</u>. Each party shall be free to replace its representative members on the Joint Steering Committee with new appointees who have authority to act on behalf of such party, on notice to the other Party.

7.3 <u>Responsibilities of Joint Steering Committee</u>. The Joint Steering Committee shall be responsible for overseeing and directing the Parties' interaction and performance of their respective obligations under this Subcontract. Without limiting the generality of the foregoing, its duties shall include: (i) monitoring the performance of the Program; (ii) resolving disagreements that arise under this Subcontract; and (iii) determining the need for and terms of any Change Orders.

7.4 <u>Meetings</u>. The Joint Steering Committee shall meet at such times as the Joint Steering Committee determines to resolve issues arising hereunder and to perform its responsibilities under this Subcontract, provided that the Joint Steering Committee shall meet not less than four (4) times per calendar year unless otherwise mutually agreed. Such meetings may be in person or by telephone as agreed by the Joint Steering Committee. To the extent that meetings are held in person, they shall alternate between the offices of the Parties unless the Parties agree otherwise. The Project Managers shall attend all meetings of the Joint Steering Committee. All decisions of the Joint Steering Committee shall be unanimous.

7.5 <u>Administration</u>. The chairperson of the Joint Steering Committee shall at all times be a representative designated by PharmAthene. The chairperson shall be responsible for calling meetings, sending notices of meetings and for leading such meetings; provided however that each member of the Joint Steering Committee may demand that the chairperson convene a meeting of the Joint Steering Committee.

7.6 <u>Minutes</u>. Within fifteen (15) days after each Joint Steering Committee meeting, the PharmAthene Project Manager shall prepare and distribute minutes of the meeting, which shall provide a description in reasonable detail of the discussions had at the meeting and a list of any actions, decisions or determinations approved by the Joint Steering Committee. Minutes shall be approved or disapproved and revised, as necessary, at the next meeting. Final minutes shall be distributed to the members of the Joint Steering Committee.

7.7 <u>Dispute Resolution</u>. In the event that the Joint Steering Committee cannot reach agreement with respect to any material issue, then the issue may be submitted to dispute resolution pursuant to Article 26.

7.8 <u>Limitations</u>. The Joint Steering Committee is not empowered to amend the terms of this Subcontract.

8. Intellectual Property and Proprietary Rights.

8.1 <u>Intellectual Property Definitions</u>. For purposes of this Subcontract, "Intellectual Property Rights" shall mean all proprietary rights and proprietary information, in any tangible or intangible form, including without limitation inventions, discoveries, devices, data, patents, patent applications, designs, copyrights, trademarks, trade secrets, proprietary know-how, Confidential Information and similar rights of any type under the laws of any governmental authority, including all applications and registrations relating to any of the foregoing and any Improvements relating to any of the foregoing. For purposes of this Subcontract, "Improvements" mean all improvements, discoveries, inventions, developments, enhancements, derivative works and the like, whether or not patentable or protectable.

8.2 <u>Background IP</u>. As between the Parties, each Party shall be sole owner of any Intellectual Property Rights it owns, licenses or controls as of the Effective Date and all Improvements thereto reduced to practice by either Party during the term of this Subcontract (each Party's "Background IP"). Diosynth hereby represents and warrants that Diosynth owns or holds sufficient rights to its Background IP to perform the activities contemplated by this Subcontract relating to the Drug Substance, including without limitation all Background IP used by Diosynth in the development and manufacturing of the Drug Substance pursuant to this Subcontract.

8.3 <u>PharmAthene License to Diosynth.</u> PharmAthene hereby grants Diosynth a nonexclusive, non-sublicensable, non-transferable, fully paid, royalty-free license under any PharmAthene Intellectual Property Rights, including without limitation any PharmAthene Background IP, relating to the Drug Substance solely in order for Diosynth to provide the CMO Services to PharmAthene during the term and to otherwise perform its obligations under the terms of this Subcontract.

8.4 <u>Diosynth License to PharmAthene</u>. Diosynth hereby grants PharmAthene a nonexclusive, perpetual, worldwide, fully paid, royalty free, fully transferable license with the right to grant sublicenses, to and under Diosynth's Intellectual Property Rights, including without

limitation any Diosynth Background IP and any Process Inventions, solely for the purpose of developing, marketing, selling, manufacturing or having manufactured the Drug Substance and/or the Product and to support regulatory filings for the Drug Substance and/or Product; provided however that Diosynth may suspend this license by written notice at any time that amounts due by PharmAthene under this Subcontract have not been paid; provided further that such license shall be reinstated upon satisfaction of PharmAthene's payment obligations hereunder. Diosynth shall confirm such reinstatement by written notice to PharmAthene.

8.5 New Intellectual Property.

(a) PharmAthene shall retain all rights to, and Diosynth will, at no cost or further action by PharmAthene, assign to PharmAthene, any Product improvement or use invention or other trade secret or other intellectual property right to the extent relating to the Product, discovered by Diosynth as a result of performing the CMO Services under this Subcontract ("Product Invention"). Any Product Invention is deemed included in PharmAthene's Intellectual Property Rights and the license set forth in Section 8.3. Diosynth shall retain all rights to any patentable invention other than a Product Invention relating to manufacturing and analytical methods and processes discovered in connection with the CMO Services and any pre-existing know-how ("Process Invention"). Any Process Invention is deemed included in Diosynth's Intellectual Property Rights and the license set forth in Section 8.4.

(b) If PharmAthene requests and at PharmAthene's expense, Diosynth will execute any and all applications, assignments or other instruments and give such testimony as shall be necessary to apply for and obtain Letters of Patent of the United States or of any foreign country with respect to the Product Invention. PharmAthene shall compensate Diosynth for the time devoted to such activities and reimburse it for expenses incurred. If Diosynth requests and at Diosynth's expense, PharmAthene will execute any and all applications, assignments or other instruments and give such testimony as shall be necessary to apply for and obtain Letters of Patent of the United States or of any foreign country with respect to the Process Invention and Diosynth shall compensate PharmAthene for the time devoted to such activities and reimburse it for expense pharmAthene for the time devoted to such activities and reimburse it for expenses pharmAthene for the time devoted to such activities and reimburse it for expenses pharmAthene for the time devoted to such activities and reimburse it for expenses pharmAthene for the time devoted to such activities and reimburse it for expenses incurred.

(c) Diosynth shall promptly disclose to PharmAthene any Product Invention or Process Invention generated by Diosynth during the performance of this Subcontract, and all such Product Invention shall be deemed to the fullest extent possible to be works made for hire exclusively for PharmAthene, with PharmAthene having sole ownership of such Product Invention and the sole right to obtain and to hold in its own name patents, copyrights, or such other protection as PharmAthene may deem appropriate to the subject matter, and any extensions or renewals thereof (though PharmAthene is under no obligation to file any patent application, secure or maintain any patent or register any copyright).

8.6 Rights in Data.

Diosynth agrees to use its best efforts to complete the requirements of (a) this Subcontract and the Scope without having to include any Diosynth Intellectual Property Rights in the items, data, and information required to be delivered in the performance of this Subcontract. As soon as Diosynth knows or should have known that it plans to deliver to PharmAthene any item, data or information that will include any element of Diosynth's Intellectual Property Rights, Diosynth agrees to notify PharmAthene in writing that it plans to deliver said item, data, or information with limited rights as defined in FAR 52.227-14 Rights in Data-General (the "Limited Rights Data") and the rationale for the required inclusion of Diosynth's Intellectual Property Rights and the impact if the same is not included in the deliverable product. Without limiting PharmAthene's rights under Section 8.4, subject to the immediately preceding sentence and the fulfillment of any payment-related obligations by PharmAthene to Diosynth under this Subcontract, Diosynth hereby grants to PharmAthene an irrevocable, perpetual, worldwide, fully paid, royalty free, non-exclusive license to use the Limited Rights Data provided pursuant to this Subcontract for the purpose of fulfilling its obligations to the U.S. Government under the Prime Contract and any future contract with the U.S. Government or any foreign government related to the Product (the "Permitted Use"), and to deliver the same as Limited Rights Data per FAR 52.227-14 Rights in Data-General. PharmAthene may sublicense, disclose, reproduce, modify, prepare derivative works of, distribute copies of, and perform or display the Limited Rights Data solely for the Permitted Use. Diosynth agrees to provide, if requested in writing by PharmAthene pursuant to a valid request of the Prime Contract's Contracting Officer, written substantiation of the propriety of any limited rights legend.

(b) Diosynth is responsible for marking its Limited Rights Data in accordance with FAR 52.227-14, <u>Rights in Data-General</u>.

(c) Unless otherwise marked at time of delivery, all data, information, and other items delivered under this Subcontract shall be provided to PharmAthene with unlimited rights per FAR 52.227-14, <u>Rights in Data-General</u>. Diosynth reserves the right to use data during the course of the CMO Services to support applications, assignments or other instruments necessary to apply for and obtain Letters of Patent of the United States or any foreign country with respect to Process Inventions so long as no information which Diosynth is required to keep confidential under this Subcontract is disclosed in any such application, assignment, or other instrument. To the extent practicable, Diosynth shall notify PharmAthene at least ninety (90) days in advance of intent to file such application, assignment or other instrument and PharmAthene shall have an opportunity to review same prior to filing.

(d) At the time of the execution of this Subcontract, Diosynth is not aware of any item, data or information to be provided under this Subcontract that is or will be deemed Limited Rights Data.

8.7 Enforcement.

(a) Diosynth shall immediately notify PharmAthene in writing of (i) any unauthorized or improper use by any person, entity or organization of the PharmAthene

Intellectual Property Rights and activities which are likely to amount to infringement, misuse, passing-off or counterfeiting in respect of such Intellectual Property Rights, and/or (ii) any allegations, claims or demands (actual or threatened) in respect of infringement of any third party proprietary rights by virtue of Diosynth's use of the PharmAthene Intellectual Property Rights. PharmAthene may, at it sole discretion, bring an action based on infringement, misappropriation or misuse or passing off in relation to its Intellectual Property Rights, at its own cost. Diosynth shall provide such assistance to PharmAthene as may be reasonably required in connection with such proceedings. Any damages, awards or settlement monies actually received by PharmAthene pursuant to this Article 8 upon the final judgment or settlement of any such action shall belong to PharmAthene.

(b) PharmAthene shall immediately notify Diosynth in writing of (i) any unauthorized or improper use by any person, entity or organization of the Diosynth Intellectual Property Rights and activities which are likely to amount to infringement, misuse, passing-off or counterfeiting in respect of such Intellectual Property Rights, and/or (ii) any allegations, claims or demands (actual or threatened) in respect of infringement of any third party proprietary rights by virtue of PharmAthene's use of the Diosynth Intellectual Property Rights. Diosynth may, at it sole discretion, bring an action based on infringement, misappropriation or misuse or passing off in relation to its Intellectual Property Rights, at its own cost. PharmAthene shall provide such assistance to Diosynth as may be reasonably required in connection with such proceedings. Any damages, awards or settlement monies actually received by Diosynth pursuant to this Article 8 upon the final judgment or settlement of any such action shall belong to Diosynth.

9. Representations and Warranties. The applicable Party indicated below represents and warrants to the other Party as of the date hereof and as of the date on which such Party enters into each Scope as follows:

9.1 <u>Requisite Experience, Etc.</u> Diosynth represents and warrants that it has the experience, capability, personnel and resources necessary to perform the CMO Services under this Subcontract in accordance with the Scope, this Subcontract, the Quality Agreement, cGMP (as defined in the Scope), the Federal Food, Drug, and Cosmetic Act, as amended (the "FFDCA") and other Applicable Law.

9.2 <u>Technology</u>. PharmAthene represents and warrants that it owns or otherwise has sufficient legal rights to the Drug Substance, the Product, and all technology that will be provided to Diosynth so it may perform under this Subcontract.

9.3 Power and Authority, Non-Contravention. Each Party represents and warrants that (a) it has the corporate power and authority to enter into and perform its obligations under this Subcontract; and (b) entering into and performing this Subcontract will not conflict with or result in a violation of any of the terms or provisions, or constitute a default under any of its organizational documents any mortgage, indenture, lease, contract or other agreement or instrument binding upon it or by which any of its properties are bound, or any permit,

concession, franchise, license, judgment, order, decree, statute, law ordinance, rule or regulation applicable to it or its properties.

9.4 <u>Debarment</u>. Diosynth represents and warrants that it does not use the services of any persons debarred or suspended under 21 U.S.C. § 335a (a) or (b) in any capacity associated with or related to the CMO Services. Diosynth further represents and warrants that it shall not hire or retain as an officer or employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the FFDCA.

9.5 Diosynth Warranties. Diosynth represents and warrants that: (i) work it performs hereunder will be in accordance with Sections 2.1 and 2.7, (ii) all work performed hereunder shall be in accordance with the regulatory approvals for the Drug Substance, cGMP (as defined in the Scope), OSHA and applicable federal, state and local regulations related to manufacturing and (iii) Diosynth possesses and shall maintain in full force and effect at all times during the term of this Subcontract all licenses, permits and similar certificates required for the operation of the Facility and for the production of Drug Substance and the storage of the materials and components for manufacturing of Drug Substance and Diosynth shall promptly notify PharmAthene if Diosynth receives any notice that any such license, permit, or approval is or may be revoked or suspended.

9.6 <u>DISCLAIMER OF WARRANTIES</u>. EXCEPT AS OTHERWISE SET FORTH IN THIS SUBCONTRACT OR ATTACHMENTS HERETO, PHARMATHENE AND DIOSYNTH MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH REGARD TO THE DRUG SUBSTANCE OR THE PRODUCT INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS EXPRESSLY SET FORTH IN THIS SUBCONTRACT OR ATTACHMENTS HERETO, DIOSYNTH MAKES NO WARRANTIES THAT THE EXECUTION OF THE SCOPE WILL RESULT IN ANY SPECIFIC QUANTITY OR QUALITY OF PRODUCT.

10. Indemnification.

10.1 SAFETY Act.

(a) <u>Application</u>. Notwithstanding anything to the contrary contained in this Article 10, the indemnification provisions contained in this Subcontract are intended by the Parties to be fully consistent with the application of the SAFETY Act. The Parties recognize that PharmAthene has not yet received recognition of the Product as a QATT and, as such, the provisions of the SAFETY Act may not apply to this Subcontract. However, to the extent anything contained herein conflicts with the SAFETY Act and the terms of the SAFETY Act apply to the activities described in this Subcontract and the Drug Substance and/or Product, the provisions of the SAFETY Act shall govern.

(b) <u>Limitations</u>. PharmAthene and Diosynth agree that with respect to all third party claims, suits, actions and demands brought against either PharmAthene or Diosynth

or both to which the provisions of the SAFETY Act apply to limit the liability of PharmAthene and/or Diosynth, each party retains responsibility for Losses (as defined below), including business interruption Losses, that it sustains, and for Losses sustained by its own employees resulting from an Act of Terrorism when Drug Substance has been deployed in defense against, response to, or recovery from such act, but only to the extent that such Party's liability is actually limited by the application of the SAFETY Act.

10.2 <u>PharmAthene Indemnification</u>. PharmAthene agrees to defend, indemnify and hold Diosynth, its Affiliates, officers, directors, employees and agents harmless against any and all losses, damages, fines, costs, claims, demands, judgments and liability (including reasonable legal fees and court costs) (collectively, "Losses") to which the provisions of the SAFETY Act do not apply resulting from, or relating to: (i) the negligence, gross negligence or intentional misconduct of PharmAthene; (ii) the infringement or alleged infringement of the Product on the intellectual property rights of a third party; (iii) PharmAthene's breach of its agreements, representations or warranties under this Subcontract or (iv) the handling, distribution, storage, sales, use or testing of the Drug Substance and/or Product that is manufactured by Diosynth in accordance with this Agreement, including without limitation Section 2.1(a) and the Scope; except in any such case to the extent that any such Losses are due to the negligence or intentional misconduct of Diosynth or its Affiliates or their respective officers, employees, contractors or agents;.

10.3 <u>Diosynth Indemnification</u>. Diosynth agrees to defend, indemnify and hold PharmAthene, its Affiliates, officers, directors, employees and agents harmless against any and all Losses to which the provisions of the SAFETY Act do not apply, resulting from, or relating to (i) the negligence, gross negligence or intentional misconduct of Diosynth or its subcontractors; (ii) the infringement or alleged infringement of any Diosynth Intellectual Property, including without limitation any Diosynth Background IP, on the intellectual property rights of a third party; (iii) Diosynth's breach of its agreements, representations or warranties under this Subcontract or (iv) failure to take safety precautions to prevent known risks of the Sponsor Deliverables, the Drug Substance or the Product as communicated in writing to Diosynth by PharmAthene; except in any such case to the extent that any such Losses are due to the negligence or intentional misconduct of PharmAthene or its Affiliates or their respective officers, employees, contractors or agents.

10.4 Indemnification Procedures.

(a) All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents (each, an "Indemnitee") will be made solely by the applicable Party (the "Indemnified Party"). The Indemnified Party will give the indemnifying Party (the "Indemnifying Party") prompt written notice (an "Indemnification Claim Notice") of any Losses for which Indemnified Party intends to request indemnification under any Section of this Article 10. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss, to the extent that the nature and amount of

such Loss are known at such time. The Indemnified Party will furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

(b) At its option, the Indemnifying Party may assume the defense of any third party claims, suits, actions and demands (each a "Third Party Claim") by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party's receipt of an Indemnification Claim.

(c) Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party and acceptable to the Indemnified Party in its reasonable judgment. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis defense or settlement of the Third Party Claim.

(d) Without limiting the preceding Section 10.4(c), any Indemnitee will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnitee's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with the preceding Section 10.4(b), in which case the Indemnified Party will control the defense.

With respect to any Losses relating solely to the payment of money (e) damages in connection with a Third Party Claim and that will not result in the Indemnitee becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnitee in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, will deem appropriate, and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the entry of judgment. With respect to all other Losses in connection with a Third Party Claim, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 10.4(b), the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Losses provided it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party's sole and absolute discretion). The Indemnifying Party will not be liable for any settlement or other disposition of Losses by an Indemnitee that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no

Indemnitee will admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party.

(f) The Indemnified Party will, and will cause each other Indemnitee to, cooperate in the defense or prosecution of any Third Party Claim and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation will include access during normal business hours afforded to the Indemnifying Party, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

10.5 <u>Definition of Affiliates</u>. As used in this Subcontract, "Affiliate" of any Party means any corporation, firm, partnership, joint venture, limited liability company or other entity or association which is controlled by or is under common control with a Party. For the purpose of this definition, "control" shall mean the power to direct, or cause the direction of, the management and policies of such entity or association through the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity, by contract, or by ownership interest.

11. Insurance.

11.1 <u>Diosynth Requirement</u>. Diosynth shall have and maintain throughout the term, at a minimum, the insurance coverage listed below but in no event shall the policy limits, deductibles, and other terms of such insurance afford less protection than that required by the Department of Homeland Security under the SAFETY Act. All insurance shall be with an insurance carrier with an A.M. Best rating of at least "A" or greater or the equivalent rating:

 (a) workers compensation insurance, including occupational disease, in the statutory limits of the state in which the CMO Services will be performed;

 (b) employers liability insurance in each state in which the CMO Services will be performed with minimum limits of \$500,000 each accident and a \$1,000,000 disease policy limit;

(c) comprehensive general liability insurance with minimum limits of \$5,000,000 per occurrence and \$5,000,000 aggregate for bodily injury and property damage, also providing coverage for (i) broad form contractual liability insurance insuring the hold harmless and indemnification provisions contained in this Subcontract, (ii) broad form property damage insurance, (iii) completed operations insurance for a term of two (2) years, which term shall commence upon expiration or termination of this Subcontract and (iv) the exclusion in the

comprehensive general liability policy commonly referred to as the x, c, u exclusion shall be deleted therefrom; and

(d) comprehensive automobile liability insurance covering claims arising from owned, hired, and non-owned vehicles for bodily injury and property damage with minimum limits of \$2,000,000 per occurrence and \$2,000,000 aggregate.

11.2 <u>Excess Insurance</u>. Diosynth may fulfill its insurance obligations under this Article 11 by providing \$5,000,000 primary coverage limits for comprehensive general liability and for automobile liability, and by providing excess or umbrella liability insurance with minimum limits of \$5,000,000 per occurrence and \$5,000,000 aggregate in excess of the primary coverage limits, but only so long as such excess policy includes broad form contractual liability, broad form property damage, and completed operations coverage.

11.3 <u>Certificates of Insurance and Other Requirements</u>. Certificates of the above insurance must be filed with PharmAthene within five (5) days before the time performance under this Subcontract is commenced. Diosynth covenants, represents and warrants to PharmAthene that (a) all policies of insurance required hereunder shall by appropriate endorsement, or otherwise, provide for thirty (30) days prior written notice of cancellation to PharmAthene, (b) the contractual liability insurance required hereunder, shall, by appropriate endorsement, or otherwise, specifically insure the terms and conditions as expressed in this Subcontract, (c) all insurance policies, except worker's compensation, shall identify PharmAthene as an additional insured under such policies, (d) all policies required to be provided by Diosynth shall be primary and not secondary to any policies held by PharmAthene; and (e) all policies referenced in Section 11.1 include waivers of all rights of subrogation.

11.4 <u>PharmAthene Requirement</u>. PharmAthene shall secure and maintain in full force and effect throughout the performance of the Program policies of insurance for (a) general liability and (b) product liability having policy limits, deductibles and other terms appropriate to the conduct of PharmAthene's business in PharmAthene's reasonable judgment.

12. Prime Contract and FAR Provisions.

12.1 <u>Applicable FAR Provisions</u>. Diosynth recognizes that, under this Subcontract, it will provide commercial item goods and/or services as defined in the Federal Acquisition Regulation ("FAR") 2.101. All work conducted by Diosynth shall be in accordance with the terms of this Subcontract, including the flow-down terms and other obligations set forth in <u>Exhibit C</u>.

12.2 Cost Accounting Standards; Support of Earned Value Management System.

(a) In providing the commercial item goods and/or services under this Subcontract, Diosynth shall be exempt from the Cost Accounting Standards pursuant to Part 48 of the Code of Federal Regulations, Section 9903.201-1(b)(6).

(b) PharmAthene will be operating an Earned Value Management System ("EVMS") for the assessment and reporting of progress to the U.S. Government with respect to work under the Prime Contract. In support of PharmAthene's EVMS, Diosynth will periodically and as otherwise requested by PharmAthene from time to time: report progress against timeline (by, among other things, updating appropriate gantt chart(s) with % completion, recorded by task); report status of work against the agreed payment schedule; report time deviations and how they will be addressed; and provide input necessary for PharmAthene to update its risk register. <u>Exhibit E</u> sets forth additional requirements with respect to the Earned Value Management System applicable to Diosynth. Diosynth shall provide the required report(s) covering these activities electronically by the 2nd working day of each calendar month. PharmAthene shall provide Diosynth with electronic templates for such reports.

13. Inspections and Audits.

13.1 <u>Inspections and Audits</u>. During the term of this Subcontract, Diosynth shall permit PharmAthene, it's authorized representatives or representatives of a Regulatory Authority to inspect and audit the Facility in connection with this Subcontract. The terms and conditions of such inspections or audits are provided in the Quality Agreement.

13.2 <u>Post-Termination Audits</u>. For five (5) years following the completion or termination of any Scope authorized under this Subcontract, the applicable Regulatory Authority and/or government audit agency shall have access to Diosynth's records and documentation related to the CMO Services being performed under this Subcontract for audit purposes during normal business hours and upon twenty (20) day's notice. Diosynth will accommodate any such a request on the specified date, and in the event that a visit on the specified date is not possible, on the next available date.

13.3 <u>Record Retention</u>. During the term of this Subcontract, Diosynth shall maintain and safeguard all materials and all other data obtained or generated by it in the performance of the Scope, including all computerized records and files in a secure environment. Archive data will be retained in accordance with the Quality Agreement for a period of five (5) years following the completion or termination of any Scope authorized under this Subcontract. Following the retention period in this Section 13.3, PharmAthene may request that Diosynth destroy any such data or return it to PharmAthene at PharmAthene's expense.

14. Force Majeure; Other Delays.

14.1 <u>Excusing Performance</u>. Neither Party shall be liable for the failure to perform its obligations under this Subcontract if such failure is not preventable, was not reasonably foreseeable at the time of contracting, and is caused by a contingency beyond such Party's reasonable control, including, but not limited to, riots, wars, fires, floods or storms, strikes, public utilities or common carriers. A failure or delay of performance of suppliers or contractors shall not excuse performance hereunder.

14.2 <u>Notice</u>. A Party claiming a right to excused performance under this Article 14 shall promptly notify the other Party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance.

14.3 <u>Resumption</u>. Each Party shall employ all reasonable efforts toward resumption of its performance hereunder if such performance is delayed or interrupted by reason of force majeure. Each Party shall bear its own costs and losses arising from any event described in Section 14.1, including all costs of resuming performance under this Section 14.3.

15. Non-Solicitation; Independent Contractors. During the term of this Subcontract, neither Diosynth nor PharmAthene shall directly solicit employees of the other Party without the other Party's prior written authorization. Neither party shall be in breach of this Article 15 to the extent that one Party's employee responds to a bona fide advertisement for employment offered to the public by the other Party. The Parties shall be deemed to be independent contractors, and this Subcontract shall not be construed to create between PharmAthene and Diosynth any other relationship such as, by way of example only, that of employer-employee, principal and agent, joint-venturer, co-partners or any similar relationship, the existence of which is expressly denied by the Parties hereto.

16. Publications; Public Statements. Diosynth may not publish any articles or make any presentations relating to any Scope or referring to data, information or materials generated as part of any Scope without the prior written consent of PharmAthene. Diosynth understands that the written consent of the federal government may also be required. Except as required by Applicable Law, or as required by the rules of the exchange on which a Party's stock is traded, no Party will originate any publication, news release or other public announcement, written or oral, whether in the public press, stockholders' reports or otherwise, relating to this Subcontract or referring to the other Party without the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed, provided, however, that information previously mutually approved for disclosure by the Parties may be reiterated by each Party without addition approval by the other Party. The Parties shall agree on a mutual press release and the timing of such press release to announce the timing of this Subcontract.

17. Subcontracting. Diosynth shall not, without prior written approval of PharmAthene (which shall not be unreasonably withheld, conditioned or delayed), subcontract any part of its responsibilities under this Subcontract to another party; provided however that Diosynth may subcontract raw material testing to an approved Diosynth vendor without obtaining prior written approval from PharmAthene. PharmAthene expressly approves of and consents to Diosynth's use of **bitter provided through as detailed in the** Scope. Diosynth shall have the obligation to ensure its subcontractors are monitored and audited through Diosynth's internal management program.

18. Assignment. This Subcontract shall not be assigned in whole or in part by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Any attempt to assign this Subcontract without such consent

shall be void and of no effect. Notwithstanding the foregoing, either Party shall be entitled, without the prior written consent of the other Party, to assign all or part of its rights under this Subcontract to a purchaser of all or substantially all of its assets, or an entity with which it may merge where it is not the surviving company, provided that the assignee agrees in writing to assume all obligations undertaken by its assignor in this Subcontract and, with respect to an assignment by Diosynth, the assignee possesses adequate technical capabilities to perform the CMO Services. The terms of this Subcontract shall inure to the benefit of all successors and permitted assigns.

19. Governing Law. This Subcontract and any Scope will be governed by and construed and interpreted in accordance with the law of the State of Maryland without reference to conflicts of law principles that may dictate application of the laws of another jurisdiction, except that any applicable flow-down clauses as set forth in <u>Exhibit C</u> will be construed and interpreted according to the federal common law of government contracts as enunciated and applied by federal judicial bodies, Boards of Contract Appeal, and quasi-judicial agencies of the U.S. Government.

20. Notices. Any notice, approval, instruction or other written communication required or permitted hereunder shall be sufficient if made or given to the other Party by personal delivery, courier service or Certified First Class U.S. Mail to the mailing address set forth below:

If to PharmAthene:

PharmAthene, Inc. One Park Place, Suite 450 Annapolis, MD 21401 Attn: Director of Contracts

with separate correspondence to

PharmAthene, Inc. One Park Place, Suite 450 Annapolis, MD 21401 Attn: General Counsel

If to Diosynth:

Diosynth RTP Inc. 101 J Morris Commons Lane Morrisville, North Carolina 27560 Attn: Henrik Edeback or Jenifer Wheat

with separate correspondence to:

Diosynth RTP Inc. c/o Schering-Plough Corporation 2000 Galloping Hill Road Kenilworth, NJ 07033 Attn: Legal Director, Business Development and Licensing

or to such other addresses provided to the other Party in writing in accordance with the terms of this Article 20. Notices of written communication made or given by personal delivery or courier service shall be deemed to have been sufficiently made or given when sent (receipt acknowledged).

21. Entire Agreement. This Subcontract, which includes the exhibits hereto, the Scope and any Change Order (s) entered into hereunder constitute the full, complete, final and integrated agreement between the Parties hereto relating to the subject matter hereof and supersede all previous written or oral negotiations, commitments, agreements, transactions, or understandings with respect to the subject matter hereof. Nothing herein shall be deemed to require the parties to enter into a Development and Supply Subcontract. Nothing in this Subcontract shall be deemed or construed to establish any precedent with respect to any other or future agreement, if any, between the Parties.

22. Amendments; No Waiver. No provision of this Subcontract may be amended, revoked or waived except in writing signed and delivered by an authorized officer of each Party. No failure or delay on the part of either Party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.

23. Validity. Should any part or provision of this Subcontract be held unenforceable or invalid, the invalid or unenforceable provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such provision in a valid and enforceable manner, and the remainder of this Subcontract shall remain binding upon the Parties.

24. Headings. The descriptive headings in this Subcontract are inserted for the convenience of reference only and are not intended to be part of or affect the meaning of or interpretation of this Subcontract.

25. Execution in Counterparts. This Subcontract may be executed, either by original or by facsimile signature, in one or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

26. Dispute Resolution. The Parties shall attempt in good faith to resolve any dispute arising out of this Subcontract. Except for claims for injunctive relief as provided in Section

26.6, any dispute, controversy or claim arising under, out of or in connection with this Subcontract, or the validity, enforceability, construction, performance or breach hereof, shall be submitted by the Parties to binding arbitration as the exclusive forum for resolving such dispute in lieu of filing suit in a court of law or seeking other remedies. The Parties agree not to take any action, including the filing of any lawsuit or other proceeding, in contravention thereof.

26.1 <u>Binding Arbitration</u>. Binding arbitration will be conducted in Washington, D.C. in accordance with: (i) the Federal Arbitration Act; (ii) the then-current commercial arbitration rules of the American Arbitration Association (the "AAA"); and (iii) this Subcontract. The terms set forth in this Subcontract will control in the event of any inconsistency between such terms and the AAA rules.

26.2 <u>Arbitrator</u>. The arbitration will be conducted by a single arbitrator reasonably familiar with the technology and business covered by this Subcontract selected by mutual agreement of the Parties. If the Parties fail to select an arbitrator within thirty (30) days following the date of either party's notice of demand to conduct arbitration, then the AAA will, in accordance with its rules, appoint an arbitrator reasonably familiar with the technology and business covered by this Subcontract. The award of the arbitrator will be in writing setting forth findings of fact and conclusions of law.

26.3 Judgment and Fees. Judgment on the arbitrator's award will be final and binding upon the Parties and may be entered in any court having jurisdiction thereof. The arbitrator's fees will be shared equally by the Parties and each party will bear its own costs and attorneys' fees; provided that the arbitrator may in his or her discretion award to the prevailing Party the costs and expenses incurred by the prevailing Party in connection with the arbitration proceeding.

26.4 Discovery. All papers, documents, or evidence, whether written or oral, filed with or presented in connection with the arbitration proceeding shall be considered confidential and not disclosed to anyone without prior written consent of the Parties. Highly sensitive documents produced by a producing party may be designated "outside counsel only", and in that event, subject to any de-designation by the arbitrator, shall be limited to outside counsel only, may not be shown to any officer, director, employee or independent contractor of the non-producing party (except non-party expert witnesses), and may not be shown to any attorney or patent agent that is responsible for prosecuting patent applications for the nonproducing party ("patent counsel"). In the event that any attorney, patent counsel or a nonparty expert witness is given access to such "outside counsel only" documents of the producing party, such person may not thereafter have any role in the prosecution of patents for the nonproducing party for a period of not less than one year. Nothing herein shall limit a party's counsel with respect to that party's own highly sensitive documents. In all events, documents produced pursuant to the arbitration shall not be used for any purpose other than the conduct of the arbitration. The arbitrator shall permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. Each party shall be permitted but not required to take the deposition of not more

than five (5) persons, each such deposition not to exceed seven (7) hours in length. If the arbitrator believes that exceptional circumstances exist, and additional discovery is necessary for a full and fair resolution of the issue, the arbitrator may order such additional discovery as the arbitrator deems necessary. At the hearing the Parties may present testimony (either by live witness or deposition) and documentary evidence.

26.5 <u>Pre-Arbitration Dispute Resolution</u>. No dispute under this Subcontract shall be referred to arbitration under this Article 26 until the following procedures in this Section 26.5 have been satisfied. Executive officers of Diosynth and PharmAthene shall meet as soon as practicable, as reasonably requested by either Party to review any dispute with respect to the interpretation of any provision of this Subcontract or the Quality Agreement, or with respect to the performance of either Party under this Subcontract or the Quality Agreement. If the dispute is not resolved by the officers by mutual agreement within thirty (30) days after a meeting to discuss the dispute, either Party may at any time thereafter provide the other Party written notice specifying the terms of such dispute in reasonable detail and notifying the other Party of its decision to institute arbitration proceedings under Article 26.

26.6 <u>Injunctive Remedy</u>. Nothing in this Subcontract shall limit the right of either Party to seek to obtain in any court of competent jurisdiction any injunctive relief and seeking or obtaining such equitable relief shall not be deemed a waiver of this Subcontract to arbitrate. For clarity, any such equitable remedies shall be cumulative and not exclusive and are in addition to any other remedies that either Party may have under this Subcontract or Applicable Law.

27. Survival. The rights and obligations of the Parties set forth in Sections 2.1(b), 2.5, 4.3, 4.4, Article 5, Article 8, Article 9, Article 10, Section 13.2 and 13.3, Article 16 and Article 26 shall survive expiration or earlier termination of this Subcontract.

PharmAthene, Inc.

Name

Title

IN WITNESS WHEREOF, the Parties have executed this Subcontract as of the Effective Date.

Diosynth RTP Inc.

Title:

Stephen A. Spearman, Ph.D., MBA

Name General Manager

Title: By: F Name: Henr

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Exhibit A

Scope of Work for Technology Transfer, Scale-Up and cGMP Manufacturing of rPA Drug Substance

Diosynth Biotechnology

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EXHIBIT B

Program Price and Payment Schedule

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EXHIBIT C

Prime Contract Flow-Down Terms

Incorporation of FAR Clauses: The Federal Acquisition Regulation ("FAR") clauses clauses referenced below are incorporated herein by reference, with the same force and affect as if they were given in there full text, during the performance of this Contract. The reference to the Contractor in the FAR clauses shall mean the Diosynth acting as the immediate subcontractor to PharmAthene.

The full text of a FAR clause may be accessed electronically at: http://www.arnet.gov

Notes:

- Substitute PharmAthene for "Government" or United States as applicable throughout this clause.
- Substitute PharmAthene "Director of Contracts" for "Contracting Officer," "Administrative Contracting Officer," and "ACO" throughout this clause.
- Insert "and PharmAthene after "Government" or Contracting Officer throughout this clause.
- 4. Insert "or PharmAthene" after Government throughout this clause.
- Communication or notification required under this clause from or to the Contracting Officer and to and from the Contracting Officer shall be through PharmAthene.
- "Contracting Officer" shall mean the US Government Contracting Officer for PharmAthene's government Prime Contract under which this Contract is entered.

Item #	FAR Section	Date	Title	
3	52.246-16	Apr 1984	Responsibility for Supplies	See Note 1: title passes upon formal acceptance. Does not eliminate right of rejection
8	52.203-12	Sept 2005	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)	See Note 3: Required Certification by Subcontractor shall be submitted upon written request.
9	52.203-13	Dec 2007	Contractor Code of Business Ethics and Conduct	
11	52.211-5	Aug 2000	Material Requirements	See Note 2
12	52.222-19	Jan 2006	Child Labor – Cooperation with Authorities and Remedies	

13	52.222-20	Dec 1996	Walsh-Healey Public Contracts Act	Applicable if the work is to be performed in United States, Puerto Rico, and or the US Virgin Islands.
14	52.222-21	Feb 1999	Prohibition of Segregated Facilities	
15	52.222-26	Mar 2007	Equal Opportunity	
16	52.222-35	Sept 2006	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	
17	52.222-36	Jun 1998	Affirmation Action for Workers with Disabilities	
18	52.222-37 پار	Sept 2006	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	
19	52.222-50	Aug 2007	Combating Trafficking in Persons	Must be flown down to Contractor's subcontractors
21	52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over \$100,000)	
22	52.225-1	Jun 2003	Buy American Act – Supplies	
23	52.225-13	Feb 2006	Restrictions on Certain Foreign Purchases	See Notes 5 and 6
24	52.227-1	Jul 1995	Authorization and Consent	See Notes 3 and 4
25	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)	See Note 3
27	52.227-14	Jun 1987	Rights in Data – General	See Notes 1 and 2
89	52.222- 39	Dec. 2004	Notification of Employee Rights Concerning Payment of Union Dues or Fees	
90	52.247- 64	Feb 2006	Preference for Privately Owned U.SFlag Commercial Vessels	

EXHIBIT D

Quality Agreement

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Definitions and Abbreviations

Analytical Test Methods	Methods used for analytical testing, including Standard Test Methods and Compendial Methods.
Anomalous	A result that does not follow the expected trend, either in comparison with other batches or with respect to previous results collected during a stability study.
API	Active Pharmaceutical Ingredient, may be used interchangeably with Bulk Drug Substance.
Approval	The term "Approval" is defined as concurrence between PharmAthene and Diosynth, such as agreement on a proposed Change, as evidenced in writing and signed by both companies' Authorized Quality Representatives.
Approved Supplier	A supplier who has met minimum approval standards and who has been approved to provide required items or services that may impact product quality.
Authorized Quality Representatives	An individual named within the Quality Agreement with the authority to resolve any disputes or conflicts relating to this Quality Agreement in a timely and equitable manner and in compliance with all applicable quality and regulatory requirements.
Batch	Batches are defined as the material represented at the end of the processing step for Bulk Drug Substance.
Batch Packet	 Relevant documentation to be transferred to PharmAthene to facilitate the release of a Batch. This packet consists of copies of QA reviewed; executed processing batch records all Deviations and NOEs, which references CAPA's initiated investigations in-process and release assay results including raw data Certificate of Analysis (CoA) or analytical results QA disposition of product statement batch genealogy (when applicable) restriction summary facility summary including associated laminar flow environmental data

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Bulk Drug Substance (BDS)	Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the Drug Product. Such substances are intended to furnish pharmacological activity or other direct effect on the diagnosis, cure mitigation, treatment, or prevention of disease or to affect the structure and function of the body.
Certificate of Analysis (CoA)	An authentic document that states that a specific batch of material has been evaluated in accordance with the Item Specification for that material.
Certificate of Conformance (CoC)	A PharmAthene supplied document that states a specific lot of material has been evaluated by PharmAthene and conforms to all product and regulatory requirements for further manufacturing or release.
сGMP	Current Good Manufacturing Practices pursuant to (a) the U.S. Federal Food, Drug and Cosmetics Act as amended (21 USC 301 et seq.), (b) U.S. regulations in Title 21 of the U.S. Code of Federal Regulations Parts 210, 211, 600 and 610, (c) the EU Guide to Good Manufacturing Practice for Medicinal Products, Volume 4, Part II including relevant sections of DIR 2003/94/EC, and (d) International Conference on Harmonization (ICH) Guidance for Industry Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.
Change Management	Any change that: (a) has the potential to impact the quality of PharmAthene's Product; (b) impacts the regulatory commitments and/or reporting requirements of the bulk drug substance; (c) requires re-qualification or re-validation of PharmAthene's methods, process or reference standards; and/or (d) results in changing or modifying PharmAthene's approved Item Specifications, test methods or any document approved by PharmAthene.
Critical Raw Materials	Critical raw materials are raw materials that have the potential to impact process performance attributes and/or product quality, compromise the final formulation components or combine structurally or chemically with the active pharmaceutical ingredient or drug product.
Critical Consumable	A consumable that comes into direct contact with the product post the CSIB stage.

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Date of Manufacturing	At Diosynth determined from the first date of fill into final container or packaging for intermediate or Bulk Drug Substance.
Deviation	An unplanned event requiring investigation with 1) may affect the quality or compliance status of the product, process, materials, equipment or facility involved or 2) may not be in alignment with regulatory submissions.
Disposition	A recommendation given by Diosynth Quality on the suitability of the Intermediate or BDS for further processing.
Drug Substance (DS)	Synonymous with Bulk Drug Substance (BDS).
Drug Próduct	The dosage form in the final immediate packaging intended for clinical use.
Exception	An exception to a validation protocol is either a deviation from or modification to pre-established acceptance criteria; or an issue encountered after approval of the protocol that requires retesting or additional test plans.
For Cause Visit	The term "for cause visit" is used to describe site visits, other than internal audits or business discussions, for the purpose of reviewing documentation, facilities or processes related to a specific deviation affecting Product disposition.
Item Specification	A set of criteria to which a material must conform to be considered acceptable for its intended use.
Master Batch Record	A detailed description of PharmAthene specific production process outlining the different actions an operator has to perform to complete the BDS production process. A scaled copy of the master batch record is the batch production record.
Notice of Events (NOE)	Events which are not considered deviations. These events have no impact to products or materials because the incident is a departure from Standard Operating Procedures (SOPs), manufacturing/testing instructions, maintenance/calibration out of tolerances, environmental monitoring excursions, deemed minor in nature and can be verified by existing documentation available at the time of observation.
Out-of-Specification (OOS)	A test that is valid but the sample result does not comply with the established specification. In this case, "result" is defined as the final reportable value as determined according to the test
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	method. Such a reportable value may be comprised of multiple individual determinations (i.e., replicates) as per the test method. Only reportable values are compared to specifications; therefore only a reportable value may constitute an OOS.
Process Consumable	Disposable equipment or equipment parts that may/may not come in contact with an intermediate or bulk drug substance. A consumable may be single or for multiple use, and may/may not be sterile.
Process Consumables	Process Consumables include any Process Consumable or Raw Material used in the manufacture of an intermediate or BDS that do not themselves participate in a chemical or biological reaction. Such other materials include: media, resins, filters, membranes, product-contact materials or surfaces, disposable analytical test kits, analytical columns dedicated to the Program, disposable containers, and subcontracted analytical testing are considered to be process consumables.
Process Profiling	A campaign of three (or more) batches performed at scale, in advance of Process Validation, to demonstrate the final process can perform effectively and reproducibly and meet the pre- defined acceptance criteria.
Product	Any (a) API/Bulk Drug Substance, or (b) Drug Product comprised of API/Bulk Drug Substance, or (c) intermediate(s) of (a) or (b), in each case as specified in the applicable Scope.
Production Batch Record	An accurate reproduction of a Master Batch Record used as instruction for and documentation of production activities.
QC Raw Data	Analytical worksheets or notebook pages used to record analyses, including details of preparation and expiry dates of reagents, sample and standard solutions and details of instruments used and associated printouts, sequences and methods. For HPLC, single injection reports for all injections, this includes integration events and the sequence table. For SDS-PAGE and IEF, original gel scans, processed gels and details of processing parameters. Any analytical report or CoA from a sub-contractor.
Raw Material	Any ingredient intended for use in the manufacture of an intermediate or API, including those that may not appear in the final formulation. These include chemicals used directly and/or indirectly in the manufacturing process.
Release	Dispositioned material is approved by PharmAthene for further processing, as evidence by Diosynth's receipt of PharmAthene's CoC.
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Significant Deviation	An unplanned event requiring investigation which has a known serious negative impact on the quality of the product, process, materials, equipment or facility, represents a quality system failure with serious negative impact, or is not in alignment with regulatory submissions.
Standard Test Methods	An approved document describing a method of testing which establishes a particular course of action or way of performing an activity as established by Diosynth.
Statement of Compliance	A Diosynth QA Disposition of Product Statement stating that a specific Batch of BDS complies with all Product, GMP and regulatory requirements and is signed by an authorized representative of Diosynth.
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EXHIBIT E

Earned Value Management System

- 1. Reporting
 - a. Diosynth shall provide a detailed schedule in line with the Work Breakdown Structure (WBS), provided by PharmAthene.
 - b. Diosynth shall submit monthly reports to PharmAthene compared against the agreed baseline plan. The monthly reports will be submitted electronically by the end of the 2nd business day following the end of each calendar month.
 - c. Diosynths' reporting will be submitted in accordance with the WBS structure. Each report must include:
 - i. Monthly Technical Progress Report by work package;
 - ii. Any schedule changes or slippages by work package; and
 - iii. An updated cash flow analysis spreadsheet.

2. Schedule

- a. Setting the Baseline schedule
 - PharmAthene will provide Diosynth with a WBS for its portion of the work.
 - ii. Diosynth will provide a detailed schedule (Microsoft project gantt) that breaks down the tasks into activities that are four (4) weeks or less in duration. Some management activities may be longer, but tasks that are discretely measurable and/or have defined products should follow this guideline wherever possible.
- b. Monthly Schedule Status Reports
 - i. Diosynth shall provide schedule updates to PharmAthene on a monthly basis (in accordance with the project schedule outlined above). Actual start and end dates must be reported and percentage (%) completion against all active activities. Any proposed changes to the forward planned activities should be listed, for discussion/agreement by PharmAthene.
- 3. Budget

- a. Diosynth shall provide a payment schedule by work package to PharmAthene. The time-phased budget will include all subcontracted costs, purchased materials costs as well as Diosynth costs. This payment schedule will be structured to show how the invoices will be presented.
- b. Monthly Status Reports
 - i. As the program progresses, changes to the cost and schedule may be negotiated between PharmAthene and Diosynth. If those changes impact either the program Master Schedule or budget, those changes must be formally approved.
- c. Cost to complete. Diosynth shall highlight in the monthly report any changes to the Scope or to the proposed costs, and therefore any change to the overall cost to complete.
- 4. Risk Management
 - a. Diosynth shall, however, provide input and feedback to PharmAthene during routine program status meetings on high impact/high probability risks and opportunities on the program and discuss and agree how identified risks should be mitigated. Monthly program management updates shall include any changes in risk assessment.

Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)

I, David P. Wright, certify that:

- 1. I have reviewed this Form 10-Q of PharmAthene, Inc. for the quarter ended September 30, 2009;
- 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(s) 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 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 statement for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) 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 the 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.

Dated: November 13, 2009

/s/ David P. Wright Name: David P. Wright Title: Chief Executive Officer

Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)

I, Charles A. Reinhart III, certify that:

- 1. I have reviewed this Form 10-Q of PharmAthene, Inc. for the quarter ended September 30, 2009;
- 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(s) 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 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 statement for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) 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 the 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.

Dated: November 13, 2009

/s/ Charles A. Reinhart III Name: Charles A. Reinhart III Title: Chief Financial Officer

Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

In connection with the Quarterly Report of PharmAthene, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2009, as filed with the Securities and Exchange Commission (the "Report"), I, David P. Wright, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David P. Wright

David P. Wright Chief Executive Officer November 13, 2009

Certification Pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code

In connection with the Quarterly Report of PharmAthene, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2009, as filed with the Securities and Exchange Commission (the "Report"), I, Charles A. Reinhart III, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Charles A. Reinhart III

Charles A. Reinhart III Chief Financial Officer November 13, 2009