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# 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, 2008**

**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** | **20-2726770** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **One Park Place, Suite 450, Annapolis, MD** | **21401** |
| (Address of principal executive offices) | (Zip Code) |

**(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 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.

| | | | |
|---|---|---|---|
| o | Large Accelerated Filer | o | Accelerated Filer |
| o | Non-Accelerated Filer (Do not check if a smaller reporting company) | x | 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 13, 2008 was 25,886,977.

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**PHARMATHENE, INC.**

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**PART I**

**Item 1. Financial Statements**

**PHARMATHENE, INC.**

**CONSOLIDATED BALANCE SHEETS**

| | September 30, 2008 (unaudited) | December 31, 2007 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 10,140,919 | $ 40,582,643 |
| Restricted cash | 5,000,000 | — |
| Short-term investments | 3,107,108 | 12,153,945 |
| Accounts receivable | 10,912,569 | 4,005,693 |
| Other receivables | 543,309 | 1,240,069 |
| Prepaid expenses and other current assets | 844,375 | 492,294 |
| Total current assets | 30,548,280 | 58,474,645 |
| Long-term restricted cash | 9,500,000 | — |
| Property and equipment, net | 6,191,093 | 6,571,024 |
| Patents, net | 1,128,222 | 1,312,991 |
| Other long-term assets | 183,588 | 183,588 |
| Deferred costs | 251,193 | 68,884 |
| Goodwill | 2,502,909 | — |
| Total assets | $ 50,305,285 | $ 66,611,132 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities: | | |
| Accounts payable | $ 3,205,696 | $ 1,393,664 |
| Accrued expenses and other liabilities | 9,299,964 | 3,602,886 |
| Convertible notes | 12,932,973 | — |
| Current portion of long-term debt | 4,000,000 | 4,000,000 |
| Total current liabilities | 29,438,633 | 8,996,550 |
| Other long-term liabilities | 7,793,835 | 374,040 |
| Long-term debt | 1,904,936 | 16,668,458 |
| Total liabilities | 39,137,404 | 26,039,048 |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value; 100,000,000 shares authorized; 22,113,684 and 22,087,121 shares issued and outstanding; respectively, | 2,212 | 2,209 |
| Additional paid-in capital | 128,705,555 | 126,490,647 |
| Accumulated other comprehensive income | 1,075,828 | 1,481,779 |
| Accumulated deficit | (118,615,714) | (87,402,551) |
| Total stockholders' equity | 11,167,881 | 40,572,084 |
| Total liabilities and stockholders' equity | $ 50,305,285 | $ 66,611,132 |

See the accompanying notes to the consolidated financial statements.

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**PHARMATHENE, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2008 | 2007 | 2008 | 2007 |
| | (unaudited) | | (unaudited) | |
| Contract revenue | $ 10,643,705 | $ 3,371,299 | $ 27,377,207 | $ 8,672,485 |
| Other revenue | 32,461 | 831 | 53,612 | 7,831 |
| | 10,676,166 | 3,372,130 | 27,430,819 | 8,680,316 |
| Operating expenses: | | | | |
| Research and development | 9,414,093 | 3,647,329 | 26,475,436 | 10,734,292 |
| General and administrative | 4,803,190 | 3,150,894 | 14,655,971 | 8,605,147 |
| Acquired in-process research and development | 225,000 | — | 16,131,002 | — |
| Depreciation and amortization | 205,409 | 209,420 | 641,425 | 518,713 |
| Total operating expenses | 14,647,692 | 7,007,643 | 57,903,834 | 19,858,152 |
| Loss from operations | (3,971,526) | (3,635,513) | (30,473,015) | (11,177,836) |
| Other income (expense): | | | | |
| Interest income | 200,979 | 275,550 | 1,034,914 | 424,763 |
| Gain on the extinguishment of debt | — | 1,206,743 | — | 1,206,743 |
| Other income (expense) | 49,035 | — | 49,035 | — |
| Interest expense | (628,470) | (593,893) | (1,947,245) | (1,365,165) |
| Change in market value of derivative instruments | 7,604 | 2,430,199 | 123,148 | 2,423,370 |
| Total other income (expense) | (370,852) | 3,318,599 | (740,148) | 2,689,711 |
| Net loss | (4,342,378) | (316,914) | (31,213,163) | (8,488,125) |
| Accretion of redeemable convertible preferred stock to redemptive value | — | (653,197) | — | (4,133,733) |
| Net loss attributable to common shareholders | $ (4,342,378) | $ (970,111) | $ (31,213,163) | $ (12,621,858) |
| Basic and diluted net loss per share | $ (0.20) | $ (0.07) | $ (1.41) | $ (2.44) |
| Weighted average shares used in calculation of basic and diluted net loss per share | 22,095,545 | 14,154,116 | 22,089,949 | 5,181,823 |

See the accompanying notes to the consolidated financial statements.



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**PHARMATHENE, INC.**

**CONSOLIDATED STATEMENTS OF CASHFLOWS**

| | Nine months ended September 30, | |
|---|---|---|
| | 2008 | 2007 |
| | (unaudited) | (unaudited) |
| Operating activities | | |
| Net loss | $ (31,213,163) | $ (8,488,125) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Acquired in-process research and development | 16,131,002 | |
| Change in market value of derivative instruments | (123,148) | (2,423,370) |
| Extinguishment of debt | — | (1,206,743) |
| Depreciation and amortization | 641,425 | 522,050 |
| Compensatory option expense | 1,976,497 | 304,543 |
| Non cash interest expense on debt | 1,292,598 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,521,184) | (1,631,850) |
| Prepaid expenses and other assets | (124,912) | 314,279 |
| Accounts payable | (1,446,808) | 957,503 |
| Accrued expenses | 5,012,542 | 3,873,094 |
| Net cash used in operating activities | (9,375,151) | (7,778,619) |
| **Investing activities** | | |
| Purchases of property and equipment | (455,242) | (993,486) |
| Purchases of Avecia, net of cash acquired | (11,556,117) | — |
| Increase of restricted cash and letter of credit | (14,500,000) | — |
| Purchase of available-for-sale investments | (11,577,455) | — |
| Sales of available-for-sale investments | 20,624,293 | — |
| Net cash used in investing activities | (17,464,521) | (993,486) |
| **Financing activities** | | |
| Net cash proceeds from reverse merger with Healthcare Acquisition Corporation | — | 58,720,689 |
| Proceeds from issuance of long-term debt | — | 10,000,000 |

| | | |
|---|---|---|
| Payments of long-term debt obligations | (3,000,000) | — |
| Financing costs | (206,154) | (4,792,455) |
| Net cash (used in) provided by financing activities | (3,206,154) | 63,928,234 |
| Effects of exchange rates on cash | (395,898) | 68,832 |
| (Decrease) increase in cash and cash equivalents | (30,441,724) | 55,224,961 |
| Cash and cash equivalents, at beginning of year | 40,582,643 | 5,112,212 |
| Cash and cash equivalents, at end of the quarter | $ 10,140,919 | $ 60,337,173 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 643,331 | $ 592,514 |
| Cash paid for income taxes | $ — | $ — |

See the accompanying notes to the consolidated financial statements.



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**PHARMATHENE, INC.**
**Notes to Consolidated Financial Statements**
**September 30, 2008**
**(unaudited)**

**Note 1 - Organization and Business**

PharmAthene, Inc. ("PharmAthene" or the "Company") was incorporated under the laws of the State of Delaware as Healthcare Acquisition Corp. ("HAQ") on April 25, 2005, a special purchase acquisition corporation formed to serve as a vehicle for the acquisition of a then unidentified business. HAQ became a public company on August 3, 2005. On August 3, 2007, HAQ consummated a merger (the "Merger") with PharmAthene, Inc., a Delaware corporation ("Former PharmAthene"), pursuant to an Agreement and Plan of Merger, dated as of January 19, 2007, by and among HAQ, PAI Acquisition Corp., a Delaware corporation and a wholly-owned subsidiary of HAQ, and Former PharmAthene, whereby Former PharmAthene became a wholly-owned subsidiary of HAQ. Effective upon the consummation of the Merger, HAQ changed its name from "Healthcare Acquisition Corp." to "PharmAthene, Inc." and Former PharmAthene changed its name to "PharmAthene US Corporation." Our operations are conducted by our wholly-owned subsidiary, PharmAthene US Corporation.

Upon completion of the Merger, approximately 12.2 million shares of common stock were issued to the stockholders of Former PharmAthene and the Company assumed all of Former PharmAthene's stock options and warrants that were not cancelled as part of the Merger and 587,249 shares of common stock have been reserved for issuance upon the exercise of such options and warrants. Also, Former PharmAthene's $12.8 million of outstanding secured convertible notes ("Bridge Notes"), including interest, were exchanged for $12.3 million of new unsecured 8% convertible notes maturing on August 3, 2009 (the "Notes"). The Notes are convertible at the option of the holders into common stock at $10.00 per share and became redeemable by PharmAthene without penalty after August 3, 2008. Immediately following the closing of the Merger, the Former PharmAthene stockholders, option holders and warrant holders held approximately 56% of the common stock of PharmAthene on a fully-diluted basis and former stockholders, option holders and warrant holders of HAQ prior to the Merger owned approximately 44% of PharmAthene's common stock on a fully-diluted basis after the Merger. Following completion of the Merger, the business conducted by PharmAthene became the one operated by Former PharmAthene prior to the completion of the Merger.

On March 20, 2008, PharmAthene, Inc. and certain of its affiliates (including a newly-formed UK subsidiary, "PharmAthene UK") (collectively, "PharmAthene" or the "Company") entered into a Sale and Purchase Agreement (the "Purchase Agreement") with Avecia Biologics Limited and certain of its affiliates (collectively, "Avecia") for the acquisition of substantially all of the assets and liabilities related to Avecia's vaccines business which includes a second generation recombinant protective antigen ("rPA") anthrax vaccine, which is now referred to as SparVax™, a recombinant dual antigen plague vaccine ("rYP") which is now referred to as RypVax™, and a third generation rPA anthrax vaccine program (the "Avecia Acquisition"). On April 2, 2008, the parties amended the Purchase Agreement and the Company completed the Avecia Acquisition acquiring substantially all of the assets and assuming the liabilities, in each case exclusively associated with Avecia's biodefense vaccines business in accordance with the terms of the Purchase Agreement, as amended, including certain products, patents, trademarks, domain names and other intellectual property, license agreements, contracts, goodwill and other intangibles for approximately $18.6 million. See Note 3 Avecia Acquisition for additional information.

PharmAthene is a biopharmaceutical company focused on developing biodefense countermeasure applications. The Company is subject to those risks associated with any biopharmaceutical company that has substantial expenditures for research and development. There can be no assurance that the Company's 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, the Company operates in an environment of rapid technological change and is largely dependent on the services and expertise of its employees, consultants and other third parties.

**Note 2 - Summary of Significant Accounting Policies**

**Basis of Presentation**

These financial statements reflect the historic results of Former PharmAthene prior to the Merger and that of the combined company following the Merger, and do not include the historic financial results of HAQ prior to the completion of the Merger.

Unless specifically noted otherwise, as used throughout these consolidated financial statements, "the Company", "PharmAthene", "we", "us" or "our" refers to the business of the combined company after the Merger and the business of Former PharmAthene prior to the Merger. Unless specifically noted otherwise, as used throughout these consolidated financial statements, "HAQ" refers to the business of the Healthcare Acquisition Corp. prior to the completion of the Merger. The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States.

**Interim financial information**

During the third quarter, we identified certain immaterial items in the interim financial statements that should have been recorded in the first and second quarters of 2008. We assessed the nature and magnitude of these items in accordance with SEC Staff Accounting Bulletin No. 99, *Materiality* in determining that these errors were not material. Accordingly, we have made adjustments to our accompanying financial statements for the third quarter to correct these items in the current period. The adjustments have no effect on our September 30, 2008 balance sheet or the statement of operations for the nine months ended September 30, 2008 as all items originated in prior 2008 interim periods and have been corrected.

During the quarter ended June 30, 2008, the Company did not record certain revenue earned under government contracts during the period. However, the Company did reflect the related expenses during the quarter. As a result, the net loss for the period included the expenses without the related revenue, and the reported net loss was greater than it should have been. In addition, certain development expenses under these and other government contracts were not recorded during the proper periods. The adjustments described below also reflect the reclassification of certain expenses from general and administrative to research and development during the third quarter for employee related costs that were not properly classified. Overall, net loss for the quarters ended March 31, 2008 and June 30, 2008 was overstated by $268,000 ($0.01 per share) and $267,000 ($0.01 per share) respectively. The effect of all of these adjustments during the third quarter had the following effect on the statement of operations for the three-month period ended September 30, 2008:

**Selected Statement of Operations Data**
(amounts in thousands)

| | Three months ended September 30, 2008, without adjustments | Adjustments | Three months ended September 30, 2008, as reported |
|---|---|---|---|
| Revenue | $ 9,887 | $ 789 | $ 10,676 |
| Research and development | $ 8,271 | $ 1,143 | $ 9,414 |
| General and administrative | $ 5,692 | $ (889) | $ 4,803 |
| Operating loss | $ (4,507) | $ 535 | $ (3,972) |
| Net loss | $ (4,877) | $ 535 | $ (4,342) |
| Net loss per share | $ (0.22) | $ 0.02 | $ (0.20) |

**Principles of Consolidation**

The consolidated financial statements include the accounts of PharmAthene and its subsidiaries, PharmAthene U.S. Corporation, PharmAthene Canada, Inc., which was formed in March 2005, and PharmAthene UK Limited, which was formed in March 2008. All significant intercompany transactions and balances have been eliminated.



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**PHARMATHENE, INC.**
**Notes to Consolidated Financial Statements**
**September 30, 2008**
**(unaudited)**

**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.

**Segment Information**

The Company currently operates in one material business segment. The entire business is comprehensively managed by a single management team that reports to the Chief Executive Officer. The Company does not operate any material separate lines of business or separate business entities with respect to products or product candidates. Accordingly, the Company does not have separately reportable segments as defined by Statement of Financial Accounting Standards No. 131, *Disclosures about Segments of a Enterprise and Related Information*.

**Comprehensive Loss**

The Company reports comprehensive loss in accordance with the provisions of Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income*. Comprehensive loss includes all changes in equity for cumulative translation adjustments resulting from the consolidation of foreign subsidiaries as the financial statements of the subsidiary located outside of the United States are measured using the local currency as the functional currency. Assets and liabilities of these subsidiaries are translated at the rates of exchange at the balance sheet date. The resultant translation adjustments are included in accumulated other comprehensive income (loss), a separate component of stockholders' equity. Comprehensive loss for each of the three month periods ended September 30, 2008 and 2007 was approximately $4.5 million and $0.2 million, respectively. For the nine months ended September 30, 2008 and 2007, comprehensive loss was approximately $31.6 million and $7.2 million, respectively.

**Cash and Cash Equivalents**

Cash and cash equivalents, which consist of short-term money market accounts, are stated at cost, which approximates market value. The Company considers all highly-liquid investments with maturities of three months or less when purchased to be cash equivalents. Interest income resulting from cash and cash equivalents and short-term investments was $0.2 million and $0.3 million for the three months ended September 30, 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, interest income resulting from cash and cash equivalents and short-term investments was $1.0 million and $0.4 million, respectively.

**Restricted Cash and Letter of Credit**

In connection with the March 20, 2008 Consent and First Loan Agreement with Silicon Valley Bank and Oxford Finance Corporation, the Company maintains a segregated account at the Lenders in the amount of at least one and one-quarter times the principal amount of its obligations outstanding to the Lenders. As of September 30, 2008, the Company recorded $5.0 million and $2.5 million in short-term and long-term restricted cash, respectively, under this agreement.

As further disclosed in Note 3, the Company agreed to provide a letter of credit in the amount of $7.0 million as security for the deferred consideration related to the acquisition of assets related to the Avecia Acquisition. This letter of credit will be payable upon the earlier to occur of the completion of a financing transaction in the amount of $15.0 million or more or eighteen months following the closing of the acquisition. As of September 30, 2008, the letter of credit is shown on the balance sheet as long-term restricted cash and is included in other long term liabilities as it is due to Avecia.

**Short-Term Investments**

Short-term investments consist of investment grade government agency and corporate debt securities due within one year. All investments are classified as available-for-sale and are recorded at market value. Unrealized gains and losses are reflected in other comprehensive income. The estimated fair value of the available-for-sale securities is determined based on quoted market prices or rates for similar instruments. Management reviews the Company's investment portfolio on a regular basis and seeks guidance from its professional portfolio manager related to US and global market conditions. We assess the risk of impairment related to securities held in our investment portfolio on a regular basis and noted no impairment during the nine months ended September 30, 2008. Additionally, the Company's Audit Committee reviews the investment portfolio and strategy on an annual basis.



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**PHARMATHENE, INC.**
**Notes to Consolidated Financial Statements**
**September 30, 2008**
**(unaudited)**

**Accounts Receivable**

From inception to date, substantially all of PharmAthene's accounts receivable have been associated with US Government contracts and grants. Amounts invoiced or recorded as billed under these programs but not yet collected are reported as outstanding accounts receivable.

While the Company has a policy to provide an allowance for any amount of accounts receivable which it determines to be uncollectible and to write off any uncollectible account when the likelihood of collection is determined to be not probable, the Company has not historically found it necessary to record any write-offs of accounts receivable or to record an allowance for uncollectible accounts. At September 30, 2008, the Company's accounts receivable balance included approximately $10.9 million, including unbilled receivables of approximately $5.8 million, related to U.S Government contracts.

**Property and Equipment**

Property and equipment consists of land, building and leasehold improvements, laboratory, computer, farm and office equipment and furniture and are recorded at cost. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the respective assets as follows:

| Asset Category | Estimated Useful Life (in Years) |
|---|---|
| Building and leasehold improvements | 4 - 20 |
| Laboratory equipment | 7 |
| Furniture, farm and office equipment | 5 - 7 |
| Computer equipment | 3 |

**Intangible Assets**

Intangible assets consist of patents and are being amortized using the straight-line method over an eleven year period.

**Impairment of Long-Lived Assets**

Long-lived assets consist primarily of patents and property and equipment. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company reviews long-lived assets and certain identifiable intangibles for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. Recoverability measurement and estimating of undiscounted cash flows is done at the lowest possible level for which there is identifiable assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

**Revenue Recognition**

The Company generates its 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. The Company considers fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. The Company analyzes each cost reimbursable grant to ensure reporting of revenues gross versus net is appropriate based on the guidance in the AICPA Federal Government Contractors Guide or the Financial Accounting Standards Board's Emerging Issues Task Force Issue 99-19, *Gross Versus Net*, whichever is most appropriate. For the three and nine months ended September 30, 2008, the Company recorded approximately $0.9 million and $1.7 million of costs reimbursed from the government as a reduction to research and development expense as they are viewed as reduction of research and development costs under the guidance.

The Company's contracts may include the provisions of more than one of its services. Collaborative research and development agreements can provide for one or more of up-front license fees, research payments, and milestone payments. In these situations, the Company recognizes revenue in accordance with the Financial Accounting Standards Board's Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Accordingly, for applicable arrangements, revenue recognition includes the proper identification of separate units of accounting and the allocation of revenue across all elements based on relative fair values, with proper consideration given to the guidance provided by other authoritative literature.

Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, the Company recognizes such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process. Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as deferred revenue.



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**Research and Development and Purchased In-Process Research and Development**

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. On January 1, 2008, the Company adopted the Financial Accounting Standards Board's Emerging Issues Task Force Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. As of September 30, 2008, the Company has recorded $0.3 million in prepaid development costs relating to non-refundable advance payments. All other costs are charged to expense, as incurred.

The Company accounts for purchased in-process research and development in accordance with the SFAS No. 2, *Accounting for Research and Development Costs* ("SFAS No. 2") along with Financial Accounting Standards Board ("FASB") Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method — an interpretation of FASB Statement No. 2* ("FIN 4"). Under these standards, the Company is required to determine whether the technology relating to a particular research and development project acquired through an acquisition has an alternative future use. If the determination is that the technology has no alternative future use, the acquisition amount assigned to assets to be used in the particular research and development project is expensed. If the technology is determined to have an alternative future use, the Company capitalizes and amortizes the costs incurred over the estimated useful lives of the technology acquired.

**Share-Based Compensation**

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (Revised 2004), *Share-Based Payment* ("SFAS No. 123R") which establishes accounting for share-based awards exchanged for employee services and requires companies to expense the estimated fair value of these awards over the requisite employee service period. Under SFAS No. 123R, 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.

The Company has estimated the fair value of each award using the Black-Scholes option pricing model, which was developed for use in estimating the value of traded options that have no vesting restrictions and that are freely transferable. The Black-Scholes model considers, among other factors, the expected life of the award and the expected volatility of the Company's stock price.

Employee share-based compensation expense recognized in the three and nine months ended September 30, 2008 and 2007 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures at a rate of either 7 percent or-16.3 percent, based on the Company's historical option forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Share-based compensation expense recognized under SFAS No. 123R for the three and nine month periods ended September 30, 2008 and 2007, respectively, was:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2008 | 2007 | 2008 | 2007 |
| Research and development | $ 124,038 | $ 28,272 | $ 317,967 | $ 92,445 |
| General and administrative | 784,030 | 94,793 | 1,658,530 | 212,098 |
| Total share-based compensation expense | $ 908,068 | $ 123,065 | $ 1,976,497 | $ 304,543 |
| | | | | |
| Share-based compensation expense, per common share: | | | | |
| Basic and diluted | $ 0.04 | $ 0.01 | $ 0.09 | $ 0.06 |



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**Basic and Diluted Net Loss Per Share**

The Company applies Statement of Financial Accounting Standards No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings per share. Basic net loss per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net loss by the weighted-average number of shares outstanding for the period. Diluted net loss per share reflects the potential dilution that could occur if securities were exercised into common stock. However, for all periods presented, diluted net loss per share is the same as basic net loss attributable to common shareholders per share as the inclusion of weighted average shares of common stock issuable upon the exercise of stock options and warrants would be anti-dilutive. Securities outstanding in the amount of 16,229,900 shares for both the three and nine months ended September 30, 2008, respectively, and 15,168,000 for the three and nine months ended September 30, 2007, respectively, were excluded from the calculation of diluted net loss per share since their inclusion would be anti-dilutive.

The following table provides a reconciliation of the numerators and denominators used in computing basic and diluted net loss per share:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2008 | 2007 | 2008 | 2007 |
| Numerator: | | | | |
| Net loss | $ (4,342,378) | $ (316,914) | $ (31,213,163) | $ (8,488,125) |
| Dividends on and accretion of convertible preferred stock | — | (653,197) | — | (4,133,733) |
| Net loss available to common stockholders | $ (4,342,378) | $ (970,111) | $ (31,213,163) | $ (12,621,858) |
| | | | | |
| Denominator: | | | | |
| Weighted-average shares of common stock outstanding - basic diluted | 22,095,545 | 14,154,116 | 22,089,949 | 5,181,823 |

**Income Taxes**

The Company accounts for income taxes in accordance with Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes* ("SFAS 109"), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. SFAS 109 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. In evaluating the need for a valuation allowance, the Company takes into account various factors, including the expected level of future taxable income and available tax planning strategies. If actual results differ from the assumptions made in the evaluation of the Company's valuation allowance, the Company records a change in valuation allowance through income tax expense in the period such determination is made.

The Company adopted the provisions of Financials Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes- an Interpretation of FASB Statement No. 109* ("FIN 48") on January 1, 2007. The Company has analyzed tax positions in all jurisdictions where it is required to file an income tax return and has concluded that it does not have any material unrecognized tax benefits. As a result, there were no material effects on our financials position or results of operations due to the implementation of FIN 48. As of September 30, 2008, the Company has recognized a valuation allowance to the full extent of its deferred tax assets since the likelihood of realization of the benefit cannot be determined. The Company believes that any of its uncertain tax positions would not result in adjustments to its effective income tax rate because likely corresponding adjustments to deferred tax assets would be offset by adjustments to recorded valuation allowances. We file a US federal income tax return as well as returns for various state and foreign jurisdictions. The Company's income taxes have not been subject to examination in any tax jurisdiction since its inception. Accordingly, all income tax returns filed by the Company are subject to examination in the relevant taxing jurisdictions.

The Company policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of tax expense. As of the date of adoption of FIN 48, we did not have interest or penalties accrued for any unrecognized tax benefits and there was no interest expense recognized during the current year.

**Fair Value of Financial Instruments**

The Company's financial instruments include primarily cash and cash equivalents, accounts receivable, short-term investments and other current assets, accounts payable, accrued and other liabilities, notes payable 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



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and accrued and other liabilities, the carrying amounts of these assets and liabilities approximate their fair value. The fair value of the Company's notes payable and long term debt approximates fair value, based on current incremental borrowing rates of the Company.

**Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents, short-term investments and accounts receivable. The Company maintains its cash, cash equivalent and short-term investment balances in the form of money market accounts, debt and equity securities and overnight deposits with financial institutions that management believes are creditworthy. All of the Company's accounts receivables are from either the U.S., Canadian or United Kingdom governments.

**Reclassifications**

Certain prior period amounts in the consolidated financial statements have been reclassified to conform to the current period presentation.

**Recent Accounting Pronouncements**

In December 2007, the EITF reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements*. In EITF 07-1, the EITF defined a collaborative arrangement as a contractual agreement involving a joint operating activity between two (or more) parties, each of which is both (1) an active participant in the activity and (2) exposed to significant risks and rewards that are dependent on the joint activity's commercial success. Additionally, EITF 07-1 provides information to be disclosed on an annual basis by each collaborative arrangement participant for every significant collaborative arrangement, including the nature of the arrangement, the participant's rights and obligations under the arrangement, the accounting policy followed for collaborative arrangements, and the income statement classification and amounts arising from the collaborative arrangement. EITF 07-01 is effective for financial statements issued for fiscal years beginning after December 15, 2008. This consensus is to be applied retrospectively for all periods presented. We are evaluating the potential impact of this consensus and do not expect it to have a material effect on our financial statements.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141 (revised 2007), *Business Combinations* ("SFAS 141R"). SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company is currently evaluating the potential impact of the adoption of SFAS 141R on its consolidated financial position and results of operations.

**Note 3 – Avecia Acquisition and Goodwill**

On April 2, 2008, the Company completed the Avecia Acquisition, acquiring substantially all of the assets and assuming the liabilities exclusively associated with Avecia's biodefense vaccines business in accordance with the terms of the Purchase Agreement, as amended, including certain products, patents, trademarks, domain names and other intellectual property, license agreements, contracts, goodwill and other intangibles. The transaction was valued at approximately $18.6 million, consisting of the initial consideration of $10.0 million in cash, deferred consideration of approximately $7.0 million, secured by a letter of credit, and transaction costs of approximately $1.6 million. The Purchase Agreement also provides for potential milestone considerations totaling $23.0 million and royalties of 1%-2.5% of net sales depending on product sales within the period of ten years from the consummation of the Avecia Acquisition.

The assets acquired were accounted for in accordance with the provisions of Statement of Financials Accounting Standards No. 141, *Business Combinations* ("SFAS No. 141"). All of the tangible and intangible assets acquired and liabilities assumed of Avecia Vaccines were recorded at their estimated fair market values on the acquisition date. The preliminary purchase price was allocated as follows:

| **(in thousands)** | | |
|---|---|---|
| Current assets | $ | 5,340 |
| Current liabilities | | (5,417) |
| Goodwill | | 2,502 |
| In-process research and development | | 16,131 |
| Total purchase consideration | $ | 18,556 |



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In connection with the transaction, the Company recorded, in the second quarter 2008, a charge of $15.9 million for acquired research projects associated with products in development for which, at the acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed. An additional charge of $0.2 million to acquired in-process research and development was recorded in the third quarter of 2008 as the Company revised its purchase price allocation.

*Pro Forma Financial Information*

The unaudited financial information in the table below summarizes the combined results of operations of PharmAthene and Avecia Vaccines on a pro forma basis (as if the companies had been combined as of the beginning of each of the periods presented). The pro forma financial information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition and the reverse merger with Healthcare Acquisition Corp had taken place at the beginning of each of the periods presented. The pro forma financial information for all periods presented includes adjustments to interest expense, interest income and related tax effects.

The unaudited pro forma financial information for the nine months ended September 30, 2008 and 2007 combines the historical results for PharmAthene for the nine months ended September 30, 2008 and 2007 and the historical results for Avecia for the same periods. The unaudited pro forma financial information for the three months ended September 30, 2007 combines the historical results for PharmAthene for the three months ended September 30, 2007 and the historical results for Avecia for the same period. The unaudited financial information for the three months ended September 30, 2008 reflects the operations of the consolidated company post acquisition.

| | **Three months ended September 30,** | | **Nine months ended September 30,** | |
|---|---|---|---|---|
| **(in thousands, except per share data)** | **2008** | **2007** | **2008** | **2007** |
| | **(unaudited)** | **(unaudited)** | **(unaudited)** | **(unaudited)** |

| | | | | |
|---|---|---|---|---|
| Total revenue | $ 10,676 | $ 12,254 | $ 32,056 | $ 35,325 |
| Net loss | (4,342) | (86) | (31,602) | (7,794) |
| Basic and diluted net loss per share | $ (0.20) | $ (0.00) | $ (1.43) | $ (1.50) |

**Note 4 – Fair Value Measurements**

Effective January 1, 2008, the Company adopted Statement of Financials Accounting Standards No. 157, *Fair Value Measurements*, ("SFAS No. 157") which defines 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. SFAS No. 157 establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize 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.

The Company's adoption of SFAS No. 157 did not have a material impact on its consolidated financial statements. The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) 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. FSP FAS 157-2 delayed the effective date for all nonfinancial assets and liabilities until January 1, 2009, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis.

As of September 30, 2008, financial assets and liabilities subject to fair value measurements were as follows:

| | As of September 30, 2008 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Balance |
| Assets | | | | |
| Available-for-sale securities | $ 3,107,108 | $ — | $ — | $ 3,107,108 |
| Liabilities | | | | |
| Derivative | $ — | $ 1,502 | $ — | $ 1,502 |



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The Company recognized gains of approximately $115,000 and approximately $505,000 on available-for sale securities investments for the three and nine months ended September 30, 2008, respectively.

**Note 5 - Property and Equipment**

Property and equipment consisted of the following:

| | September 30, 2008 | December 31, 2007 |
|---|---|---|
| Land | $ 529,763 | $ 560,081 |
| Building and leasehold improvements | 5,528,385 | 5,670,628 |
| Furniture, farm and office equipment | 266,649 | 219,855 |
| Laboratory equipment | 833,509 | 866,084 |
| Computer equipment | 793,150 | 556,601 |
| | 7,951,457 | 7,873,249 |
| Less accumulated depreciation | (1,760,364) | (1,302,225) |
| Property and equipment, net | $ 6,191,093 | $ 6,571,024 |

Depreciation expense for the three months ended September 30, 2008 and 2007 was $164,547 and $157,164, respectively. Depreciation expense for the nine months ended September 30, 2008 and 2007 was $505,898 and $394,938, respectively.

**Note 6 - Patents**

In conjunction with the Company's purchase of the assets of Nexia Biotechnologies Ltd. in March 2005 (the "Nexia Acquisition"), the Company recorded intangible assets related to patents of $1,407,000 with a useful life of eleven years. The gross carrying value and accumulated amortization, adjusted based on current foreign currency rates, was $1,665,984 and $537,762, respectively, at September 30, 2008. The gross carrying value and accumulated amortization, adjusted based on current foreign currency rates, was $1,761,329 and $448,338, respectively, at December 31, 2007. For the three months ended September 30, 2008 and 2007, the Company has recorded amortization expense of $40,862 and $52,256, respectively. For the nine months ended September 30, 2008 and 2007, the Company has recorded amortization expense of $135,527 and $123,775, respectively. Amortization expense related to the above intellectual property is expected to be approximately $127,910 per year for the next five years.

**Note 7 – Accrued Expenses and Other Liabilities**

Accrued expenses and other liabilities consisted of the following:

| | September 30, 2008 | December 31, 2007 |
|---|---|---|
| Accrued development expenses | $ 6,092,029 | $ 1,486,918 |
| Accrued other services | 1,257,157 | 552,098 |
| Accrued employee expenses | 1,814,141 | 856,659 |
| Restructuring liability | — | 498,596 |
| Deferred rent | 49,262 | 46,754 |
| Accrued interest | 57,009 | 89,357 |
| Other | 30,365 | 72,504 |
| Accrued expenses and other liabilities | $ 9,299,963 | $ 3,602,886 |

Accrued expenses consist primarily of research and development activities and legal and professional services.

**Note 8 - Long Term Debt**

**Convertible 8% Notes**

The Convertible Notes accrue interest at an interest rate of 8% per annum, except in the event of a default in which instance the interest rate will increase to 12%. The principal amount of the Notes and any accrued interest are 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. The Notes have a maturity date of August 3, 2009. The Company recognized interest expense of approximately $431,100 and $1.2 million on the Notes for the three and nine months ended September 30, 2008. For the three months ended September 30, 2007, the Company recognized interest expense of $243,100. The Company recognized interest expense of approximately $84,600 and $558,000 for the three and nine months ended September 30, 2007 related to Former PharmAthene's Bridge Notes.





**$10 Million Debt Financing**

On March 30, 2007, the Company entered into a $10 million credit facility with Silicon Valley Bank and Oxford Finance Corporation (together, the "Lenders"). Under the credit facility the Company borrowed $10 million, which bears interest at the rate of 11.5%. Pursuant to the terms of the loan and security agreement evidencing the credit facility, the Company made monthly payments of interest only through September 30, 2007 and, thereafter, makes monthly payments of principal and interest over the remaining 30 months of the loan. The loan is secured by a security interest on all of the Company's assets other than certain intellectual property. The Company may prepay the debt provided it pays certain prepayment fees. In connection with the credit facility, the Company issued to Silicon Valley Bank and Oxford Financial Corporation warrants, which expire on March 30, 2017 to purchase an aggregate of 100,778 shares of common stock with an exercise price of $4.06 per share.

The loan agreement ("Loan Agreement") contains customary affirmative and negative covenants which, among other things, restricts the Company's ability to undertake certain acquisitions, incur certain indebtedness or make certain investments. Due to the then-anticipated merger with Avecia Biologics Limited, PharmAthene sought to obtain the consent of the Lenders to the Avecia Acquisition and entered into a Consent and First Loan Modification Agreement, dated as of March 20, 2008, with the Lenders (the "Loan Modification Agreement") pursuant to which, among other things, the Lenders consented to the Avecia Acquisition provided that (i) PharmAthene (or its UK subsidiary involved in the acquisition) is the surviving entity in the acquisition, (ii) the total initial cash consideration upon the consummation of the acquisition does not exceed $11 million, (iii) the consummation of the acquisition will not otherwise result in an event of default as defined under the Loan Agreement, after giving effect to the acquisition and (iv) within 20 days following the consummation of the acquisition, PharmAthene causes its UK subsidiary to become a co-borrower or a secured guarantor under the Loan Agreement.

The Loan Modification Agreement also amends the Loan Agreement to provide (i) that PharmAthene shall maintain, at all times, at a segregated account, at either Silicon Valley Bank or Silicon Valley Bank Securities, unrestricted and unencumbered cash or cash equivalents in the amount of at least one and one-quarter times the outstanding obligations of PharmAthene to the Lenders, (ii) that if PharmAthene or any of its affiliates creates or acquires any subsidiary, PharmAthene shall notify the Lenders and take all such action as to cause each domestic subsidiary to guarantee the obligations of PharmAthene under the Loan Agreement granting a continuing pledge and security interest in and to the assets of such subsidiary, (iii) that PharmAthene shall deliver to the Lenders a control agreement with M&T Bank granting the lenders a first perfected security interest in the accounts of PharmAthene held at M&T Bank and (iv) amending the definition of "material adverse change" under the Loan Agreement to provide that a material adverse change shall be a determination of the Lenders based upon information available to them and in their reasonable judgment that there is a reasonable likelihood that PharmAthene shall fail to comply with one or more of the financial covenants contained in the Loan Agreement. As discussed in Note 2, the Company has recorded $5.0 million and $2.5 million in short-term and long-term restricted cash, respectively, in connection with provision (i) above.

The Company has recognized interest expense on this credit facility of approximately $203,500 and $693,700 for the three and nine months ended September 30, 2008. The Company has recognized interest expense on this credit facility of approximately $294,700 and $592,500 for the three and nine months ended September 30, 2007.

**Note 9 - Commitments and Contingencies**

**Leases**

The Company leases offices in the United States under a 10 year office lease, which commenced on May 1, 2007. Additionally, with the Avecia Acquisition, the Company leases offices in the United Kingdom under a lease expiring in 2010. Remaining annual minimum payments are as follows:

| | | |
|---|---|---|
| 2008 | $ | 157,000 |
| 2009 | | 630,800 |
| 2010 | | 603,300 |
| 2011 | | 404,300 |
| 2012 and thereafter | | 2,450,400 |
| | $ | 4,245,800 |

For the three months ended September 30, 2008 and 2007, total rent expense under operating lease agreements was approximately $197,700 and $231,200, respectively. Total rent expense under operating lease agreements was approximately $598,600 and $410,600 for the nine months ended September 30, 2008 and 2007, respectively.

During September 2008, the Company entered into an agreement to lease additional office space at its headquarters in Annapolis, MD commencing in the first half of 2009. The Company has the option to terminate this lease before December 31, 2008 but would be required to pay termination fees of either approximately $140,000 or $373,000 depending on when the Company elects to terminate the lease.



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**License Agreements**

In January 2006, the Company licensed certain patent rights from a research company. The license agreement required a $50,000 up-front payment. Additionally, the agreement provides for a sublicense fee of 20% and milestone payments of $25,000 upon the granting of a US patent, $200,000 upon the initiation of certain studies or trials, and $250,000 upon BLA approval. Upon commercialization, the license agreement requires royalty payments equal to a specified percentage of future sales of products for both government procurement and commercial market sales subject to the license through the expiration of the licensed patents. No sublicense fee or milestone payments have been incurred for the nine months ended September 30, 2008 and 2007, respectively.

In August 2006, the Company entered into a research and licensing agreement allowing for the licensing of certain patent rights from a research company. The agreement includes research expense reimbursement payments and certain development milestone payments. Upon commercialization, the license agreement requires royalty payments equal to a specified percentage of future sales of products for both government procurement and commercial market sales subject to the license through the expiration of the licensed patents. No research expense reimbursement payments or milestone payments have been incurred for the nine months ended September 30, 2008 and 2007, respectively.

In connection with the Nexia Acquisition, the Company acquired a license agreement originally executed in September 2004 for the rights to certain technologies. This agreement included an option to license product processing technology necessary to perform development of Protexia® as required under the Company's government contract with the Department of Defense. The Company executed a new licensing agreement with a development company on March 12, 2007 which results in a license to all technology provided under the original agreement including the necessary purification technology previously included in an option and access to additional information and technology deemed to be essential for development of Protexia® and performance under the Department of Defense contract. Under the new agreement, the Company must pay initial license fees totaling $700,000 and royalty payments based on net sales, with $100,000 due in the first year. These expenses are eligible for reimbursement by the US Government under the contract with the Department of Defense. During 2007, the Company expensed $100,000 related to this agreement. During the third quarter of 2008, the Company expensed an additional $200,000 related to this agreement.

In connection with the Avecia Acquisition, the Company acquired license agreements with The Defence Science and Technology Laboratory of the United Kingdom Ministry of Defence ("DSTL") originally executed May and December 2006 for the rights to certain technologies. These agreements allow for the licensing of certain patents and technology necessary to perform development of the rPA and rYP programs as required under the Company's government contracts with the NIAID. Upon commercialization, the license agreements require that PharmAthene 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.

**Note 10– Medarex Collaboration**

In November 2004, the Company and Medarex, Inc. ("Medarex") entered into a collaboration agreement under which the companies are working to develop and commercialize MDX-1303 (known as Valortim®), a fully human monoclonal antibody targeting the *Bacillus anthracis* protective antigen. MDX-1303 was developed by Medarex using its UltiMAb Human Antibody Development System®, and this antibody is currently in clinical development by PharmAthene for use against human anthrax infection.

Under the terms of the agreement, Medarex and PharmAthene have agreed jointly to continue to investigate the potential for MDX-1303 to be used as a therapeutic for individuals with active disease as well as for prophylactic treatment of individuals exposed to anthrax. For the three months ended September 30, 2008 and 2007, PharmAthene recorded research and development expenses of approximately $103,000 and $106,600 related to the development activities for MDX-1303. Research and development expenses under this agreement of approximately $315,000 and $526,100 were recorded for the nine months ended September 30, 2008 and 2007, respectively. PharmAthene is fully responsible for funding all future research and development activities that are not supported by government funds. The companies will share future profits, if any, according to a pre-agreed allocation percentage.

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**Note 11– Stockholders' Equity**

**2002 Long-Term Incentive Plan**

In connection with the Merger, the Company assumed awards that were granted by Former PharmAthene under Former PharmAthene's 2002 Long-Term Incentive Plan (the "2002 Plan") which provided for the grant of incentive stock options, restricted common stock and stock appreciation rights. Under the 2002 Plan, option awards were granted to eligible employees, officers, directors and consultants. The fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model based on selected inputs. The board of directors of Former PharmAthene established the vesting schedule for the awards. Grants made to new employees upon commencement of employment, typically provided for annual vesting of 25% of shares on the first anniversary date of hire. For annual grants to existing employees, grants typically provided for monthly vesting over four years. These options had a maximum term of no more than 10 years. As of September 30, 2008, an aggregate of 400,876 shares of common stock are reserved for issuance upon the exercise of outstanding assumed awards. The 2002 Plan was not assumed by the Company in connection with the Merger. No further grants are being made under the 2002 Plan.

The following tables summarize the activity of the 2002 Plan:

| | Shares | Weighted-Average Exercise Price | Weighted-Average Contractual Term |
|---|---|---|---|
| Outstanding, January 1, 2007 | 404,314 | $ 3.64 | 7.7 years |
| Granted | 121,950 | 3.90 | |
| Exercised | 67 | 3.90 | |
| Forfeited | (84,340) | 4.10 | |
| Outstanding, December 31, 2007 | 441,857 | $ 3.67 | 7.7 years |
| Granted | — | | |
| Exercised | — | | |
| Forfeited | (40,981) | 3.69 | |
| Outstanding, September 30, 2008 | 400,876 | $ 3.69 | 6.7 years |
| Exercisable, September 30, 2008 | 304,839 | $ 3.50 | 6.7 years |
| | | | |
| Vested and expected to vest, September 30, 2008 | 336,736 | | |

**2007 Long-Term Incentive 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 any independent consultants. At that time, the Company reserved 3,500,000 shares of common stock for distribution of awards under the 2007 Plan. At the 2008 annual meeting held on June 13, 2008, the Company's shareholders approved proposed amendments to the 2007 Plan, increasing from 3,500,000 shares to 4,600,000 shares the maximum number of shares subject to the plan and adding an evergreen provision pursuant to which the number of shares subject to 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 no more than ten years.

On August 30, 2007, the Board of Directors of the Company granted to the Company's Chief Executive Officer options to purchase 780,000 shares of common stock pursuant to the 2007 Plan at an exercise price of $5.36 per share, determined as the closing price of the Company's common stock on such date, and granted him 100,000 restricted shares of common stock. The options have a term of ten years and both the options and restricted stock award vest over a five year period with 25% vesting on the first anniversary of the grant, and the remainder vesting monthly on a pro rata basis over the succeeding 48 months following the first anniversary.





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The following tables summarize the activity of the 2007 Plan as related to option awards:

| | Shares | Weighted-Average Exercise Price | Weighted-Average Contractual Term |
|---|---|---|---|
| | | | |

| | | | | |
|---|---|---|---|---|
| Outstanding, January 1, 2007 | — | $ | — | — |
| Granted | 2,356,867 | | 5.25 | 9.5 years |
| Exercised | — | | — | |
| Forfeited | (54,717) | | 5.20 | |
| Outstanding, December 31, 2007 | 2,302,150 | $ | 5.25 | 9.5 years |
| | | | | |
| Granted | 1,336,750 | $ | 2.75 | 9.6 years |
| Exercised | — | | — | |
| Forfeited | (55,677) | | 5.17 | |
| Outstanding, September 30, 2008 | 3,583,223 | | 4.12 | 9.2 years |
| Exercisable, September 30, 2008 | 326,721 | $ | 5.20 | 9.2 years |
| | | | | |
| Vested and expected to vest, September 30, 2008 | 3,009,907 | | | |

The following tables summarize the activity of the 2007 Plan as related to restricted stock awards:

| | Shares | | Weighted-Average Exercise Price | Weighted-Average Contractual Term |
|---|---|---|---|---|
| Restricted Shares | | | | |
| Outstanding, January 1, 2007 | — | $ | — | — |
| Granted | 216,836 | | 5.27 | 9.9 years |
| Vested | — | | — | |
| Forfeited | (1,529) | | 5.20 | |
| Outstanding, December 31, 2007 | 215,307 | $ | 5.27 | 9.9 years |
| Granted | 17,500 | | 3.18 | 9.7 years |
| Vested | (26,563) | | 5.36 | |
| Forfeited | — | | — | |
| Outstanding, September 30, 2008 | 206,244 | $ | 5.12 | 8.9 years |
| | | $ | | |
| | | | | |
| Vested and expected to vest, September 30, 2008 | 218,370 | | 5.36 | |



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***Valuation assumptions used to determine fair value of share-based compensation***

The fair value for the 2008 and 2007 awards were estimated at the date of grant using the Black-Scholes option-pricing model using the following assumptions:

| | September 30, | |
|---|---|---|
| | 2008 | 2007 |
| Weighted average volatility | 66% | 72% |
| Risk-free interest rate | 3.0-3.9% | 4.6% |
| Expected annual dividend yield | — | — |
| Expected weighted average life, in years | 7.0 | 9.8 |

The valuation assumptions were determined as follows:

- Weighted average volatility: We determine the expected volatility by using an average historical volatility from comparable public companies with an expected term consistent with ours.
- Risk-free interest rate: The yield on zero-coupon US Treasury securities for a period that is commensurate with the expected term of the award.
- Expected annual dividend yield: The estimate for annual dividends is zero because we have not historically paid a dividend and do not intend to do so in the foreseeable future.
- Expected life: The expected term of the awards represents the period of time that the awards are expected to be outstanding. We use historical data and expectations for the future to estimate employee exercise and post-vest termination behavior and do not stratify employees into multiple groups.

**Unit Purchase Option**

In connection with the initial public offering, 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 different exercise price as further discussed in the warrant section below. This option became exercisable at $10.00 per

unit on August 3, 2007, and expires on July 28, 2010. The exercise price and number 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.

Under an amendment to the unit purchase option agreement, the Company is 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.

**Warrants**

In connection HAQ's initial public offering in 2005, HAQ sold 9.4 million warrants to acquire shares of common stock at an exercise price of $6.00 Each warrant entitles the holder to purchase from the Company one share of common stock and expires four years from the effective date of the offerings on July 28, 2009. Furthermore, in connection with the initial public offering, HAQ 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 225,000 warrants to acquire shares of common stock at an exercise price of $7.50 per share.

Pursuant to the credit facility further discussed in Note 8, the Company issued 100,778 common stock warrants with an exercise price of $4.06 per share.



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**PHARMATHENE, INC.**
**Notes to Consolidated Financial Statements**
**September 30, 2008**
**(unaudited)**

**Note 12 – Subsequent Events**

On September 30, 2008 PharmAthene signed a securities purchase agreement with Kelisia Holdings Ltd., an indirect wholly-owned subsidiary of Panacea Biotec Limited, pursuant to which Kelisia acquired 3,733,334 shares of PharmAthene common stock at a negotiated price of $3.50 per share and a 12-month warrant to purchase up to 2,745,098 additional shares of PharmAthene common stock at an exercise price of $5.10 per share. The Company received gross proceeds from this transaction, which closed on October 10, 2008, of approximately $13.1 million.

Upon the closing of the transaction, Panacea Biotec, through its subsidiary Kelisia, owns approximately 14.5% of PharmAthene's issued and outstanding common stock. While the warrant gives Kelisia the right to purchase up to an additional 2,745,098 shares, this right is subject to a stock ownership cap, following any warrant exercise, of 19.99% of PharmAthene's issued and outstanding common stock as of such exercise date.



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**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 SparVax™ 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, 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-K and 10-Q under the caption "Risk Factors" and in its other reports filed with the U.S. Securities and Exchange Commission (the "SEC"). Forward-looking statements describe management's current expectations regarding our future plans, strategies and objectives and are generally 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 payments under government contracts or grants, potential regulatory approvals, future product advancements, anticipated financial or operational results and expected benefits from our acquisition of the biodefense vaccines business ("Avecia Acquisition") from Avecia Biologics Limited and certain of its affiliates ("Avecia"). Forward-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. 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.*

*Unless specifically noted otherwise, as used throughout this Quarterly Report on Form 10-Q, "the Company", "PharmAthene", "we", "us" or "our" refers to the business of the combined company after the merger with Former PharmAthene (the "Merger") and to the business of Former PharmAthene prior to the Merger, and "HAQ" refers to the business of Healthcare Acquisition Corp. prior to the Merger.*

The following discussion should be read in conjunction with the consolidated financial statements for the Company which present PharmAthene's results of operations for the three and nine month periods ended September 30, 2008 and 2007 as well as its financial positions at September 30, 2008 and December 31, 2007, 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, 2007 filed on March 31, 2008, including the consolidated financial statements contained therein, and the Form 8-K/A filed on June 19, 2008 presenting the period historical financial statements for the vaccines business acquired from Avecia Biologics.

**Overview**

PharmAthene is a biodefense company engaged in the development and commercialization of medical countermeasures against biological and chemical weapons. In addition to our own efforts, we collaborate with pharmaceutical companies to support clinical development of product candidates. 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,
- RypVax™ - a recombinant dual antigen vaccine for pneumonic and bubonic plague ("rYP"), and
- a third generation rPA anthrax vaccine.

Our lead product candidate, SparVax™, is a second generation recombinant (produced using genetic engineering technology) version of Protective Antigen for use against human anthrax infection. It is intended to be used to protect individuals before and potentially after exposure to the *Bacillus anthracis* (the anthrax bacterium). Phase I and Phase II clinical trials involving over 700 healthy adult human subjects have been completed with the clinical trials showing that SparVax™ is safe, well tolerated and induces





an immune response in humans. Earlier preclinical studies have demonstrated that SparVax™ can protect non-human primates against a lethal aerosol challenge of Ames strain anthrax spores.

On February 29, 2008, the U.S. Department of Health and Human Services issued a formal Request for Proposal (RFP-BARDA-08015) 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.

Valortim®, our second most advanced product candidate, is a fully human monoclonal antibody designed to protect against and treat human inhalation anthrax, the most lethal form of infection caused by the *Bacillus anthracis* bacterium. The Company is co-developing Valortim® with Medarex, Inc., a biopharmaceutical company that specializes in developing fully human antibody-based therapeutic products, and will share with Medarex any profits derived from sales of Valortim®. Preclinical studies in animal models have demonstrated Valortim® to be effective as both a prophylaxis and a therapeutic for inhalation anthrax infection. The Company and Medarex have completed dosing of healthy volunteers in a Phase I open-label, dose-escalation clinical trial to evaluate the safety, tolerability, immunogenicity (eliciting an undesired immune response), and pharmacokinetics (the study of absorption, metabolism and action of drugs) of a single dose of Valortim® administered intravenously or intramuscularly. No drug-related serious adverse events were reported. Final results from the Phase I trial were presented at the Infectious Disease Society of America meeting in October 2006. Valortim® was granted Fast Track Status by the U.S. Food and Drug Administration (the "FDA"), which may permit the Company to submit portions of a Biologics License Application ("BLA") or efficacy supplement before the complete BLA is submitted. Fast Track Status can expedite the review process depending upon whether the FDA has sufficient resources to review the portions submitted. In addition, the FDA granted Valortim® orphan drug status for the treatment of inhalation anthrax**.** On September 28, 2007, the NIAID and the Biomedical Advanced Research and Development Authority ("BARDA") awarded to PharmAthene a $13.9 million contract for the advanced development of Valortim® as an anti-toxin therapeutic to treat inhalation anthrax infection, of which $0.7 million have been received through September 30, 2008. The contract will continue to be funded in installments through fiscal year 2009.

Protexia®, our nerve agent countermeasure, is a recombinant form of human butyrylcholinesterase, a naturally occurring enzyme ("BChE"), for use in the prophylaxis and treatment of organophosphate chemical nerve agent poisoning. Preclinical studies in animal models suggest that Protexia® may be effective prophylactically and therapeutically for chemical nerve agent poisoning. We filed an Investigational New Drug application, or IND, with the FDA in the third quarter of 2008 and began a Phase I clinical trial in humans in October 2008**.**

The procurement process for the scale-up development and sale of Protexia® is already underway with the U.S. Department of Defense (the "DoD"), the department charged with purchasing biodefense countermeasures for military use. The DoD requested competitive bids in a Request for Proposal for a recombinant form of BChE drug for the prophylaxis treatment of chemical nerve agent poisoning, which we submitted in November 2005. In September 2006, the Company was awarded a multi-year contract by the DoD. The contract provides an initial $41 million for the advanced development of Protexia® through March 2009 and, thereafter, the U.S. Government, at its sole discretion, may elect to continue development assistance with further funding of $65 million. Assuming development milestones are met and contract extensions are exercised by the U.S. Government, at its sole discretion, and that the U.S. Government elects to procure an initial 90,000 doses of Protexia® from PharmAthene, we could receive up to $219 million in total funding under this contract (including the $41 million and $65 million disclosed above for advanced development), of which $31.5 million has been received through September 30, 2008.

RypVax™ is a recombinant dual antigen plague vaccine intended to be used to protect individuals before exposure to *Yersinia pestis* (the bacterium that causes plague). In the war fighter, vaccination is anticipated to take place before deployment, to be administered in two or three doses over several weeks, and to be sufficient to induce protective immunity. This vaccine candidate has successfully completed three Phase I clinical trials in healthy adult human subjects. The Phase I trials demonstrated that RypVax™ is safe, well tolerated and elicits an immune response. In preclinical animal models, RypVax™ demonstrated the ability to fully protect against a lethal aerosol challenge.

In 2004, Avecia Vaccines was awarded a multi-year contract, valued at up to approximately $50 million, from the NIAID to support the advanced development of the plague vaccine for military use. PharmAthene acquired this contract as part of the Avecia Acquisition. As of September 30, 2008, $33.3 million has been received by Avecia Vaccines and PharmAthene under this contract. Future government funding for RypVax™ beyond our existing contract (which expires in the first half of 2010) remains uncertain at this time.

The main objective for our third generation rPA anthrax vaccine is to meet the U.S. government's longer term primary goal to obtain an rPA-based anthrax vaccine that can be stored, transported and used without the need for a conventional "cold chain" — an important advantage for civilian biodefense deployment within the U.S. Strategic National Stockpile ("SNS"). In particular, we



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intend to produce a vaccine that can maintain stability for three years at 35º C and induce protective immunity in two or fewer doses. By way of comparison, the currently available first generation anthrax vaccine (BioThrax® Anthrax Vaccine Adsorbed), which was initially licensed by the FDA in 1970, requires six doses over a period of eighteen months to achieve protective immunity and is required to be stored at between 2º and 8º C.

Two grants from the NIH made in 2005 and 2007 in the aggregate amount of $6.9 million for funding of research activities through April 2009 have supported the development of our third generation anthrax vaccine candidate. On September 25, 2008, we were awarded a contract by the National Institutes of Health, National Institute of Allergy and Infectious Diseases ("NIAID") for additional development work on our third generation rPA anthrax vaccine. We expect to receive funding of up to approximately $13.2 million during the initial three year base period of the contract. Assuming all development milestones are met and all contract extensions are exercised by NIAID at its sole discretion, PharmAthene could receive up to approximately $83.9 million over a nine year period (including the base period) under this contract, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestone events.

For the next several years, we believe our main customer will be national governments, primarily the U.S. Government. Currently, the U.S. Government may, at its discretion, purchase critical biodefense products for the U.S. Strategic National Stockpile prior to FDA approval based on Emergency Use Authorization enabled under the Project Bioshield legislation. On an ongoing basis we monitor notices for requests for proposal, grants and other potential sources of government funding that could potentially support the development and commercialization of our product candidates. Nevertheless, changes in government budgets, priorities and agendas as well as political pressures could result in a reduction in overall government financial support for the biodefense sector in general and/or specifically the product candidates we are developing. Our existing contracts with the government typically contain provisions that permit the government unilaterally to cancel or reduce the scope of these contracts. (For further information, see *"Risk Factors — Risks Related to Our Business — U.S. government agencies have special contracting requirements which give them the ability to unilaterally control our contracts.")* As a result, further development of our product candidates and ultimate product sales to the government could be delayed or stopped altogether.

**Recent Events**

***Strategic Financing with Panacea Biotec Subsidiary***

On September 30, 2008 we signed a securities purchase agreement with Kelisia Holdings Ltd., an wholly-owned subsidiary of Panacea Biotec Limited, pursuant to which Kelisia acquired approximately 3.73 million shares of PharmAthene common stock at a negotiated price of $3.50 per share and a 12-month warrant to purchase up to approximately 2.75 million additional shares of PharmAthene common stock at an exercise price of $5.10 per share. We received gross proceeds from this transaction, which closed on October 10, 2008, of approximately $13.1 million.

Upon the closing of the transaction, Panacea Biotec, through its subsidiary Kelisia, owned approximately 14.5% of PharmAthene's issued and outstanding common stock. While the warrant gives Kelisia the right to purchase up to an additional 2,745,098 shares, this right is subject to a stock ownership cap, following any warrant exercise, of 19.99% of PharmAthene's issued and outstanding common stock as of such exercise date.

PharmAthene and Kelisia also entered into an investor rights agreement in connection with the strategic financing, which provides Kelisia with registration rights in connection with the shares issued at closing and issuable upon exercise of the warrant. In addition, the investor rights agreement grants rights to Kelisia to maintain its ownership percentage by purchasing shares of all common stock,



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preferred stock or securities convertible or exchangeable into common stock that we issue in private placements within three years of the closing (except issuances in connection with M&A transactions, employee benefit plans, commercial financing transactions, strategic alliances and in certain other circumstances). Furthermore, for a three year period following the closing, Kelisia, Panacea Biotec and their affiliates are prohibited from purchasing, offering to purchase, entering into any agreement relating to the purchase of, or otherwise engaging in any transaction relating to, any of our securities. Kelisia and its affiliates are also subject to certain restrictions on transferring the warrant, the shares issued at closing and issuable upon exercise of the warrant, and any rights in the warrant or such shares.

In a related agreement, (i) Panacea Biotec has agreed, among other things, to continue to have at least a majority ownership of Kelisia while Kelisia owns at least 500,000 of our shares, and (ii) both Panacea Biotec and PharmAthene have agreed to engage in discussions from time to time relating to, among other things, the manufacture and/or process development by Panacea Biotec of a portion of our proprietary biodefense medical countermeasures under development and Panacea Biotec has granted us a right of first negotiation with respect to the possible commercialization and marketing of certain of Panacea Biotec's products.

**Results of Operations**

***Revenue***

The Company recognized revenues of $10.7 million and $3.4 million during the three months ended September 30, 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, the Company recognized revenues of $27.4 million and $8.7 million, respectively. These revenues consisted primarily of contract funding from the U.S. Government for the development of Protexia®, SparVax™ and RypVax™. As a result of the Avecia Acquisition in the second quarter of 2008, and particularly the acquired U.S. Government contracts supporting the development of the SparVax™, third generation rPA and RypVax™ product candidates, revenues for the three and nine month periods ended September 30, 2008 were further boosted by $5.5 million and $8.9 million, respectively.

During the three and nine months ended September 30, 2008 and 2007, PharmAthene recognized revenues related to U.S. Government awarded contracts and grants as follows:

- Under the Company's September 2006 contract for the advanced development of Protexia®, the Company recognized $4.9 million and $3.4 million of revenue for the three months ended September 30, 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, revenue recognized under this contract was $17.6 million and $8.6 million, respectively.

- Under the September 2007 contract for the advanced development of Valortim®, the Company recognized $0.5 million and $1.0 million of revenue in the three and nine months ended September 30, 2008, respectively. No amounts were recognized during the corresponding periods in 2007.

- Under our contract for the development of SparVax™, which the Company acquired as part of the Avecia Acquisition, the Company recognized approximately $3.8 million and $6.0 million of revenue for the three and nine months ended September 30, 2008, respectively. Revenue for the three months ended September 30, 2008 includes approximately $0.6 million of revenue relating to research conducted during the quarter ended June 30, 2008 for the anthrax program. The associated costs for this research were accrued during the quarter ended June 30, 2008.

- Under the contract for the advanced development of a plague vaccine RypVax™, which the Company acquired as part of the Avecia Acquisition, the Company recognized approximately $1.6 million and $2.9 million of revenue for the three and nine months ended September 30, 2008, respectively. Revenue for the three months ended September 30, 2008 includes approximately $0.2 million of revenue relating to research conducted during the quarter ended June 30, 2008 for the plague program. The associated costs for this research were accrued during the quarter ended June 30, 2008.

***Research and Development Expenses***

The Company's research and development expenses were $9.4 million and $3.6 million for the three months ended September 30, 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, expenses related to research and development activities were $26.5 million and $10.7 million, respectively. These expenses resulted from research and development activities related to programs for Valortim® and for Protexia®, as well as expenses related to the SparVax™ and RypVax™ programs which



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were acquired in the second quarter of 2008. These research and development expenses are primarily funded through US Government contracts and grant awards. The Company incurred both direct expenses, which included salaries and other costs of personnel, raw materials and supplies, and 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 months ended September 30, 2008 and 2007, respectively, were attributable to research programs as follows:

| | Three months ended September 30, | |
|---|---|---|
| (amounts in millions) | 2008 | 2007 |
| Anthrax vaccines | $ 4.1 | $ 0.6 |
| Chemical nerve agent protectants | 3.1 | 2.6 |
| Recombinant dual antigen plague vaccine | 2.0 | — |
| Internal research and development | 0.2 | 0.4 |
| Total research and development expenses | $ 9.4 | $ 3.6 |

Research and development expenses for the nine months ended September 30, 2008 and 2007, respectively, were attributable to research programs as follows:

| | Nine months ended September 30, | |
|---|---|---|
| (amounts in millions) | 2008 | 2007 |
| Anthrax vaccines | $ 11.5 | $ 2.1 |
| Chemical nerve agent protectants | 10.4 | 7.2 |
| Recombinant dual antigen plague vaccine | 4.1 | — |
| Internal research and development | 0.5 | 1.4 |
| Total research and development expenses | $ 26.5 | $ 10.7 |

Research and development expense increased $5.8 million for the quarter ended September 30, 2008 as compared to the quarter ended September 30, 2007 primarily as a result of increased process development, manufacturing activities and clinical development of Anthrax vaccines of $3.1 million. Additionally, the Company incurred costs related to manufacturing and clinical development associated with the recombinant dual antigen vaccine program acquired from Avecia Vaccines in the second quarter of 2008 of approximately $2.0 million. Research and development costs further increased as a result of additional internal resource costs. For the nine months ended September 30, 2008, research and development costs increased $15.8 million as compared to the nine months ended September 30, 2007. In addition to the $9.7 million of costs incurred due to newly acquired programs, anthrax vaccine program expense increased $2.5 million as a result of increased development activity to date this year, and chemical nerve agent protectant program expenses increased $2.7

million as a result of increased process development and manufacturing activities. Research and development costs further increased as a result of additional internal resource costs.

The research and development expense amounts disclosed above for the three and nine months ended September 30, 2008 are net of the following cost reimbursements under PharmAthene's government grants - See Note 2 to our Financial Statements - Summary of Significant Accounting Policies – Revenue Recognition:

- In October 2006, the National Institutes of Health (NIH) Countermeasures Against Chemical Threats (Counter ACT) Research Network awarded a $1.7 million grant to support continued development of Protexia®. The Company recognizes cost reimbursements under this contract as a reduction to offset research expenses. Through September 30, 2008, $0.1 million of funding on this grant has been recognized as an offset to research and development costs.

- The Company was awarded approximately $2.7 million in congressional appropriations from the United Stated Army Medical Research and Material Command (USAMRMC) for the development to advance the Valortim® program. We recognized cost reimbursements of approximately $0.3 million and $0.8 million under this funding as a reduction to offset research expenses for the three and nine month periods ended September 30, 2008, respectively, and approximately $0.1 million for the nine months ended September 2007.

- PharmAthene recognized cost reimbursements of approximately $0.6 million and $0.9 million under the NIH grant funding for development of its third generation anthrax vaccine candidate, which it acquired from Avecia Vaccines in the second quarter of 2008, as a reduction to offset research expenses for the three and nine months ended September 30, 2008.



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Internal research and development costs include activities related to the development of future programs, support costs for internal resources and non-cash stock compensation expenses.

***General and Administrative Expenses***

General and administrative functions for the Company include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal, and compliance. For each function, the Company 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 awards. Indirect costs such as facilities, utilities and other administrative overhead are also included in general and administrative expenses.

Expenses associated with general and administrative functions for the Company were $4.8 million and $3.2 million for the three months ended September 30, 2008 and 2007, respectively. For the nine months ended September 30, 2008 and 2007, the Company incurred general and administrative costs of $14.7 million and $8.6 million, respectively. These amounts include non-cash stock compensation expense of $0.8 million and $0.1 million for the three months ended September 30, 2008 and 2007, respectively, and $1.7 million and $0.2 million for the nine months ended September 30, 2008 and 2007, respectively.

General and administrative expenses increased $1.6 million for the three months ended September 30, 2008 as compared to the three months ended September 30, 2007 primarily due to increased stock compensation expense (non-cash expenditure) of $0.7 million and an additional $0.6 million due to higher legal costs associated with compliance and operating as a publicly traded entity and increased employee costs of $0.3 million resulting from the additional headcount acquired through the Avecia Acquisition. Expenses related to general and administrative activities increased $6.1 million for the nine months ended September 30, 2008 as compared to the nine months ended September 30, 2007. This increase in expenses resulted primarily from increased employee costs, including travel expenses, of $2.8 million, increased non-cash stock compensation expense of $1.4 million and an additional $1.7 million in consulting and legal services associated with compliance and operating as a publicly traded entity, costs related to preparing and submitting various bids and proposals and litigation efforts.

***Acquired In-process Research and Development***

For the nine months ended September 30, 2008, PharmAthene recorded acquired in-process research and development of $16.1 million associated with the Avecia Acquisition. PharmAthene paid a total purchase consideration of $17.0 million, with the acquisition valued at $18.6 million after the inclusion of acquisition costs. The $16.1 million represented the value of the purchase attributable to the development programs and technology, which was determined to have no future alternative use and was charged to acquired in-process research and development.

***Depreciation and Intangible Amortization***

Depreciation and intangible amortization expense was $0.2 million and $0.2 million for the three months ended September 30, 2008 and 2007, respectively, and $0.6 million and $0.5 million for the nine months ended September 30, 2008 and 2007, respectively. Depreciation expense for the three months ended September 30, 2008 and 2007 was $0.2 million and $0.2 million respectively, and for the nine months ended September 30, 2008 and 2007 was $0.5 million and $0.4 million, respectively. Depreciation expenses result primarily from farm building improvements, leasehold improvements related to newly leased office space and lab equipment.

For the nine months ended September 30, 2008 and 2007, PharmAthene incurred amortization expense of $0.1 million and $0.1 million, respectively.

***Other Income and Expenses***

Other income and expenses primarily consists of income on the Company's investments, interest expense on the Company's debt and other financial obligations and the change in market value of our derivative financial instruments. For the three months ended September 30, 2008 and 2007, the Company's interest income was $0.2 million and $0.3 million, respectively. For the nine months ended September 30, 2008 and 2007, PharmAthene recognized interest income of $1.0 million and $0.4 million, respectively. The increase in interest income for the three and nine months ended September 30, 2008 as compared to the same periods in 2007 resulted from higher average investment balances in the first nine months of 2008 as a result of the $58.7 million cash proceeds from the Merger received in September 2007.

The Company incurred interest expense of $0.6 million and $0.6 million for the three months ended September 30, 2008 and 2007, respectively. Interest expense for the nine months ended September 30, 2008 and 2007 was $1.9 million and $1.4 million,



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respectively. Interest expense results primarily from PharmAthene's outstanding 8% convertible notes and its $10.0 million credit facility.

During the fiscal year ended December 31, 2006, the Company originally issued 8% convertible notes in an aggregate principal amount of $11.8 million. These notes plus accrued interest were converted into new convertible 8% notes (the "Notes") in an aggregate principal amount of $12.3 million in conjunction with the Merger on August 3, 2007. The Company recognized interest expense related to the Notes of $0.4 million and $1.2 million for the three and nine months ended September 30, 2008, respectively, and $0.2 million for both the three and nine months ended September 30, 2007.

The Company entered into a $10.0 million credit facility on March 30, 2007 with Silicon Valley Bank and Oxford Financial Corporation. The Company recognized interest expense of $0.2 million and $0.7 million related to this facility for the three and nine months ended September 30, 2008, respectively. For the three and nine months ended September 30, 2007, the Company recognized interest expense of $0.3 million and $0.6 million, respectively.

PharmAthene recorded a change in market value of $0.1 million related to the conversion feature of its Notes for the nine months ended September 30, 2008.

**Liquidity and Capital Resources**

***Overview***

The Company's primary cash requirements are to fund its research and development programs, general and administrative expense, and acquisition activity. Our cash requirements in future periods could change materially as a result of changes in our business and strategy. These changes could arise from our management team's evaluation of our business strategy, the progress of our research and development activities and clinical programs, licensing activities, acquisitions, divestitures or other corporate developments.

Since inception in March 2001, we have not generated positive cash flow. 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 to utilize these types of financing vehicles and potentially others to help fund our future operating and capital requirements.

Our consolidated financial statements have been prepared on a basis which assumes that PharmAthene 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. The Company has incurred cumulative net losses and expects to incur additional losses in conducting further research and development activities. The Company does not have commercial products and, given the substantial costs relating to the development of pharmaceutical products, has comparatively limited 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 financing on commercially reasonable terms or at all or that we will be able to secure additional funding through government contracts and grants.

Continuation of PharmAthene as a going concern is dependent upon, among other things, the success of the Company's research and development programs and our ability to obtain adequate financing. The Company's consolidated financial statements do not



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include any adjustments relating to recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

At our current rate of cash consumption, if we do not access sufficient additional funding through contracts and grants with the U.S. and foreign governments, and we do not defer or renegotiate repayment of the outstanding Notes in the amount of $12.9 million as of September 30, 2008, we will need to engage in one or more additional financing transactions of the types listed above by no later than August 3, 2009, the current maturity date of the Notes.

***Sources and Uses of Cash***

Cash and cash equivalents for the Company were $10.1 million and $40.6 million at September 30, 2008 and December 31, 2007, respectively. The $30.4 million decrease in cash and cash equivalents as of September 30, 2008 from December 31, 2007 primarily was attributable to (i) the Avecia Acquisition, in connection with which we paid an initial consideration of $10.0 million and funded the $7.0 million letter of credit, (ii) $7.5 million funding of restricted cash obligations per our amended loan agreement with Silicon Valley Bank and Oxford Finance Corporation, (iii) the repayment of debt, and (iv) the funding of operations.

On October 10, 2008, in exchange for gross proceeds of $13,066,669, PharmAthene sold and issued to a subsidiary of Panacea Biotec 3,733,334 shares of PharmAthene common stock and a 12-month warrant to purchase up to 2,745,098 additional shares of PharmAthene common stock at an exercise price of $5.10 per share (subject to a stock ownership cap, following any warrant exercises, of 19.99% of PharmAthene's issued and outstanding common stock as of such exercise date).

***Operating Activities***

Net cash used in operating activities was $9.4 million and $7.8 million for the nine months ended September 30, 2008 and 2007, respectively. Cash used in operations during the nine months ended September 30, 2008 reflects a net loss after the effect of non-cash adjustments of $11.3 million, an increase in accounts receivable of $1.5 million, and an increase in accrued expenses and accounts payable of $3.6 million. Non-cash adjustments for the nine months ended September 30, 2008 included a write off of acquired in-process research and development of $16.1 million as a result of the Avecia Acquisition, non-cash stock compensation expense of $2.0 million and non-cash interest expense of $1.3 million related to our convertible notes. Accounts receivable increased due to contract award receivables due from NIAID related to the further development of SparVax™ and RypVax™ under contracts acquired in the second quarter of 2008 as part of the Avecia Acquisition and from DoD related to increased activities for the advanced development of Protexia®. Accounts payable and accrued expenses increased due to increased development activities primarily related to SparVax™ and RypVax™, $0.7 million compliance-related and financing activities and approximately $1.3 million for the accrual of performance-based employee bonuses.

Cash used in operations during the nine months ended September 30, 2007 resulted primarily from a net loss after the effect of non-cash adjustments of $11.3 million and increased accounts receivable of approximately $1.6 million due to contract award receivables. These increases were partially offset by increased accounts payable and accrued expenses of approximately $4.8 million resulting from increased development activities and Merger related costs. Non cash adjustments for the nine months ended September 30, 2008 included a $2.4 million charge that resulted from the cancellation of Former PharmAthene's preferred stock warrants and a $1.2 million gain on the extinguishment of debt.

***Investing Activities***

Net cash used in investing activities was $17.5 million for the nine months ended September 30, 2008 as compared to $1.0 million for the nine months ended September 30, 2007. In the first nine months of 2008, the Company paid $10 million to Avecia and funded a $7 million letter of credit in connection with the Avecia Acquisition. 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. In order to fund the Avecia Acquisition transaction and the restricted cash obligations pursuant to the Loan Modification Agreement, approximately $20.6 million of available-for-sale securities were sold.

All investing activities in the first nine months of 2007 related to the purchase of property and equipment. The Company finances capital expenditures primarily through direct purchases utilizing the Company's existing cash.

***Financing Activities***

Net cash used by financing activities was $3.2 million for the nine months ended September 30, 2008 as compared to net cash provided by financing activities of $63.9 million for the nine months ended September 30, 2007. The Company made principal repayments of $3.0 million under outstanding credit facilities for the nine months ended September 30, 2008.

PharmAthene is a party to a $10 million secured credit facility evidenced by a Loan and Security Agreement, dated as of March 30, 2007 (the "Loan Agreement"), with Silicon Valley Bank and Oxford Finance Corporation (together, the "Lenders"). Under the credit facility, the Company has borrowed $10 million, which bears interest at an annual rate of 11.5%.



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The Loan Agreement contains customary affirmative and negative covenants which, among other things, restrict the Company's ability to undertake certain acquisitions, incur certain indebtedness or make certain investments. As a consequence, PharmAthene sought to obtain the consent of its Lenders to the Avecia Acquisition and entered into a Consent and First Loan Modification Agreement, dated as of March 20, 2008, with the Lenders. The Company has made principal repayments of $4.0 million through September 30, 2008.

Net cash provided by financing was $63.9 million for the three months ended September 30, 2007. The 2007 cash provided in financing results from the $58.7 million in cash proceeds from the reverse merger with Healthcare Acquisition Corporation, and the $10 million credit facility partially offset by $4.8 million in merger related costs.

***Future Cash Needs***

Since inception in March 2001, we have not generated positive cash flow. 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 to utilize these types of financing vehicles and potentially others to help fund our future operating and capital requirements. In evaluating alternative sources of financing, we consider, among other things, the dilutive impact, if any, on our stockholders, the ability to leverage stockholder returns through debt financing, the particular terms and conditions of each alternative financing arrangement and our ability to service our obligations under such financing arrangements. As disclosed under "Recent Events" above, we recently received gross proceeds of approximately $13.1 million from the strategic investment by Panacea Biotec's subsidiary. At our current rate of cash consumption, however, if we do not access sufficient additional funding through contracts and grants with the U.S. and foreign governments, and we do not defer or renegotiate repayment of the outstanding Notes in the amount of $12.9 million as of September 30, 2008, we will need to engage in one or more additional financing transactions of the types listed above by no later than August 3, 2009, the current maturity date of the Notes. The current 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 funding will be available to us on reasonably acceptable terms, or at all. In addition, due to the US Government's substantial efforts to stabilize the economy, the US 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 and/or the likelihood that the government will exercise its right to extend any of its existing contracts with us or to procure products from us.

The Company's future capital requirements and liquidity will depend on many factors including, but not limited to, the progress of its 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 its existing research relationships, competing technological and marketing developments; its ability to establish collaborative arrangements and to enter into licensing agreements and contractual arrangements with others; and any future change in its business strategy.

***Off-Balance Sheet Arrangements***

The Company has entered into facility and equipment operating lease agreements. The Company's obligations under these agreements are presented under the ''Contractual Obligations'' section below.



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**Critical Accounting Policies**

***Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires the Company 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. The Company believes the following critical accounting policies, among others, affect its more significant estimates and assumptions and require the use of complex judgment in their application.

***FASB 123R regarding share-based payments***

The FASB issued FAS 123R, which requires that all share-based payments to employees, including grants of employee stock options, be recognized in the income statement based on their grant date fair values. Costs of all share-based 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 operating expense associated with that employee.

***Revenue Recognition***

The Company generates its 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. The Company considers fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. The Company analyzes each cost reimbursable grant to ensure reporting of revenues gross versus net is appropriate based on the guidance in the AICPA Federal Government Contractors Guide or the Financial Accounting Standards Board's (FASB's) Emerging Issues Task Force (EITF) Issue 99-19, *Gross Versus Net*, whichever is most appropriate.

The Company's contracts may include the provisions of more than one of its services. Collaborative research and development agreements can provide for one or more of up-front license fees, research payments, and milestone payments. In these situations, the Company recognizes revenue in accordance with the Financial Accounting Standards Board's (FASB's) Emerging Issues Task Force (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Accordingly, for applicable arrangements, revenue recognition includes the proper identification of separate units of accounting and the allocation of revenue across all elements based on relative fair values, with proper consideration given to the guidance provided by other authoritative literature.

Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. If not deemed substantive, the Company recognizes such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process. Milestones are considered substantive if all of the following conditions are met; (1) the milestone is non-refundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as deferred revenue.

***Research and Development Expenses***

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. On January 1, 2008, the Company adopted the Financial Accounting Standards Board's (FASB's) Emerging Issues Task Force (EITF) Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. All other costs are charged to expense as incurred.

***Intangible Assets***

When the Company acquires development products, it allocates the purchase price, including acquisition expenses and assumed liabilities, to tangible and intangible assets. The portion allocated to intangible assets may be allocated to trademarks, patents and other intangibles. The Company estimates the useful lives of the assets by considering the remaining life of the patents, estimated future introductions of competing products, and other related factors.

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 the Company works and the government's related funding provisions, factors that affect the estimate of the life of the asset are often more uncertain than other non-bioterrorist pharmaceutical research. On an annual basis, the Company assesses recoverability of intangibles from future operations, using undiscounted future cash flows 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.



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***Contractual Obligations***

The following are contractual commitments at September 30, 2008 associated with leases, research and development arrangements, collaborative development obligations and long term debt:

| Contractual Obligations(1) | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 years |
|---|---|---|---|---|---|
| Operating facility leases | $ 4,404,000 | $ 701,000 | $ 1,149,000 | $ 839,000 | $ 1,715,000 |
| Research and development agreements | 27,528,000 | 25,648,000 | 1,880,000 | — | — |
| Notes payable, including interest | 20,629,000 | 18,913,000 | 1,716,000 | — | — |
| Total contractual obligations | $ 52,561,000 | $ 45,262,000 | $ 4,745,000 | $ 839,000 | $ 1,715,000 |

(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.

**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, 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.

**Management's Quarterly Report on Internal Control Over Financial Reporting**

PharmAthene's management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. PharmAthene's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. PharmAthene's internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of PharmAthene's assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of PharmAthene's management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of PharmAthene's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of PharmAthene's internal control over financial reporting as of September 30, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.



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Based on this assessment, management determined that PharmAthene maintained effective internal control over financial reporting as of September 30, 2008.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting, identified in connection with the evaluation required by Section 13a-15(d) of the Securities Exchange Act of 1934, as amended, that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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 1A. Risk Factors.

*Stockholders and potential investors should carefully consider the risks described below relating to investment in our common stock. Our most significant risks and uncertainties are described below, however, they are not the only risks we face. 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.*

#### Risks Related to Our Business

***If we do not receive the award by the U.S. Department of Health and Human Services for an rPA anthrax vaccine, our operations may decline and we may be placed at a competitive disadvantage.***

On February 29, 2008, the U.S. Department of Health and Human Services issued a formal Request for Proposal (RFP-BARDA-08015) 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 U.S. Department of Health and Human Services ("DHHS") has stated that it intends to make an award under the solicitation by the end of 2008, a third party bidder has filed a protest with the US Government Accounting Office challenging the decision of the DHHS to eliminate that bidder from further consideration under the solicitation, and it is unclear whether this protest will result in a delay to the timing of any award under the solicitation or otherwise have an adverse effect on the solicitation process. See also "*—The US Government's determination to award any contracts to the Company may be challenged by an interested party, such as another bidder, at the General Accounting Office or in federal court. If such a challenge is successful, a contract may be terminated.*"

We are currently aware of at least one bidder for the award with substantially greater financial and other resources, manufacturing capabilities and commercialization capabilities than we have. 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, SparVax™, which, in turn, could lead to a decline in our operations and 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 a procurement. See also "*—Most of PharmAthene's immediately foreseeable future revenues are contingent upon grants and contracts from the US Government and collaborative and license agreements and the Company may not achieve sufficient revenues from these agreements to attain profitability.*"

***It is expected that PharmAthene will incur net losses and negative cash flow for the foreseeable future, and we cannot guarantee that we will achieve profitability; therefore, our business, results of operations and financial condition may be materially adversely affected.***

We have incurred significant losses since we commenced operations. For the fiscal year ended December 31, 2007, the Company incurred an operating loss of approximately $16.5 million and had an accumulated deficit of approximately $87.4 million at



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December 31, 2007. For the nine months ended September 30, 2008, the Company incurred an operating loss of approximately $30.5 million and had an accumulated deficit of approximately $118.6 million at September 30, 2008. The Company's losses to date have resulted principally from research and development costs related to the development of its product candidates, general and administrative costs related to its operations, and costs related to the Avecia Acquisition.

As a result of our continuing losses and the Avecia Acquisition, we may need to seek additional financing. Our available cash and cash equivalents at September 30, 2008 was approximately $10.1 million. However, at September 30, 2008, we had outstanding debt to noteholders of approximately $12.9 million, approximately $6.0 million outstanding under our credit facility and, in connection with the Avecia Acquisition, we have agreed to pay $7 million upon the earlier of the consummation of a financing transaction in which we receive gross proceeds of not less than $15 million or eighteen months after the closing of the acquisition. Accordingly, to the extent that our losses continue at the current level, if we do not access sufficient additional funding through contracts and grants with the U.S. or foreign governments and we do not defer or renegotiate repayment of the outstanding Notes, we will need to engage in one or more additional financing transactions by no later than August 3, 2009, the current maturity date of the Notes. The current 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.

***We expect that PharmAthene will incur substantial losses for the foreseeable future as a result of increases in its research and development costs, including costs associated with conducting preclinical testing, clinical trials and regulatory compliance activities.***

The Company's likelihood for achieving profitability will depend on numerous factors, including success in:

- developing and testing new product candidates;
- carrying out the Company's intellectual property strategy;
- establishing the Company's competitive position;
- pursuing third-party collaborations;
- acquiring or in-licensing products;
- receiving regulatory approvals;
- 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 slower 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.***

In consideration for the Avecia Acquisition, we agreed to pay Avecia the following:

- $10 million at the time of the consummation of the acquisition; plus
- an additional $7 million payable upon the earlier to occur of (a) the completion of a financing transaction in which PharmAthene receives gross proceeds of not less than $15 million and (b) eighteen months after the consummation of the Avecia Acquisition, which payment is secured by a letter of credit; plus
- additional contingent amounts payable upon the occurrence of certain events as follows:
    - $3 million upon the entry by PharmAthene into a multi-year funded contract or series of contracts with the US Department of Defense (or other agency or representative or sub-contractor of the US government) or the Defence Science Technology Laboratory, an agency of the UK Ministry of Defence (or any other agency or representative or sub-contractor of the US or UK government) for the further development of Avecia's pneumonic and bubonic plague ("rYP") vaccine, RypVax™, with a total committed aggregate value in excess of $30 million;
    - $10 million upon the entry by PharmAthene into a multi-year funded contract with the US Department of Defense (or other agency or representative or sub-contractor of the US Government) for the further development of the



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RypVax™ rYP vaccine, as a result of (a) a Resources Allocation Decision of the Resource Allocation Review Board and the Resource Allocation Advisory Committee of the US Department of Defense or (b) some other similar substantial funding in excess of $150 million (including the value of any option elements within such contract); and

- $5 million upon the entry by PharmAthene into a multi-year funded development contract to be issued by the Biological Advanced Research and Development Authority (part of the US Department of Health and Human Services) under solicitation number RFP-BARDA-08-15 for the further development of Avecia's anthrax (rPA) vaccine, SparVax™; and
- $5 million upon the entry by PharmAthene into a contract or contracts for the supply of rPA vaccine, SparVax™, into the Strategic National Stockpile; and
- 2.5% of net sales (as defined under the Purchase Agreement) of rPA vaccine, SparVax™, made by PharmAthene to the US Government within the period of ten years from the consummation of the Avecia Acquisition after the first 25 million doses; and
- 1% of net sales (as defined under the Purchase Agreement) of third generation anthrax vaccine made by PharmAthene to the US Government within the period of ten years from the consummation of the Avecia Acquisition.

PharmAthene is a party to a $10 million secured credit facility bearing interest at an annual rate of 11.5% evidenced by the Loan Agreement with the Lenders which required consent of the Lenders to the Avecia Acquisition. Consequently, PharmAthene obtained the consent of its Lenders to the acquisition and entered into the Loan Modification Agreement, in connection with which PharmAthene maintains, at a segregated account at the Lenders unrestricted and unencumbered cash or cash equivalents in the amount of at least one and one-quarter times the principal amount of its obligations outstanding to the Lenders.

As a result of the Avecia Acquisition and the Loan Modification Agreement, we have less available cash to use for operations, working capital or additional acquisitions, and may be required to raise additional capital or debt financing for same. Our inability to raise additional capital or to obtain adequate financing, if necessary, would result in the need to reduce the pace of implementing our business objectives and could be materially harmful to our business, which would force us to curtail or cease our business operations. As a consequence, our stock price could fall.

***PharmAthene is in various stages of product development and there can be no assurance of successful commercialization.***

PharmAthene has not commercialized any products or recognized any revenues from product sales. In general, our research and development programs are at early stages. To obtain FDA approval for our biological warfare defense products under current FDA regulations, the Company will be required to perform two animal model studies for efficacy and provide animal and human safety data. The Company's other products will be subject to the relevant approval guidelines under FDA requirements, which include a number of phases of testing in humans. Even if PharmAthene initially receives positive early stage pre-clinical or clinical results, such results may not be indicative of similar results that could be anticipated in the later stages of drug development.

Our drug candidates will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercial sale. We cannot be sure that our approach to drug discovery will be effective or will result in the development of any drug. In addition, applicable laws, regulations, and policies may change, and our products may be subject to new legislation or regulations that may delay or suspend research and development. PharmAthene cannot assure you that any drugs resulting from our research and development efforts will be commercially available. Even if we succeed in developing and commercializing our product candidates, the Company may never generate sufficient or sustainable revenues to enable us to be profitable. Furthermore, even if our product candidates are successful when tested in animals, such success would not be a guarantee of the effectiveness and safety of such product candidates in humans. There can be no assurances that one or more of the Company's future product candidates would not fail to meet safety standards in human testing, even if those product candidates were found to be effective in animal studies. There can be no assurances that any such product candidates will prove to be effective in humans.

***Most of PharmAthene's immediately foreseeable future revenues are contingent upon grants and contracts from the US Government and collaborative and license agreements and the Company may not achieve sufficient revenues from these agreements to attain profitability.***



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Until and unless PharmAthene successfully markets a product, our ability to generate revenues will largely depend on our ability to enter into additional collaborative agreements, strategic alliances, research grants, contracts and license agreements with third parties, including, without limitation, the US Government and branches and agencies thereof, and maintain the agreements we currently have in place. Substantially all of the revenues of the Company to date have been derived from grants and government contracts, primarily with the US Government. There can be no assurances that existing government contracts will be renewed or that we can enter into new contracts or receive new grants. For example, our existing contracts for the advanced development of plague vaccine, RypVax™, expires in the first half of 2009, and future government funding for this development program remains uncertain at this time. Furthermore, under the terms of our 2006 contract with the DoD regarding Protexia®, the DoD may elect not to continue development assistance of this nerve agent countermeasure after initial funding of $41million has been received, or, if it does so elect to continue funding and we meet all development milestones, it may nevertheless choose not to procure any doses of Protexia® under the procurement portion of the contract.

The Company has an agreement with Medarex, Inc., to develop Valortim®, a fully human monoclonal antibody product designed to protect against and treat inhalation anthrax. Under the agreement with Medarex, the Company will be entitled to a variable percentage of profits derived from sales of Valortim®, if any, depending, in part, on the amount of its investment. In addition, the Company has 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 product candidates capable of generating revenues for the Company.

***PharmAthene may need additional capital in the future. If additional capital is not available or not available on commercially reasonable terms, the Company may be forced to delay or curtail the development of our product candidates.***

PharmAthene's requirements for additional capital may be substantial and will depend on many other factors, including:

- continued funding by the DoD and other branches and agencies of the US Government;
- payments received under present or future collaborative partner agreements;
- continued progress of research and development of the Company's products;
- the Company's ability to license compounds or products from others;
- costs associated with protecting the Company's intellectual property rights;
- development of marketing and sales capabilities; and
- market acceptance of the Company's products.

To the extent PharmAthene's capital resources are insufficient to meet future capital requirements, it will have to raise additional funds to continue the development of our product candidates. To the extent that our losses continue at the current level, if we do not access sufficient additional funding through contracts and grants with the US or foreign governments and we do not defer or renegotiate repayment of the outstanding Notes, we will need to engage in one or more additional financing transactions by no later than August 3, 2009, the current maturity date of the Notes. The current 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. To the extent the Company raises additional capital through the sale of securities, the issuance of those securities could result in dilution which may be substantial to the Company's stockholders. In addition, if the Company incurs additional debt financing, a 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 the Company's business activities. If adequate funds are not available, the Company may be required to curtail significantly our development and commercialization activities.

***Drug development is an expensive and uncertain process, and delay or failure can occur at any stage of PharmAthene's development process, increasing our development costs and/or adversely affecting the commercial prospects of our product candidates.***

To develop and commercialize biodefense treatment and drug candidates, the Company must provide the FDA and foreign regulatory authorities with clinical and non-clinical data that demonstrate adequate safety and effectiveness. This involves engaging in clinical trials, which is a lengthy and expensive process, the outcome of which is uncertain. Because humans are not normally exposed to anthrax, nerve agents, plague, smallpox or other lethal biotoxins or chemical agents and it would be unethical to expose humans to such, effectiveness of the Company's biodefense product candidates cannot be demonstrated in humans, but instead, under the FDA's



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"Animal Rule" (see Code of Federal Regulations (21 CFR 601 Subpart H)), can be demonstrated, in part, by utilizing animal models. This effect has to be demonstrated in more than one animal species expected to be predictive of a response in humans, but an effect in a single animal species may be acceptable if that animal model is sufficiently well-characterized for predicting a response in humans. The animal study endpoint must be clearly related to the desired benefit in humans and the information obtained from animal studies allows selection of an effective dose in humans.

For many of the biological and chemical threats, the animal models are not available, and as such the Company will have to develop appropriate animal models, a time-consuming research effort. Further, we may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as

these correlates are difficult to establish and are often unclear. FDA may decide that our 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. Finally, 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 in countries other than the United States, 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. See also "*—If we experience delays in obtaining regulatory approvals, or are unable to obtain or maintain regulatory approvals, PharmAthene may be unable to commercialize any products.*"

Delays in obtaining results can occur for a variety of reasons such as slower than anticipated enrollment by volunteers in the trials, adverse events related to the products and unsatisfactory results of any trial. Any delay or adverse clinical event arising
during any of our clinical trials could force the Company to abandon a product altogether or to conduct additional clinical trials in order to obtain approval from the FDA and other regulatory bodies. The Company's development costs will increase substantially if it experiences material delays in any clinical trials or if it needs to conduct more or larger trials than planned.

Additionally, few facilities in the US 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 as well. As such, PharmAthene may not be able to secure contracts to conduct the testing in a predictable timeframe or at all. Further, if delays are significant, or if any of the Company's products do not prove to be safe, pure, and potent (including efficacy) or do not receive required regulatory approvals, the Company will be unable to recognize revenues from the sale of products, and the commercial prospects for our product candidates will be adversely affected.

***Even if the Company completes the development of our nerve agent, plague and anthrax products, if the Company fails to obtain contracts to supply products to the US or foreign governments or the US or foreign governments do not purchase sufficient quantities of our products, PharmAthene may be unable to generate sufficient revenues to continue operations.***

For the next several years, we believe our main customer will be national governments, primarily the U.S. Government. The US Government has undertaken commitments to help secure improved countermeasures against bioterrorism including the stockpiling of treatments and vaccines for anthrax, plague and nerve agents through the SNS and other military stockpiling efforts. However, the process of obtaining government contracts is lengthy and uncertain and the Company will have to compete with other companies for each contract. There can be no assurances that the Company will be awarded any contracts to supply the US or other governments with our products as such awards may be made, in whole or in part, to the Company's competitors. If the US Government makes significant future contract awards for the supply of our emergency stockpile to PharmAthene's competitors, the Company's business will be harmed, and it is unlikely that the Company 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 may result in a decreased and de-prioritized emphasis on procuring the biodefense products PharmAthene is developing. In addition, government contracts typically contain provisions that permit cancellation in the event that funds become unavailable to the governmental agency. If the US or foreign governments make significant future contract awards to the Company's competitors to the exclusion of the Company or otherwise fail to purchase the Company's products, it is unlikely that the Company will ultimately be able to commercialize that particular treatment or product or that it will be able to generate sufficient revenues to continue operations.

Due to the current economic downturn and the US Government's efforts to stabilize the economy, the US 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. For more details on these risks, see "*—Most of PharmAthene's immediately foreseeable future revenues are contingent upon grants and contracts from the US Government and collaborative and license agreements and the Company may not achieve sufficient revenues from these agreements to attain profitability.*"

***US Government agencies have special contracting requirements which give them the ability to unilaterally control our contracts.***



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PharmAthene anticipates that our primary sales will be to the US Government. US Government contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject the Company to additional risks. These risks include the ability of the US Government to unilaterally:

- suspend or prevent the Company 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 PharmAthene's contracts;
- reduce the scope and value of PharmAthene's contracts;
- audit and object to the Company's contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of the Company's products; and
- change certain terms and conditions in the Company's contracts.

The US Government will be able to terminate any of its contracts with the Company either for its convenience or if the Company defaults by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions would generally enable the Company to recover only the Company's 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 the Company liable for excess costs incurred by the US Government in procuring undelivered items from another source.

Due to the current economic downturn and the US Government's efforts to stabilize the economy, the US Government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood that the government will exercise its right to extend any of its existing contracts with us or to procure products from us. For more details on these risks, see "*—Most of PharmAthene's immediately foreseeable future revenues are contingent upon grants and contracts from the US Government and collaborative and license agreements and the Company may not achieve sufficient revenues from these agreements to attain profitability*".

***PharmAthene may fail to fully realize the potential of Valortim® and of our co-development arrangement with our partner in the development of Valortim® which would have an adverse affect upon our business.***

PharmAthene and our development partner have completed the first Phase I clinical trial for Valortim® without any reported adverse reactions. However, before we may begin selling any doses of Valortim®, we will need to conduct a more comprehensive Phase I trial in a significantly larger group of human subjects. The Company will be required to expend a significant amount to scale up manufacturing capability through a contract manufacturer in order to conduct the more extensive clinical trials. If the Company's contract manufacturer is unable to produce sufficient quantities at a reasonable cost, or has any other obstacles to production, such as violative manufacturing, then the Company will be unable to commence the clinical trials necessary to begin marketing Valortim®. Even after the Company expends sufficient funds to complete the development of Valortim® and when and if it enters into an agreement to supply Valortim® to the US Government, it will be required to share any and all profits from the sale of products with our partner in accordance with a pre-determined formula.

***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 trials, non-clinical animal efficacy studies, and such 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 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 FDA's "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 pre-qualify 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 drug 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 the failure of these third parties to perform successfully or our inability to find suitable manufacturing sites could harm our business.***



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We have utilized, and intend to continue utilizing, third parties to manufacture, package and distribute our product candidates. We do not have any manufacturing facilities. Any material disruption in manufacturing could cause a delay in our development programs and potentially future sales. Furthermore, certain compounds, media, or other raw materials used to manufacture our drug candidates are available from 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 (for instance, their inability to meet strict manufacturing specifications) could significantly delay or disrupt our commercialization activities. Similarly, if such third parties have capacity limitations, we may not be able to manufacture and commercialize our products at the rate we would otherwise deem desirable.

***If PharmAthene cannot enter into new licensing arrangements, our ability to develop a diverse product portfolio could be limited and our ability to compete would be harmed.***

A key component of the Company's business strategy is in-licensing compounds and products developed by other pharmaceutical and biotechnology companies or academic research laboratories. Competition for promising compounds or products can be intense. If the Company is not able to identify new licensing opportunities or enter into other licensing arrangements on acceptable terms, it may be unable to develop a diverse portfolio of products.

Our plan to use collaborations to leverage our capabilities and to grow in part through the strategic acquisition of other companies and technologies may not be successful if we are unable to integrate our partners' capabilities or the acquired companies with our operations or if our partners' capabilities do not meet our expectations.

As part of our strategy, we intend to continue to evaluate strategic partnership opportunities and consider acquiring complementary technologies and businesses. In order for our future collaboration efforts to be successful, we must first identify partners whose capabilities complement and integrate well with ours. Technologies to which we gain access may prove ineffective or unsafe. Our current agreements that grant us access to such technology may expire and may not be renewable or could be terminated if we or our partners do not meet our obligations. These agreements are subject to differing interpretations, and we and our partners may not agree on the appropriate interpretation of specific requirements. 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.

In order 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 this 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 which 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 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.

***PharmAthene faces, 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. The Company's 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 also are many companies, 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 companies 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 are being developed by the Company or may obtain FDA approval for products more rapidly.

If the Company commences 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 companies also have manufacturing facilities and established marketing capabilities that would enable such companies to market competing products through existing channels of distribution. The



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Company's commercial opportunities will be reduced or eliminated if our competitors develop and market products for any of the harmful effects that it targets that:

- are more effective;
- have fewer or less severe adverse side effects;
- 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 the Company will be developing.

Further, the regulatory climate for generic versions of biological products approved under a Biological License Application (BLA) in the U.S. remains uncertain. 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 the Company is successful in developing effective products, and obtains 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 PharmAthene may develop, alone or with our collaborators, making our products obsolete, or that are marketed before any products that the Company develops are marketed.

Companies that are developing products that would compete with the Company's products include: Avant Immunotherapeutics, Inc., which has vaccine programs for agents of biological warfare, including plague and anthrax; Human Genome Sciences, Inc., Elusys Therapeutics, Inc. and Avanir Pharmaceuticals, Inc., all of which are developing monoclonal antibodies as anthrax treatments. Other competitors of the Company include: Emergent Biosolutions Inc., BioSante Pharmaceuticals, Inc., Dynport Vaccine Company, LLC and Ligocyte Pharmaceuticals, Inc.

***Political or social factors may delay or impair PharmAthene's 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 the Company's products to market or limit pricing of our products, which would harm the Company's business.

***The US Government's determination to award any contracts to the Company may be challenged by an interested party, such as another bidder, at the General Accounting Office 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 US Government provide procedures by which other bidders and other interested parties may challenge the award of a government contract. In the event that the Company is awarded a government contract, such 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 the Company's performance under the contract while such protests are being considered by the General Accounting Office or the applicable federal court, thus potentially delaying delivery of goods and services and payment. In addition, the Company could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate the Company's contract at our convenience and reselect bids. The government could even be directed to award a potential contract to one of the other bidders.

**Legal and Regulatory Risks of Development Stage Biotechnology Companies**

***PharmAthene's commercial success will be affected significantly by our ability to obtain protection for our proprietary technology and that of our licensors and collaborators and not infringe the patents and proprietary rights of third parties.***

The patent position of biotechnology firms generally is highly uncertain and involves complex legal and factual questions. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. PharmAthene currently holds



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two US patents, has three pending US patent applications, and has a limited number of international patents pending. 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 the Company will result in patents being issued or that the patents, 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 the Company or our collaborators and limit the ability of the Company or that of our collaborators to obtain meaningful patent protection.

Further, the commercial success of PharmAthene will depend significantly on our ability to operate without infringing the patents and proprietary rights of third parties. The Company is aware of one US patent covering recombinant production of an antibody. Although PharmAthene believes that Valortim®, which is a monoclonal antibody and uses recombinant reproduction of antibodies, does not infringe any valid claim of such patent, the Company cannot provide any assurances that if a legal action based on such patent was to be brought against the Company or our distributors, licensees or collaborators, that the Company or our distributors, licensees or collaborators would prevail or that PharmAthene has sufficient funds or resources to defend such claims. The Company is 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, PharmAthene, our licensors or collaborators may be legally prohibited from researching, developing or commercializing such products or be required to obtain licenses to these patents or to develop or obtain alternative technology. The Company, our licensors and/or our collaborators may be legally prohibited from using patented technology, may not be able to obtain any license to the patents and technologies of third parties on acceptable terms, if at all, or may not be able to obtain or develop alternative technologies.

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 outcome is favorable. An outcome of any patent prosecution or litigation that is unfavorable to PharmAthene or one of our licensors or collaborators may have a material adverse effect on the Company. The expense of a protracted infringement suit, even if ultimately favorable, would also have a material adverse effect on the Company.

***Any inability to protect PharmAthene's intellectual property could harm our competitive position and adversely affect our business.***

PharmAthene's success will depend, in part, on our ability to obtain patents and maintain adequate protection of other intellectual property for our technologies and products in the US and other countries. If the Company does not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate our competitive advantages. Further, the laws of some foreign countries will not protect the Company's proprietary rights to the same extent as the laws of the U.S., and the Company may encounter significant problems in protecting our proprietary rights in these foreign countries.

The patent positions of pharmaceutical and biotechnology companies, including the Company's patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. PharmAthene will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that it covers our proprietary technologies with valid and enforceable patents or that it effectively maintains such proprietary technologies as trade secrets. The Company will apply for patents covering our technologies and product candidates as it deems appropriate. PharmAthene may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications the Company files may be challenged and may not result in issued patents. Any future patents the Company obtains may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around the Company's patented technologies. In addition, if challenged, the Company's patents may be declared invalid. Even if valid, the Company's patents may fail to provide it with any competitive advantages.

PharmAthene relies upon trade secrets protection for our confidential and proprietary information. The Company has taken measures to protect our proprietary information; however, these measures may not provide adequate protection to the Company. The Company has sought to protect their proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose the companies' proprietary information, and the Company 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 the Company's trade secrets.

***PharmAthene's use of hazardous materials and chemicals require it to comply with regulatory requirements which may result in significant costs and expose PharmAthene to potential liabilities.***

PharmAthene's research and development involves the controlled use of hazardous materials and chemicals. The Company is subject to federal, state, local and foreign laws governing the use, manufacture, storage, handling and disposal of such materials. The



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Company will not be able to eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, the Company could be held liable for significant damages or fines, and these damages could exceed our resources and any applicable insurance coverage. In addition, the Company may be required to incur significant costs to comply with regulatory requirements in the future.

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

PharmAthene faces an inherent risk of exposure to product liability suits in connection with our product candidates being tested in human clinical trials or sold commercially. The Company may become subject to a product liability suit if any product it develops causes injury, or if treated individuals subsequently become infected or otherwise 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 the Company's reputation, withdrawal of clinical trial volunteers and loss of revenues.

If a product liability claim is brought against the Company, the cost of defending the claim could be significant and any adverse determination may result in liabilities in excess of our insurance coverage. Additionally, the Company will be applying for indemnification under the Support Anti-terrorism by Fostering Effective Technologies 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, the Company cannot be certain that it will be able to obtain or maintain adequate insurance coverage on acceptable terms, if at all.

***Legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and PharmAthene cannot be certain that any such protection will apply to all of our products and, therefore, PharmAthene could become subject to product liability suits and other third party claims if such protections do not apply.***

The Public Readiness and Emergency Preparedness Act ("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 Secretary of Defense 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.

Upon a declaration by the Secretary of Health and Human Services, a compensation fund is 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." There is no assurance, however, that the Secretary of Health and Human Services will issue such a declaration. 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 one or more individuals have exhausted their remedies under the compensation program, which thereby could expose us to liability. PharmAthene may also become subject to standard product liability suits and other third party claims if its products fall outside of the scope of the Public Readiness Act cause injury or if treated individuals subsequently become infected or otherwise suffer adverse effects from such products.

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

***If we experience delays in obtaining regulatory approvals, or are unable to obtain or maintain regulatory approvals, PharmAthene may be unable to commercialize any products.***

The Company will need to conduct a substantial amount of additional preclinical and clinical research and development before any US or foreign regulatory authority will approve any of our products. In addition, the Company's product candidates will be subject to extensive and rigorous government regulation. Results of the Company's research and development activities may indicate that our potential products are unsafe or ineffective. In this case, regulatory authorities will not approve them. Even if approved, the Company's products may not be commercially successful. If the Company fails to develop and commercialize our products, it may be forced to curtail or cease operations.



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In addition, the commencement and rate of completion of clinical trials for the Company's products may be delayed by many factors, including:

- lack of efficacy during the clinical trials in animals;
- unsatisfactory results of any clinical trial;
- failure to comply with Good Clinical Practices;
- unforeseen safety issues;
- slower than expected rate of patient recruitment; or
- government or regulatory delays.

Delays in obtaining regulatory approvals may:

- adversely affect the commercialization of any products that the Company or our collaborative partners develop;
- impose costly procedures on the Company or our collaborative partners;
- diminish any competitive advantages that the Company or our collaborative partners may attain; and
- adversely affect the Company's receipt of revenues or royalties

The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. Although a new product may show promising results in initial clinical trials, it may subsequently prove unfeasible or impossible to generate sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical studies are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the Company may encounter regulatory delays or rejections as a result of many factors, including results that do not support our claims, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. The Company's business, financial condition, prospects and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials or a determination by the FDA that the results of the Company's trials are inadequate to justify regulatory approval.

Any required approvals, once obtained, may be suspended or revoked. Further, if the Company fails to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, it may encounter difficulties including:

- delays in clinical trials or commercialization;
- product recalls or seizures;
- suspension of production and/or distribution;
- revocation of previously approved marketing applications; and
- injunctions, civil penalties and criminal prosecutions.

PharmAthene's 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. If we fail to obtain required governmental approvals, we or our collaborative partners will experience delays in, or be precluded from, marketing products developed through it or, as applicable, their research.

PharmAthene and our contract manufacturers 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 before the Company will be able to use them in commercial manufacturing of our products. The Company and our contract manufacturers may not be able to comply with the applicable cGMP requirements and other FDA regulatory requirements. If the Company and our contract manufacturers fail to comply, we could be subject to fines or other sanctions, or be precluded from marketing our products.

***PharmAthene may be required to perform additional clinical trials or change the labeling of our products if we or others identify side effects after our products are on the market. Such events could harm sales of the affected products.***

If the Company or others identify side effects after any of our products are on the market, or if manufacturing problems occur:

- regulatory approval may be revoked;
- reformulation of the affected products, additional clinical trials, or changes in labeling of the Company's products may be required;
- changes to or re-approvals of the Company's manufacturing facilities may be required;
- sales of the affected products may drop significantly;



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- the Company's reputation in the marketplace may suffer; and
- lawsuits, including class action suits, may be brought against the Company

Any of the above occurrences could harm or prevent sales of the affected products or could increase the costs and expenses of commercializing and marketing these products.

**Risks Related to PharmAthene's Common Stock**

**Certain transactions that we may engage in to raise capital could dilute our shareholders.**

We will seek to raise additional capital and may do so at any time through various financing alternatives, including selling shares of common or preferred stock. For instance, we recently received gross proceeds of approximately $13.1 million from the strategic investment by Panacea Biotec's subsidiary, in which we issued approximately 3.73 million shares of our common stock at a negotiated price of $3.50 per share and a 12-month warrant to purchase up to approximately 2.75 million additional shares of our common stock at an exercise price of $5.10 per share. Raising capital through the issuance of common stock may depress the market price of our stock and any such financing will dilute the stock ownership of our existing shareholders.

***Release of 2,250,000 shares of our common stock from escrow could have an adverse effect on the market price of our common stock.***

The Company's initial stockholders hold 2,250,000 shares of common stock which have recently been released from escrow and are now eligible for trading in the public market. The presence of this additional number of shares of common stock eligible for trading in the public market may have an adverse effect on the market price of the Company's common stock.

***NYSE Alternext US may delist the Company's securities from trading which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.***

The Company's common stock and some warrants are listed on the NYSE Alternext US (formerly the American Stock Exchange, or AMEX), a national securities exchange. PharmAthene cannot assure you that our securities will continue to be listed on the NYSE Alternext US. If the NYSE Alternext US delists the Company's securities from trading on our exchange and it is not able to list our securities on another exchange or to have them quoted on Nasdaq, the Company's securities could be quoted on the OTC Bulletin Board, or "pink sheets". As a result, we could face significant adverse consequences including:

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

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

The information required by this Item is incorporated by reference to Items 1.01 and 3.02 of our Current Report on Form 8-K filed with the SEC on October 6, 2008.

**Item 6. Exhibits.**

| No. | Description |
|---|---|
| 10.38 | Contract Award by the National Institute of Allergy and Infectious Diseases (NIAID), dated September 25, 2008, relating to the advanced development of a third generation recombinant protective antigen (rPA) anthrax vaccine.* |
| 10.39 | Securities Purchase Agreement, dated September 30, 2008, between PharmAthene UK and Kelisia Holdings Ltd. |
| 10.40 | Letter Agreement, dated September 30, 2008, between PharmAthene, Inc. and Panacea Biotec, Ltd. |
| 10.41 | Investor Rights Agreement, dated October 10, 2008, between PharmAthene Inc. and Kelisia Holdings Ltd. |
| 10.42 | Warrant to Purchase up to 2,745,098 Shares of Common Stock of the Company, dated October 10, 2008. |
| 10.43 | Form of Confidentiality Agreement between PharmAthene UK Limited, and its employees. |
| 10.44 | Second Amendment to office lease, by and between the Company and Park Place Trust, dated September 16, 2008. |
| 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. |

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment.



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**SIGNATURES**

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.**

Dated: November 14, 2008

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

Dated: November 14, 2008

By: /s/ Christopher C. Camut
**Christopher C. Camut**
**Principal Financial Officer**

**PharmAthene, Inc.**
**Confidential Materials Omitted and Submitted Separately to the**
**Securities and Exchange Commission**
**Confidential Portions denoted by [***]**

**Document Control #A00821**

OMB Approval 2700-0042

**AWARD/CONTRACT**

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ► RATING N/A PAGE 1 OF PAGES 59

2 CONTRACT (*Proc Inst Ident*) NO
HHSN272200800049C

3. EFFECTIVE DATE
September 25, 2008

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
751380

5 ISSUED BY CODE

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

6. ADMINISTERED BY *(If other than Item 6)* CODE N/A
MIDRCB-B

BAA-NIH-BARDA-NIAID-DMID-AI2007007

NIAID Reference No. N01-AI-80049

7 NAME AND ADDRESS OF CONTRACTOR *(No street, county, state and ZIP Code)*
PharmAthene, Inc. VIN: 1123607
One Park Place, Suite 450
Annapolis, MD 21401

8. DELIVERY
9. DISCOUNT FOR PROMPT PAYMENT
N/A

10. SUBMIT INVOICES ITEM

CODE FACILITY CODE

ADDRESS SHOWN IN: Art. G.3.

11. SHIP TO/MARK FOR CODE N/A

Article F.2.

12. PAYMENT WILL BE MADE BY CODE N/A

See Article G.3.

13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION:

o 10 U.S.C. 2304(c)( ) o 41 U.S.C. 253(c)( )

14. ACCOUNTING AND APPROPRIATION DATA
TIN: 04-3560100 SOCC 25.55
CAN: 8-8470038 Amount: $10,000,000

| 15A ITEM NO. | 15B. SUPPLIES/SERVICES | 15C. QUANTITY | 15D. UNIT | 15E. UNIT PRICE | 15F. AMOUNT |
|---|---|---|---|---|---|
| | Title: Biodefense Vaccine Enhancement - Development of a Third Generation rPA Anthrax Vaccine<br>Period: September 25, 2008 - September 24, 2011<br>Contract Type: Cost-Plus-Fixed-Fee - Completion | Year 1<br>Year 2<br>Year 3 | | $4,572,783<br>$5,090,714<br>$3,544,751 | |

**15G. TOTAL AMOUNT OF CONTRACT ► $13,208,248**

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*CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE*

17. x CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return 2 copies to issuing office*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (*Attachments are listed herein*)

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

19A. NAME AND TITLE OF SIGNER *(Type or print)*
Joseph L. O'Connor
Director of Contracts

20A. NAME OF CONTRACTING OFFICER
Teresa A. Baughman
Contracting Officer, OA, DEA, NIAID, NIH, DHHS

| 19B. NAME OF CONTRACTOR | 19C. DATE SIGNED | 20B. UNITED STATES OF AMERICA | 20C. DATE SIGNED |
|---|---|---|---|
| PharmAthene, Inc.<br>/s/ Joseph L. O'Connor<br>*(Signature of person authorized to sign)* | 9/25/08 | By /s/ Theresa A. Baughman<br>*(Signature of Contracting Office)* | 9/25/08 |

NSN 754001-152-8069
PREVIOUS EDITION UNUSABLE

26-107
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STANDARD FORM 26 (REV. 4-85)
Prescribed by GSA
FAR (48 CFR) 53 214(a)

**Contract Number : HHSN272200800049C**
**Reference Number : N01-AI-80049**

## CONTRACT TABLE OF CONTENTS

**PART I - - THE SCHEDULE**

**SECTION A - SOLICITATION/CONTRACT FORM**

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

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

This contract will support the development of an anthrax vaccine containing rPA and CpG immunostimulant. The work will demonstrate the following: stability of the candidate vaccine and diluent at 35 degrees C over the duration of the base period; safety prior to human use through acute dose and repeat dose toxicology testing in two (2) animal species; improved vaccine efficacy over existing vaccines through non-clinical aerosol challenge studies in the pre-existing rabbit and macaque models, plus supporting studies in the mouse models; and safety and immunogenicity of the vaccine in humans through a Phase I dose escalation clinical trial. The option exists for the scale-up and validation at 200,000 doses/lot, along with a Phase II clinical trial.

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

a. The estimated cost of the Base Period of this contract is $ [* * *]

b. The fixed fee for the Base Period of this contract is $ [* * *] Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $13,208,248.

d. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

| | Estimated Cost ($) | Fixed Fee ($) | Estimated Cost Plus Fixed Fee ($) |
|---|---|---|---|
| Base Period - Process Devel. & Feasibility | [* * *] | [* * *] | $ 13,208,248 |
| Option 1 - Base Extension - Non-Clinical Development | [* * *] | [* * *] | [* * *] |
| Option 2 - Base Extension - Phase I Clinical Trial | [* * *] | [* * *] | [* * *] |
| Option 3 - Scale-Up and Validation | [* * *] | [* * *] | [* * *] |
| Option 4 - Phase II Clinical Trial | [* * *] | [* * *] | [* * *] |
| Total Base Period and Options | [* * *] | [* * *] | $ 83,891,328 |

e. Fee Payment Schedule Based on Contract Milestones

The Contractor shall complete all work in accordance with the Statement of Work and the contract milestones set forth below. The distribution of the fixed fee shall be paid in installments based on the Project Officer's written certification regarding the completion of these milestones as follows:

**Milestones**

| MILESTONE | MILESTONE DESCRIPTION | TASK: COMPLETION OF ACTIVITY | ESTIMATED COMPLETION DATE | FIXED FEE ($) |
|---|---|---|---|---|
| | BASE PERIOD - Process Development and Feasibility | | | |
| 1 | PROCESS DEVELOPMENT AND MANUFACTURING | [* * *] | Mar 2011 | [* * *] |
| 2 | ASSAYS | [* * *] | Aug 2011 | [* * *] |
| 3 | STABILITY | [* * *] | July 2011 | [* * *] |
| 4 | PRECLINICAL TOXICOLOGY | [* * *] | Mar 2011 | [* * *] |
| 5 | NON CLINICAL - MODEL FEASIBILITY STUDIES (Dstl) | [* * *] | Nov 2010 | [* * *] |
| 10 | REGULATORY | [* * *] | May 2011 | [* * *] |
| 11 | DELIVERY OF VACCINE TO NIAID | [* * *] | Apr 2011 | [* * *] |
| | TOTAL BASE PERIOD | | | [* * *] |



| | | | | |
|---|---|---|---|---|
| | **OPTION 1 - Non-Clinical Development** | | | |
| 6 | NON CLINICAL - RABBIT GUP | [* * *] | To Be Determined (TBD) | [* * *] |
| 7 | NON CLINICAL NHP GUP | [* * *] | TBD | [* * *] |
| 8 | PASSIVE TRANSFER | [* * *] | TBD | [* * *] |
| | TOTAL - OPTION 1 | | | [* * *] |
| | **OPTION - Phase I Clinical Trial** | | | |
| 9 | CLINICAL TRIAL (PHASE 1) DOSE ESCALATION | [* * *] | TBD | [* * *] |
| | TOTAL - OPTION 2 | | | [* * *] |



| | | | | |
|---|---|---|---|---|
| | **OPTION 3 - Scale-Up and Validation** | | | |
| 12 | DELIVERY OF PROCESS DEVELOPMENT PLAN FOR SCALE - UP | [* * *] | TBD | [* * *] |
| 13 | FDP DEMONSTRATION AND VERIFICATION | [* * *] | TBD | [* * *] |
| 14 | TECHNOLOGY TRANSFER OF DILUENT PROCESS TO CMO | [* * *] | TBD | [* * *] |
| 15 | OPTION 1b FDP PROCESS VALIDATION | [* * *] | TBD | [* * *] |
| 16 | OPTION 1c CONSISTENCY CAMPAIGN | [* * *] | TBD | [* * *] |
| 17 | OPTION 1b DILUENT CONSISTENCY | [* * *] | TBD | [* * *] |
| 18 | DRUG PRODUCT - ANALYTICAL METHOD | [* * *] | TBD | [* * *] |

| | | | | |
|---|---|---|---|---|
| | VALIDATION AT CRO | | | |
| 19 | DILUENT ASSAYS - TECHNOLOGY TRANSFER AND ASSAY VALIDATION | [* * *] | TBD | [* * *] |
| 20 | IMMUNOPOTENCY ASSAY DEVELOPMENT | [* * *] | TBD | [* * *] |



| | | | | |
|---|---|---|---|---|
| | **OPTION 3 - Scale-Up and Validation** | | | |
| 21 | STABILITY OF FDP | [* * *] | TBD | [* * *] |
| 22 | STABILITY OF DILUENT | [* * *] | TBD | [* * *] |
| | TOTAL OPTION 3 | | | [* * *] |
| | **OPTION 4 - Phase II Clinical Trial** | | | |
| 23 | cGMP MANUFACTURE OF FDP CLINICAL BATCHES | [* * *] | TBD | [* * *] |
| 24 | STABILITY OF CLINICAL LOTS | [* * *] | TBD | [* * *] |
| 25 | PHASE II CLINICAL TRIAL | [* * *] | TBD | [* * *] |
| 26 | RABBIT PASSIVE TRANSFER USING HUMAN PHASE I & PHASE II SERA | [* * *] | TBD | [* * *] |
| | TOTAL OPTION 4 | | | [* * *] |



f. Total funds currently available for payment and allotted to this contract are $10,000,000 of which [* * *] represents the estimated costs, and of which [* * *] represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

g. It is estimated that the amount currently allotted will cover performance of the contract through September 24, 2010.

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

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

a. **Items Unallowable Unless Otherwise Provided**

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

1. Acquisition, by purchase or lease, of any interest in real property;

2. Special rearrangement or alteration of facilities;

3. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

4. Travel to attend general scientific meetings; see subparagraph b. below

5. Foreign travel - - See subparagraph b. below;

6. Consultant costs;

7. Subcontracts;

8. Patient care costs;

9. Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and “sensitive items” (defined and listed in the Contractor’s Guide for Control of Government Property), regardless of acquisition value.

10. Light Refreshment and Meal Expenditures

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

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

b. **Travel Costs**

1. Domestic Travel

a. Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed the following amounts for the **base period and any option (if exercised)** without the prior written approval of the Contracting Officer:

- Base Period: [ * * *]
- Option 1: [* * *]
- Option 2: [* * *]
- Option 3: [* * *]
- Option 4: [* * *]

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

2. Foreign Travel

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



**ARTICLE B.4. ADVANCE UNDERSTANDINGS**

Other provisions of this contract notwithstanding, approval of the following items, **for the base period and any option** (**if exercised**), within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. **Subcontracts**

[* * *]

To negotiate a subcontract with [* * *] for [* * *] an amount not to exceed as follows:

- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]
- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.



[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]
- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]
- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]
- [* * *]
- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]
- [* * *]
- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]
- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

[* * *]

To negotiate a subcontract with [* * *] for [* * *] for an amount not to exceed as follows:

- [* * *]
- [* * *]

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

b. **Consultants** [* * *]



[* * *]

c. **Confidential Treatment of Sensitive Information**

The Government has determined that the information that the Contractor will generate, have access to, or be furnished by the Government during the performance of the contract is of a sensitive nature. The Contractor shall guarantee strict confidentiality of this information.

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



d. **Contract Number Designation**

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

Contract No. HHSN272200800049C

NIAID Reference No. N01-AI-80049

e. **Advance Copies of Press Releases**

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

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall ensure that the Project Officer has received an advance copy of any press release related to this contract not less than seven (7) calendar days prior to the issuance of the press release.

f. **Indirect Costs**

[* * *]



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

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

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated September 25, 2008, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

b. Privacy Act System of Records Number 09-25-0200 is applicable to this contract and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Project Officer(s).

**ARTICLE C.2. REPORTING REQUIREMENTS**

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Project Officer and the Contracting Officer, unless otherwise specified. **The reports included in this Article are applicable to the base period and any option (if exercised)**.

a. **Technical Reports**

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports during the period of performance of this contract:

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

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

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

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



1. **Monthly Progress Report**

The Monthly Progress Report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. A Monthly Progress Report shall not be required when an Annual Progress Report or the Final Report is due.

**Section A** - An introduction covering the purpose and scope of the contract effort.

**Section B** - The Monthly Progress Report shall describe the results of work performed during the reporting period for each milestone and key objective in the approved Product Development Plan. For each milestone, include a summary of accomplishments in sufficient detail to explain comprehensively the results achieved, and a summary of any technical issues/problems encountered during the reporting period. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved, preliminary conclusions resulting from analysis, and scientific evaluation of data accumulated to date under the project for each milestone. The current status of each milestone and sub-task shall be displayed on an updated Gantt chart as a component of the Monthly Progress Report. In addition, requests and

approvals to conduct human trials, and Inclusion Enrollment Report forms, when appropriate, shall be included. Preprints and reprints of papers, abstracts, and slides used in oral presentations shall also be submitted with the Monthly Progress Report.

**Section C** - *Substantive performance*: Describe current technical or substantive performance, any problems encountered, and corrective actions taken or proposed. Explain any differences between planned progress and actual progress, reasons for differences that have occurred, and corrective actions taken or proposed. Provide a summary of work proposed for the next year period. Submit copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period. Include a summary of any inventions developed during the course of the contract. If applicable, advise the NIAID of other government-funded activities beyond the Contractor's control that could adversely impact performance.

**Section D** - Estimated and actual total costs incurred shall be provided for each milestone and task performed during the reporting period. Costs shall be reported by a breakdown of Direct Labor, Direct Materials, Subcontracts, Consultants, Travel, etc.

2. **Annual Progress Report**

The Annual Progress Report shall include a summation of the results of the entire contract work for the period covered. The Annual Progress Report is due after each anniversary date of the contract. An Annual Progress Report will not be required for the period when the Final Report is due.

**Section A** - An introduction covering the purpose and scope of the contract effort.

**Section B** - Describe the results of work accomplished during the reporting period in relation to the approved Product Development Plan and each key objective and milestone. For each milestone, include a summary of accomplishments in sufficient detail to explain comprehensively the results achieved, and a summary of technical issues/problems encountered for the reporting period. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved, preliminary conclusions resulting from analysis, and scientific evaluation of data accumulated to date under the project for each milestone. The current status of each milestone and sub-task shall be displayed on an updated Gantt chart as a component of the Annual Progress Report. In addition, requests and approvals to conduct human trials, and Inclusion Enrollment Report forms, when appropriate, shall be included.



**Section C** - *Substantive performance*: Describe current technical or substantive performance, any problems encountered, and corrective actions taken or proposed. Explain any differences between planned progress and actual progress, reasons for differences that have occurred, and corrective actions taken or proposed. Provide a summary of work proposed for the next year period. Submit copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period. Include a summary of any inventions developed during the course of the contract.

**Section D** - Estimated and actual total costs incurred shall be provided for each milestone and task performed during the reporting period. Costs shall be reported by a breakdown of Direct Labor, Direct Materials, Subcontracts, Consultants, Travel, etc.

3. **Annual Technical Progress Report for Clinical Research Study Populations**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the Attachment entitled, "Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see Il.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

4. **Draft Final Report**

The Contractor shall provide the Project Officer with a copy of the Final Report in draft form ninety (90) calendar days prior to the completion date of the contract. The Final Report shall contain an executive summary for activities performed under the contract. The format described for the Monthly Progress Report shall be used for the Final Report. The Project Officer will review the Draft Final Report and provide the Contractor with comments within fifteen (15) calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary.

5. **Final Report**

The Final Report shall include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the methods used and the results achieved, shall use the format for the Monthly Progress Report, and shall also contain an executive summary for activities performed under the contract. Preprints and reprints not submitted previously shall be submitted as an appendix. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract.

6. **Summary of Salient Results**

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

7. **Report on Select Agents or Toxins and/or Highly Pathogenic Agents**

For work involving the possession, use, or transfer of a *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*, the following information shall also be included in each Annual Progress Report:

1. Any changes in the use of the *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

2. If work with a new or additional *Select Agent or Toxin* and/or a *Highly Pathogenic Agent* will be conducted in the upcoming reporting period, provide:

    a. A list of each new or additional *Select Agent or Toxin* and/or a *Highly Pathogenic Agent* that will be studied;

    b. A description of the work that will be done with each new or additional *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*;

    c. The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each Annual Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each Annual Progress Report.

b. **Other Reports/Deliverables**

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

1. **Product Development Plan**

Within thirty (30) calendar days after the effective date of the contract and prior to initiation of product development activities, the Contractor shall submit to the Project Officer and Contracting Officer an updated Product Development Plan to accomplish the product development activities detailed in the negotiated Statement of Work for the base period of performance, plus Options 1 and 2 (if exercised). This Plan shall be updated following any milestone change or deviation.

Within sixty (60) calendar days after the exercise of Option 3, the Contractor shall submit to the Project Officer and Contracting Officer an updated Option 3 Product Development Plan to accomplish the product development activities detailed in the negotiated Statement of Work for Option 3. This Plan shall be updated following any milestone change or deviation during this Option.



Within sixty (60) calendar days after the exercise of Option 4, the Contractor shall submit to the Project Officer and Contracting Officer an updated Option 4 Product Development Plan to accomplish the product development activities detailed in the negotiated Statement of Work for Option 4. This Plan shall be updated following any milestone change or deviation during this Option.

The Product Development Plan shall include:

a) clearly defined goals for each proposed stage of product development where “Go/No Go” decision points have been identified;

b) quantitative and qualitative criteria for assessing the scientific merit and feasibility of moving to the next stage of product development;

c) a detailed Gantt chart with a timeline with subtask, predecessor and successor logic for each milestone covering the initiation, conduct and completion of product development tasks; and

d) a task linked budget listing a breakdown of total costs linked to each milestone, task and subtask.

2. **Implementation Plan**

Within thirty (30) calendar days after the effective date of the contract and prior to initiation of product development activities the Contractor shall submit to the Project Officer and Contracting Officer an updated Implementation Plan to accomplish the product development activities

detailed in the negotiated Statement of Work for the base period of performance, plus Options 1 and 2 (if exercised). This Plan shall be updated following any milestone change or deviation.

Within sixty (60) calendar days after the exercise of Option 3, the Contractor shall submit to the Project Officer and Contracting Officer an Option 3 updated Implementation Plan to accomplish the product development activities detailed in the negotiated Statement of Work for Option 3. This Plan shall be updated following any milestone change or deviation during this Option.

Within sixty (60) calendar days after the exercise of Option 4, the Contractor shall submit to the Project Officer and Contracting Officer an Option 4 updated Implementation Plan to accomplish the product development activities detailed in the negotiated Statement of Work for Option 4. This Plan shall be updated following any milestone change or deviation during this Option.

The Implementation Plan shall contain a detailed discussion of the proposed technical approach for each activity to be performed to achieve project objectives in sufficient detail to explain and justify fully the scientific/technical rationale for the proposed approaches and/or methodologies and reflecting a clear understanding of the scope and nature of the work to be carried out.

3. **Product Development Reports**

The Contractor shall provide all Product Development Reports that document compliance with the requirements of cGMP and product characterization and release testing in compliance with GLP, including Shipping Validation Reports and Chemistry, Manufacturing and Controls (CMC) information, and all raw data and statistical analyses to the Project Officer and the NIAID Regulatory Affairs designee.

4. **Non-Clinical Study Protocols and Reports**

The Contractor shall provide to the Project Officer and to the NIAID Regulatory Affairs designee Draft and Final Non-Clinical Study Protocols and Reports, including associated Standard Operating Procedures (SOPs) and procedures necessary to support the development and submission of IND applications to the FDA.



5. **Contract Initiation Meeting, Annual Contract Review Meetings, and Additional Contract Meetings Reports**

Reports of the Contract Initiation Meeting, the Annual Contract Review Meetings, and the Additional Contract Meetings shall be prepared and submitted by the Contractor to the Project Officer and Contracting Officer within twenty-one (21) calendar days following each meeting. These reports shall include a list of attendees, summaries of discussions, and copies of all meeting materials.

6. **Publications and Presentation Materials**

The Contractor shall provide manuscripts, scientific meeting abstracts, and oral presentations containing data generated under this contract to the Project Officer for review prior to submission for publication or public presentation.

a) Manuscripts shall be submitted no less than thirty (30) calendar days in advance of submission.

b) Abstracts and oral presentations shall be submitted no less than ten (10) calendar days in advance of presentation.

7. **Serious Adverse Events Reports**

The Contractor shall submit Serious Adverse Events (SAE) Reports to the Project Officer and to the NIAID Regulatory Affairs designee according to the NIAID Clinical Terms of Award (http://www.niaidnih.gov/ncn/pdf/clinterm.pdf).

8. **Clinical Trial Monitoring Plan and Clinical Trial Protocols**

The NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the Project Officer. Protocols must be submitted using the approved DMID template and include a sample Informed Consent and Clinical Trials Monitoring Plan. The DMID templates and other important information regarding performing human subjects research are available at http://www3.niaid.nih.gov/research/resources/DMIDCIinRsrch//.

9. **FDA Correspondence and Meeting Summaries**

The Project Officer and Project Officer's designees shall be granted permission by the Contractor to be an observer at all FDA meetings and teleconferences related to any activities being performed as part of this contract, including work performed by subcontractors and collaborators. The Contractor shall provide copies of all correspondence relating to this contract sent to and received from the FDA and shall provide minutes of meetings held with the FDA within five (5) calendar days after the meeting date to the Project Officer and the NIAID Regulatory Affairs designee.

10. **Final Clinical Study Report**

The Final Clinical Study Report shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_Iiste.htm). Final Clinical Study Reports shall be provided within thirty (30) calendar days after the completion of the analysis of all clinical trial data to the Project Officer and the NIAID Regulatory Affairs designee.

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

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to:

Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the completion date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The first annual utilization report shall be due on or before due on or before the 30th of the month following each anniversary date of the contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the completion date of the contract. All reports shall be sent to the following address:

Contracting Officer
MID Research Contract Branch-B
Office of Acquisitions, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Direct Phone Number: 301-451-3690
Office Phone Number: 301-496-0612
Fax Number: 301-402-0972

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

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



**SECTION D - - PACKAGING, MARKING AND SHIPPING**

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

**SECTION E - - INSPECTION AND ACCEPTANCE**

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

b. For the purpose of this SECTION, the Project Officer identified in ARTICLE G.1. is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of Microbiology and Infectious Diseases
6610 Rockledge Drive
Bethesda, MD 20892

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

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

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).



**SECTION F DELIVERIES OR PERFORMANCE**

**ARTICLE F.1. PERIOD OF PERFORMANCE**

a. The period of performance of this contract shall be from September 25, 2008 through September 24, 2011.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

| Option | Option Period |
|---|---|
| 1 - Base Extension - Non- Clinical Development | Two (2) years beginning with the effective date of the exercise of Option 1. |
| 2 - Base Extension - Phase I Clinical Trial | Two (2) years beginning with the effective date of the exercise of Option 2. |
| 3 - Scale-Up and Validation | Five (5) years beginning with the effective date of the exercise of Option 3. |
| 4 - Phase II Clinical Trial | Three (3) years beginning with the effective date of the exercise of Option 3. |

**ARTICLE F.2. DELIVERIES**

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

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

a. **Reports and Deliverables**

| Item | Report/Deliverable | Delivery Schedule |
|---|---|---|
| 1. | Monthly Progress Report | The first report is due on or before November 15, 2008. Thereafter, each report is due on or before the 15th of the month following each reporting period. Monthly Progress Reports are not required when an Annual Progress Report or Final Report is due. |
| 2. | Annual Progress Report | The first report is due on or before October 30, 2009. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract. An Annual Progress Report is not due when a Final Report is due. |
| 3. | Annual Technical Progress Report for Clinical Research Study Populations (***Options 2 and 4***) | The first report is due the 30th of the month following the date Option 2 is exercised. Thereafter, each report is due on or before the 30th of the month following each anniversary date in **Options 2 and 4**. |
| 4. | Draft Final Report | Due 90 calendar days prior to the completion date of the contract. |
| 5. | Final Report and Summary of Salient Results | Due on or before the completion date of the contract |
| 6. | Contract Initiation Meeting, Annual Contract Review Meetings, and Additional Contract Meetings Reports | Due within 21 calendar days following each meeting. |



| Item | Report/Deliverable | Delivery Schedule |
|---|---|---|
| 7. | Publications and Presentation Materials | Manuscripts are due 30 calendar days in advance of submission.<br><br>Abstracts and oral presentations are due 10 calendar days in advance of presentation. |
| 8. | Product Development Plans | Initial Updated Plan is due October 25, 2008 and following any milestone change or deviation.<br><br>Option 3 Updated Plan is due 60 calendar days after the exercise of Option 3 and following any milestone change or deviation.<br><br>Option 4 Updated Plan is due 60 calendar days after the exercise of Option 4 and following any milestone change or deviation. |
| 9. | Implementation Plans | Initial Updated Plan is due October 25, 2008 and following any milestone change or deviation.<br><br>Option 3 Updated Plan is due 60 calendar days after the exercise of Option 3 and following any milestone change or deviation.<br><br>Option 4 Updated Plan is due 60 calendar days after the exercise of Option 4 and following any milestone change or deviation. |
| 10. | Product Development Reports including:<br><br>Shipping Validation Reports;<br><br>Chemistry, Manufacturing and Controls (CMC) Information;<br><br>All raw data and statistical analyses | To be negotiated. |
| 11. | Draft Non-Clinical Study Protocols and Reports | To be negotiated. |
| 12. | Final Non-Clinical Study Protocols and Reports | To be negotiated. |
| 13. | Standard Operating Procedures (SOPs) | To be negotiated. |
| 14. | Serious Adverse Events (SAE) Reports | In accordance with NIAID Clinical Terms of Award. |

| | | |
|---|---|---|
| | (**Options 2 and 4 only**) | |
| 15. | Sample Informed Consent and Clinical Trial Monitoring Plan (**Options 2 and 4 only**) | In accordance with NIAID Clinical Terms of Award. |
| 16. | Final Clinical Study Report<br><br>(**Options 2 and 4 only**) | Due 30 calendar days after the completion of the analysis of all clinical trial data. |
| 17. | Food and Drug Administration (FDA) Correspondence and Meeting Summaries | Due five (5) calendar days after the meeting is held or correspondence is sent. |
| 18. | Process Development Final Report (SOW, Base Period, **Milestone 1.a.**) | Prior to technical transfer and scale up of process. |
| 19. | Technical Transfer Audit Report and Quality Agreement Statement of Work (SOW, Base Period. **Milestone 1.b.**) | Prior to placing orders with CMO. |
| 20. | Technical Transfer Completion Reports, including Analytical Qualification Reports (SOW, Base Period, **Milestone 1.b.**) | Prior to GMP manufacture. |



| Item | Report/Deliverable | Delivery Schedule |
|---|---|---|
| 21. | Master Batch Records (MBRs) (SOW, Base Period, **Milestone 1.c.**) | Prior to production of the demonstration batches. |
| 22. | Executed Batch Manufacturing Records (BMRs) and Certificate of Analysis (SOW, Base Period, **Milestone 1.f.**) | Within five (5) months after manufacture. |
| 23. | Qualification of Process Assays Reports (SOW, Base Period, **Milestone 2.a.**) | Within 14 months after the effective date of the contract. |
| 24. | Qualification of Product Assays Reports (SOW, Base Period, **Milestone 2.b.**) | Within 14 months after the effective date of the contract. |
| 25. | Qualification of Stability Indicating Assays Reports (SOW, Base Period, **Milestone 2.c.**) | Within 14 months after the effective date of the contract. |
| 26. | Qualification of Immuno-Potency Assay Reports (SOW, Base Period, **Milestone 2.d.**) | Within 24 months after the effective date of the contract. |
| 27. | Stability Trials Audit Report and Quality Agreement (SOW, Base Period, **Milestone 3.0.**) | Prior to placing orders with the Clinical Research Organization (CRO) |
| 28. | cGMP Stability Protocols (SOW, Base Period, **Milestone 3.0.**) | One (1) month prior to the initiation of the stability study. |
| 29. | Stability Study Report (SOW, Base Period, **Milestone 3.0.**) | Within 30 calendar days after completion of the study. |
| 30. | Draft Safety and Toxicity Protocol(s) (SOW, Base Period, **Milestone 4.a.**) | To be negotiated. |
| 31. | CRO Audit Report and Quality Agreement (SOW, Base Period, **Milestone 4.a.**) | To be negotiated. |
| 32. | Acute Dose Safety and Toxicity Studies Reports (SOW, Base Period, **Milestone 4.b.**) | To be negotiated. |
| 33. | Repeat Dose Safety and Toxicity Studies Reports (SOW, Base Period, **Milestone 4.c.**) | To be negotiated. |
| 34. | Safety Pharmacology Study (SOW, Base Period, **Milestone 4.d.**) | To be negotiated. |
| 35. | Final Documentation of FDA Concurrence (SOW, Base Period, **Milestone 4.e.**) | To be negotiated. |
| 36. | A Draft Protocol, Animal Studies Group (ASG) Minutes and Concurrence for the each of the following mouse model studies (SOW, Base Period, **Milestone 5.a.**) :<br><br>Excipient Effects;<br><br>Immunogencity;<br><br>Dose Ranging; and,<br><br>Adjuvant Requirements. | To be negotiated. |
| 37. | Final Reports for the each of the following mouse model studies (SOW, Base Period, **Milestone 5.b.**) :<br><br>Excipient Effects;<br><br>Immunogencity;<br><br>Dose Ranging: and,<br><br>Adjuvant Requirements | To be negotiated. |

| Item | Report/Deliverable | Delivery Schedule |
|---|---|---|
| 38. | Non Clinical Study Rabbit Model Audit Report and Quality Agreement (SOW, ***Option 1*** , **Milestone 6.a.**) | Prior to placing orders with the CRO. |
| 39. | Non Clinical Study Rabbit Model Protocol (SOW, ***Option 1***, **Milestone 6.a.**) | To be negotiated. |
| 40. | Rabbit Model Immune Response Interim Report (SOW, ***Option 1***, **Milestone 6.c.**) | To be negotiated. |
| 41. | Rabbit Model Immune Response Final Report (SOW, ***Option 1***, **Milestone 6.c.**) | To be negotiated. |
| 42. | Animal Dose Ranging Challenge Study Interim Report (SOW, ***Option 1***, **Milestone 6.e.**) | To be negotiated. |
| 43. | Animal Dose Ranging Challenge Study Interim Report (SOW, ***Option 1***, **Milestone 6.e.**) | To be negotiated. |
| 44. | Non Clinical Study Non-Human Primate Model Audit Report and Quality Agreement (SOW, ***Option 1***, **Milestone 7.a.**) | Prior to placing orders with the CRO. |
| 45. | Non Clinical Study Non-Human Primate Model Protocol (SOW, ***Option 1***, **Milestone 7.a.**) | To be negotiated. |
| 46. | Non-Human Primate Model Dose Ranging Challenge Study Interim Report (SOW, ***Option 1***, **Milestone 7.c.**) | To be negotiated. |
| 47. | Non-Human Primate Model Dose Ranging Challenge Study Final Report (SOW, ***Option 1***, **Milestone 7.c.**) | To be negotiated. |
| 48. | Passive Transfer Audit Report and Quality Agreement (SOW, ***Option 1***, **Milestone 8.a.**) | Prior to placing orders with the CRO. |
| 49. | Passive Transfer Protocol (SOW, ***Option 1***, **Milestone 8.a.**) | To be negotiated. |
| 50. | Passive Transfer Final Report (SOW, ***Option 1***, **Milestone 8.c.**) | To be negotiated. |
| 51. | Phase I Clinical Trial Audit Report and Quality Agreement (SOW, ***Option 2***, **Milestone 9.a.**) | Prior to placing orders with the CRO. |
| 52. | Phase I Clinical Trial Documentation (including Protocol and Investigators Brochure) (SOW, ***Option 2***, **Milestone 9.b.**) | To be negotiated. |
| 53. | Documentation of Interactions with CBER and CBER Concurrence (SOW, ***Option 2***, **Milestone 9.c.**) | To be negotiated. |
| 54. | Phase I Clinical Trial Report (SOW, ***Option 2***, **Milestone 9.e.**) | To be negotiated. |
| 55. | 2,000 Clinical Doses of cGMP Vaccine and Associated Certificate of Analysis (SOW, ***Option 2***, **Milestone 11.a.**) | To be negotiated. |
| 56. | 2,000 Doses of cGMP Diluent and Associated Certificate of Analysis (SOW, ***Option 2***, **Milestone 11.a.**) | To be negotiated. |
| 57. | Final Approved Master Batch Records (MBRs) for Process Scale-Up of Final Drug Product (FDP)(SOW, ***Option 3***, **Milestone 13**) | Prior to cGMP manufacture. |
| 58. | Final Report of Process Scale-Up for FDP (SOW ***Option 3***, **Milestone 13**) | To be negotiated. |



| Item | Report/Deliverable | Delivery Schedule |
|---|---|---|
| 59. | Executed Batch Manufacturing Records (BMRs) and Certificate of Analysis for Process Scale-Up of FDP (SOW, ***Option 3***, **Milestone 13**) | Within six (6) months after manufacture. |
| 60. | Final Approved Master Batch Records (MBRs) for Scale-Up of Diluent (SOW, ***Option 3***, **Milestone 14**) | Prior to cGMP manufacture. |
| 61. | Executed Batch Manufacturing Records (BMRs) and Certificate of Analysis for Scale Up of Diluent (SOW, ***Option 3***, **Milestone 14**) | Within six (6) months after manufacture. |
| 62. | Validation Master Plan (VMP) for FDP and Diluent (SOW, ***Option 3***, **Milestone 15**) | Within six (6) months after exercising Option 3. |
| 63. | FDP Process Validation Protocol (SOW, ***Option 3***, **Milestone 15**) | To be negotiated. |
| 64. | Executed Batch Manufacturing Records (BMRs) and Certificate of Analysis for FDP Process Validation (SOW, ***Option 3***, **Milestone 15**) | Within five (5) months after manufacture. |
| 65. | FDP Consistency Protocol with Validation Data and VMP (SOW, ***Option 3***, **Milestone 16**) | To be negotiated. |
| 66. | Executed Batch Manufacturing Records (BMRs) and Certificate of Analysis for FDP Consistency (SOW, ***Option 3***, **Milestone 16**) | To be negotiated. |

| | | |
|---|---|---|
| 67. | Diluent Process Validation/Consistency Report (SOW, ***Option 3***, **Milestone 17**) | To be negotiated. |
| 68. | Executed Batch Manufacturing Records (BMRs) and Certificate of Analysis for Diluent Process Validation/Consistency (SOW, ***Option 3***, **Milestone 17**) | Within five (5) months after manufacture. |
| 69. | 200,000 Doses of cGMP FDP Vaccine and Associated Certificate of Analysis (SOW, ***Option 3***, **Milestone 16**) | To be negotiated. |
| 70. | 200,000 Doses of cGMP FDP Diluent and Associated Certificate of Analysis (SOW, ***Option 3***, **Milestone 16**) | To be negotiated. |
| 71. | Validation Reports for Each In-Process and Release Assay for FDP (SOW, ***Option 3***, **Milestone 18**) | To be negotiated. |
| 72. | Validation Reports of the Stability of Non- Releasable Assays for FDP (SOW, ***Option 3***, **Milestone 18**) | To be negotiated. |
| 73. | Validation Reports for Each In-Process and Release Assay for Diluent (SOW, ***Option 3***, **Milestone 19**) | To be negotiated. |
| 74. | Validation Reports of the Stability of Non- Releasable Assays for Diluent (SOW, ***Option 3***, **Milestone 19**) | To be negotiated. |
| 75. | Validation Report of Immunopotency Assay (SOW, ***Option 3***, **Milestone 20**) | To be negotiated. |



| Item | Report/Deliverable | Delivery Schedule |
|---|---|---|
| 76. | Stability Study Reports for Testing of FDP Process Verification (SOW, ***Option 3***, **Milestone 21**) | To be negotiated. |
| 77. | Stability Study Reports for Testing of FDP Process Validation (SOW, ***Option 3***, **Milestone 21**) | To be negotiated. |
| 78. | Stability Study Report for Consistency Campaign for FDP (SOW, ***Option 3***, **Milestone 21**) | To be negotiated. |
| 79. | Stability Study Reports for Testing of Diluent GMP Lot (SOW, ***Option 3***, **Milestone 22**) | To be negotiated. |
| 80. | Stability Study Reports for Testing of Diluent Process Validation/Consistency (SOW, ***Option 3***, **Milestone 22**) | To be negotiated. |
| 81. | Executed Batch Manufacturing Records (BMRs) and Certificate of Analysis for Phase II Clinical Trial (SOW, ***Option 4***, **Milestone 23**) | Within five (5) months after manufacture. |
| 82. | Stability Study Reports for Clinical Batches (SOW, ***Option 4***, **Milestone 23**) | To be negotiated. |
| 83. | Phase II Clinical Trial Audit Report and Quality Agreement (SOW, ***Option 4***, **Milestone 25**) | Prior to placing orders with the CRO. |
| 84. | Phase II Clinical Trial Documentation (including Protocol and Investigators Brochure) (SOW, ***Option 4***, **Milestone 25**) | To be negotiated. |
| 85. | Documentation of Interactions with CBER and CBER Concurrence (SOW ***Option 4***, **Milestone 25**) | To be negotiated. |
| 86. | Phase II Clinical Trial Report (SOW, ***Option 4***, **Milestone 25**) | To be negotiated. |
| 87. | Passive Transfer Study Using Clinical Trial Material Documentation of Interaction with and Concurrence from the Animal Studies Group (SOW, ***Option 4***, **Milestone 26**) | To be negotiated. |
| 88. | Passive Transfer Study Using Clinical Trial Material Final Report (SOW, ***Option 4***, **Milestone 26**) | To be negotiated. |
| 89. | Human Subjects Annual IRB Report (***Options 2 and 4***) | Due annually during the Option periods. |
| 90. | Annual Utilization Report | Due on or before the 30th of the month following each anniversary date of the contract. |
| 91. | Final Invention Statement | Due on or before the completion date of the contract. |



b. **Copies of reports shall be sent to the following addressees:**

| Recipient | Address | Item No. | Quantity and Format |
|---|---|---|---|
| Project Officer | [* * *] | [* * *] | 1 hard copy, 1 electronic copy |
| Contracting Officer | [* * *] | [* * *] | 1 original, 1 electronic copy |
| NIAID Regulatory Affairs designee | [* * *] | [* * *] | 1 hard copy, 1 electronic copy |
| Designated DMID Repository | [* * *] | [* * *] | 2,000 Clinical Doses of cGMP Vaccine and Associated Certificate of Analysis |
| Designated DMID Repository | [* * *] | [* * *] | 2,000 Doses of cGMP Diluent and |

| | | | |
|---|---|---|---|
| | | | Associated Certificate of Analysis |
| Designated DMID Repository | [* * *] | [* * *] | 200,000 Doses of cGMP FDP Vaccine and Associated Certificate of Analysis |
| Designated DMID Repository | [* * *] | [* * *] | 200,000 Doses of cGMP FDP Diluent and Associated Certificate of Analysis |
| OPERA | [* * *] | [* * *] | 1 hard copy |



**ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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



**SECTION G - - CONTRACT ADMINISTRATION DATA**

**ARTICLE G.1. PROJECT OFFICER**

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

[* * *]

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

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

The Government may unilaterally change its Project Officer designation.

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

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

(End of Clause)

The following individual is considered to be essential to the work being performed hereunder:

| Name | Title |
|---|---|
| [***] | Principal Investigator |



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

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

1. Invoices shall be submitted as identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.**

a. The original **hard copy** invoice shall be submitted to the following designated billing office:

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

b. The Contractor shall submit an **electronic copy** of the invoice to the Contracting Officer instead of a paper copy. The invoice shall be transmitted as an attachment via e-mail to the NIAID OA central invoice e-mail address listed below. The subject line of the e-mail must include the following information: Name of Contractor, Contract Number, and Unique Invoice Number. Only one (1) invoice should be submitted per email. The invoice should be in Adobe PDF format, though a MS Word or MS Excel format will also be considered acceptable. ***[Note: The original invoice must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice".]***
**E-mail**: NIAIDOAlnvoices@niaid.nih.gov

2. In addition to the requirements specified in FAR Subpart 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all invoices:

a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is NIAID.

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

c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the invoice. The VIN is the number that appears after the Contractor's name in Block 7 on the face page of the contract. If the Contractor has neither a TIN, DUNS, or VIN, they should contact the Contracting Officer.

d. DUNS or DUNS+4 number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the VIN number on the invoice. If the Contractor has neither a TIN, DUNS, or VIN, they should contact the Contracting Officer.

e. Invoice Matching Option. This contract requires a Two-Way match.



f. Unique Invoice Number. Each invoice must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

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

c. The Contractor shall provide a detailed breakdown on invoices of the following cost categories:

a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.

b. Fringe Benefits - Cite rate and amount.

c. Overhead - Cite rate and amount.

d. Materials & Supplies - Include detailed breakdown when total amount is over $1,000.

e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.

f. Consultant Fees - Identify individuals and amounts. Cite COA, if appropriate.

g. Subcontracts - Attach subcontractor invoice(s).

h. Equipment - Cite COA, if appropriate, and amount.

i. G&A - Cite rate and amount.

j. Total Cost

k. Fixed Fee

l. Total Cost Plus Fixed Fee

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

**Monthly invoices must also include a Summary page along with separate pages for costs billed per each Milestone.**

**ARTICLE G.4. INDIRECT COST RATES**

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

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 Executive Blvd., MSC-7540
Bethesda, MD 20892-7540

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



**ARTICLE G.5. GOVERNMENT PROPERTY**

a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/oamp/policies/contractors_guide_for_control_of_gov_property.pdf.

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract. A copy of this publication is available upon request to the Contracts Property Administrator.

Requests for information regarding property under this contract should be directed to the following office:

Division of Personal Property Services, NIH
6011 Building, Suite 637
6011 Executive Boulevard MSC 7670
Bethesda, MD 20892-7670
(301) 496-6466

**ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations shall be submitted as determined by the Project Officer and the Contracting Officer, but at least once during the life of the contract.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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



**SECTION H - SPECIAL CONTRACT REQUIREMENTS**

**ARTICLE H.1. HUMAN SUBJECTS**

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by NIAID, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

The Contractor is required to submit the Form OMB No. 0990-0263 on an annual basis beginning with the effective date of the contract, or the exercise of Options, as applicable.

When research involving human subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

**ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS**

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

**ARTICLE H.3. DATA AND SAFETY MONITORING IN CLINICAL TRIALS**

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.



Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Board shall be established and approved prior to beginning the conduct of the clinical trial.

**ARTICLE H.4. REGISTRATION OF CLINICAL TRIALS IN THE GOVERNMENT DATABASE (ClinicalTrials.gov)**

Pursuant to Public Law 110-85, Food and Drug Administration Amendments Act of 2007, Title VIII-Clinical Trial Databases, the Contractor shall register the clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov ( http://www.ClinicalTrials.gov) by the later of December 27, 2007, or 21 days after the first patient is enrolled.

Additional information is available at: http://prsinfo.clinicaltrials.gov .

**ARTICLE H.5. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)**

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

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

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

**ARTICLE H.6. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)**

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules ( http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) and the September 24, 2007 Notice, "Reminder of NIH Policy for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-096.html) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and/or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the Project Officer and Contracting Officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of the contract for any work related to Recombinant DNA Research or a requirement for Contracting Officer prior approval of any or all



Recombinant DNA projects under this contract. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm ).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the Project Officer and Contracting Officer. (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

**ARTICLE H.7. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

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

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

**ARTICLE H.8. NEEDLE EXCHANGE**

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

**ARTICLE H.9. PRESS RELEASES**

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

**ARTICLE H.10. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

**ARTICLE H.11. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

> "(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

**ARTICLE H.12. RESTRICTION ON ABORTIONS**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for any abortion.



**ARTICLE H.13. SALARY RATE LIMITATION LEGISLATION PROVISIONS**

a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term

"institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

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

**ARTICLE H.14. PRIVACY ACT, HHSAR 352.270-11 (January 2006)**

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.apo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is available at: http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm.

**ARTICLE H.15. ANIMAL WELFARE**

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

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



**ARTICLE H.16. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES**

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

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

**ARTICLE H.17. OMB CLEARANCE or CLINICAL EXEMPTION**

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed. In addition, in accordance with 5 CFR 1320.3(h)(5), this requirement may be eligible for a Clinical Exemption to OMB Clearance requirements subject to the approval of the NIH Clinical Exemption Review Committee (CERC). The clinical exemption must be obtained and written approval to proceed received from the Project Officer and Contracting Officer before data is collected under this contract or any subcontract.

**ARTICLE H.18. OPTION PROVISION**

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the completion date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in Article B.2. of this contract.

**ARTICLE H.19. INFORMATION SECURITY**

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

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

a. Information Type

x Administrative, Management and Support Information
Scientific and Technical Research and Innovation
o Mission Based Information

b. Security Categories and Levels

| | | | |
|---|---|---|---|
| Confidentiality Level: | x Low | o Moderate | o High |
| Integrity Level: | o Low | x Moderate | o High |
| Availability Level. | x Low | o Moderate | o High |
| **Overall Level:** | **o Low** | **x Moderate** | **o High** |



c. Position Sensitivity Designations

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

o **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI)**. Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI)

o **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI)**. Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

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

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

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

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

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

Levels 5 and 1: Contractor/subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

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

d. Information Security Training

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

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



e. Rules of Behavior

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

f. Personnel Security Responsibilities

**Contractor Notification of New and Departing Employees Requiring Background Investigations**

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five (5) working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.

2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.

3. Departing employees:

   · Provide the name, position title, and security clearance level held by or pending for the individual.

   · Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

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

1. Contractor Agreement

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

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

2. Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-53 Self-Assessment

The Contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. (http://csrc.nist.gov/publications - under Special Publications).



Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the Statement of Work to (1) develop a Federal information system(s) at the Contractor's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer. For the option periods: no later than the completion date of the option period of performance.

i. Information System Security Plan

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

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three (3) years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems. (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the Statement of Work based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

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

j. Common Security Configurations

The Contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at http://checklists.nist.gov.

**ARTICLE H.20. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)**

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http:// www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/sec508/provisions.htm.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The Contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding $100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports. The Contracting Officer may require that the Contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://508 hhs gov.

[End of HHSAR 352.270-19(b)]



Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: http://508.hhs.gov/ under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

**Schedule for Contractor Submission of Section 508 Annual Report**: To be included with the Annual Progress Report.

[End of HHSAR 352.270-19(c)]

**ARTICLE H.21. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS**

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under NIH contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541
bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51 &idno=45

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in NIH-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the NIH-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for

further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in NIH-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

**ARTICLE H.22. PUBLICATION AND PUBLICITY**

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

> "This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272200800049C"

**ARTICLE H.23. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

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

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

**ARTICLE H.24. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES**

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

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



**ARTICLE H.25. SHARING RESEARCH DATA**

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

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

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

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

**ARTICLE H.26. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS**

The Contractor shall not conduct work involving select agents or toxins under this contract until it and any associate subcontractors comply with the following:

> For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 ( http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf ) as required, before using NIH funds for work involving a *Select Agent*

or *Toxin*. **No NIH funds can be used for research involving a *Select Agent* or *Toxin* at a domestic institution without a valid registration certificate**.

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

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

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

For foreign institutions, see the NIAID Select Agent Award information:
( http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).



**ARTICLE H.27. POSSESSION, USE OR TRANSFER OF A HIGHLY PATHOGENIC AGENT**

The work being conducted under this contract may involve the possession, use, or transfer of a *Highly Pathogenic Infectious Agent (HPA)*. The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http:// www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm);

2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or

3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

**ARTICLE H.28. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)**

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

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

**ARTICLE H.29. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

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

**ARTICLE H.30. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH**

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

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



**PART II - - CONTRACT CLAUSES**

**SECTION I - CONTRACT CLAUSES**

**General Clauses for a Cost-Reimbursement Research and Development Contract**

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

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

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



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

| | | |
|---|---|---|
| *52.243-2* | *Aug 1987* | *Changes - Cost Reimbursement, Alternate V (Apr 1984)* |
| *52.244-2* | *Jun 2007* | *Subcontracts, Alternate I(June 2007)* |
| *52.244-5* | *Dec 1996* | *Competition in Subcontracting (Over $100,000)* |
| *52.244-6* | *Mar 2007* | *Subcontracts for Commercial Items* |



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

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

| HHSAR CLAUSE NO. | DATE | TITLE |
|---|---|---|
| *352.202-1* | *Jan 2006* | *Definitions - with Alternate paragraph (h) (Jan 2006)* |
| *352.216-72* | *Jan 2006* | *Additional Cost Principles* |
| *352.228-7* | *Dec 1991* | *Insurance - Liability to Third Persons* |
| *352.232-9* | *Jan 2006* | *Withholding of Contract Payments* |
| *352.233-70* | *Jan 2006* | *Litigation and Claims* |
| *352.242-71* | *Apr 1984* | *Final Decisions on Audit Findings* |
| *352.270-5* | *Jan 2006* | *Key Personnel* |
| *352.270-6* | *Jan 2006* | *Publications and Publicity* |
| *352.270-10* | *Jan 2006* | *Anti-Lobbying (Over S100,000)* |

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



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

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

a. FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18**, **Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, 52.215-19, **Notification Of Ownership Changes** (October 1997), are deleted in their entirety.

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

c. FAR Clauses **52.219-9, Small Business Subcontracting Plan** (April 2008), and **52.219-16, Liquidated Damages—Subcontracting Plan** (January 1999) are deleted in their entirety.

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



**ARTICLE I.3 Additional Contract Clauses**

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

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

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

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

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

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

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

4. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

   "....The Contracting Officer may exercise the option by written notice to the Contractor within 60 calendar days ."

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

   "(c) Waiver of evaluation preference…..
   **o** Offeror elects to waive the evaluation preference."

6. FAR Clause **52.222-29, Notification of Visa Denial** (June 2003).

7. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).

8. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

9. FAR Clause **52.224-2, Privacy Act** (April 1984).

10. **Alternate II** (December 2007), FAR Clause **52.227-14, Rights in Data—General** (December 2007).

    Additional purposes for which the limited rights data may be used are:

    None.



11. **Alternate III** (December 2007), FAR Clause **52.227-14, Rights in Data–General** (December 2007).

    Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(4) of the clause are expressly stated as follows: None.

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

    Specific data items that are not subject to paragraph (j) include: None.

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

14. FAR Clause **52.227-17, Rights in Data—Special Works** (December 2007).

15. FAR Clause **52.227-23, Rights to Proposal Data** (Technical) (June 1987).

    Excluded pages from the proposal are identified as follows:

    None.

16. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).

17. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

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

19. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).

20. FAR Clause **52.247-68, Report of Shipment** (REPSHIP) (February 2006).

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

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

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

3. HHSAR Clause **352.270-7, Paperwork Reduction Act** (January 2006).

4. HHSAR Clause **352.270-8(b), Protection of Human Subjects** (January 2006).

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

6. HHSAR Clause **352.333-7001, Choice of Law (Overseas)** (March 2005).

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

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

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

2. ***NIH(RC)-11, Research Patient Care Costs*** *(4/1/84).*



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

This contract incorporates the following clauses in full text.

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

a. FAR Clause **52.219-28, Post-Award Small Business Program Representation** (June 2007).

(a) *Definitions*. As used in this clause—

*Long-term contract* means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

*Small business concern* means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/services/contractingopportunities/sizestandardstopics/.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure they reflect current status. The Contractor shall notify the contracting office by e-mail, or otherwise in writing, that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete



the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it is a small business concern under NAICS Code assigned to contract number. (End of clause)

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

*(a) Definition. As used in this clause—*

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

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

*Notice to Employees*

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

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

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

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

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

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

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



*as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.*

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

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

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

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

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

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

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

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

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

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

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

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

*(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B—Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States*

*(End of Clause)*



**PART III - - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**

**SECTION J - LIST OF ATTACHMENTS**

The following documents are attached and incorporated in this contract:

**1. Statement of Work**

Statement of Work, dated September 25, 2008, 17 pages.

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

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

**3. Inclusion Enrollment Report**

Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

**4. Annual Technical Progress Report Format for Each Study**

Annual Technical Progress Report Format for Each Study, July 1994, 1 page.

**5. Safety and Health**

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

**6. Procurement of Certain Equipment**

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

**7. Research Patient Care Costs**

Research Patient Care Costs, NIH(RC)-11, 4/1/84, 1 page.

**8. Disclosure of Lobbying Activities, SF-LLL**

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

**9. Commitment To Protect Non-Public Information**

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

**10. Roster of Employees Requiring Suitability Investigations**

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

**11. Employee Separation Checklist**

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



**PART IV - - REPRESENTATIONS AND INSTRUCTIONS**

**SECTION K - REPRESENTATIONS AND CERTIFICATIONS**

The following documents are incorporated by reference in this contract:

1. Annual Representations and Certifications completed and located at the Online Representations and Certifications Application (ORCA) website. This includes the changes identified in paragraph (b) of the FAR provision 52.204-8, Annual Representations and Certifications, contained in the Contractor's proposal.

2. Representations and Certifications, dated August 26, 2008.

3. Human Subjects Assurance Identification Number FWA00010447.

4. Animal Welfare Assurance Number A3034-01.

**END of the SCHEDULE**



**STATEMENT OF WORK**

**"Biodefense Vaccine Enhancement - Development of a Third Generation rPA Anthrax Vaccine"**

**BACKGROUND**

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services, strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents, with the exception of the human immunodeficiency virus (HIV). This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of research grants and contracts. The NIAID is also the primary institute at the NIH for emerging infectious disease research, including research on pathogens that can be used as agents of bioterrorism. Bioterrorism is defined as the use of microorganisms or the toxins produced by microorganisms to harm people or to elicit widespread fear and intimidation of society. Recent events have significantly changed the world's perception of the nature and degree of the threats posed by the use of infectious agents as weapons of bioterrorism. The risk of using such weapons once appeared to be restricted to military encounters. However, in October of 2001, the exposure of postal workers, other government employees, and U.S. civilians at large to *Bacillus anthra*cis spores highlighted the need to devise safe and effective measures to protect all U.S. citizens from the debilitating and lethal effects of agents of bioterrorism. The NIAID supports a number of basic and applied research efforts to develop countermeasures for microbes identified by the NIAID biodefense research agenda as Category A, B and C Priority Pathogens http://www.niaid.nih.gov/Biodefense/bandc_priority.htm.

On December 19, 2006, President George W. Bush signed into law the Pandemic and All-Hazards Preparedness Act (Public Law 109-417), referred to as PAHPA. Title IV of PAHPA established the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) to facilitate the research, development, and acquisition of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases, including pandemic influenza, that threaten the U.S. civilian population. One of the central responsibilities of BARDA is to lead the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which provides an integrated approach to the development and purchase of medical countermeasures for public health medical emergencies. The HHS PHEMCE consists of NIH, ASPR, the U.S. Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC), along with ex officio participation from other federal agencies. To guide progress toward the goal of public health preparedness, the HHS PHEMCE Implementation Plan provides insight into the current priorities for medical countermeasure development.

BARDA, in partnership with the NIAID on this contract, is working through advanced product development activities supported under this contract that will contribute towards allowing candidate medical countermeasures to progress through the development pipeline toward licensure. The eventual goal is to enable the U.S. Government to stockpile these medical countermeasures to protect the American public. Product



developers should be cognizant of the logistical implications of using these products during a public health emergency.

For additional information on BARDA, the PHEMCE Implementation Plan, and Project BioShield, please visit http://www.hhs.gov/aspr/barda.

**SCOPE**

The objective of this contract is to develop an anthrax vaccine containing rPA and CpG immunostimulant. The scope of work includes demonstrating stability of the candidate vaccine and diluent at 35 degrees C over the duration of the base period; safety prior to human use through acute dose and repeat dose toxicology testing in 2 animal species; improved vaccine efficacy over existing vaccines through non-clinical aerosol challenge studies in the pre-existing rabbit and macaque models, plus supporting studies in the mouse models. Options exist for a Phase I and Phase II clinical trial.

**TECHNICAL REQUIREMENTS BY MILESTONE**

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of the contract, as needed to perform the Statement of Work.

The U.S. Government reserves the right to determine, at any time during the contract period, that a particular candidate/product has not demonstrated sufficient potential to merit further investment in the development and evaluation of that candidate/product. In addition, the U.S. Government reserves the right to modify the milestones, progress, schedule, budget, or product to add or delete products, process, or schedule as need may arise. Because of the nature of this Research and Development (R&D) contract and complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. In any event, the Government reserves the right to change product, process, schedule, or event to add or delete part or all of these elements as the needs arise.

The Contractor shall attend the following contract meetings:

- Post-Award Contract Initiation Meeting: Within thirty (30) calendar days after the effective date of the contract, the Contractor shall plan, conduct and be responsible for the logistical arrangements for a 1.5-day Post-award Contract Initiation Meeting to be held in the Bethesda, Maryland area.

- Annual Review Meetings: The Contractor, in consultation with the Project Officer, shall plan, organize and conduct 2-day Annual Review Meetings to be held at the twelve (12) month mark of each contract year at locations that will alternate between the Contractor's site and the Bethesda, Maryland area. These meetings shall include updates of the status of efforts for each milestone since the prior meeting, a description of any problem(s) that may have arisen and actions taken or recommended to resolve identified problems, and a discussion of future plans for each milestone.



- Additional Contract Meetings: Principal Investigator, Project Manager, and Contractor and subcontractor personnel shall attend at least two additional 1-day meetings per year at locations that will alternate between the Contractor's site and the Bethesda, Maryland area at the request of the Project Officer, as necessary, to discuss contract specific issues and to review recommended changes or deviations from milestones and timelines in the approved Product Development Plan.

**BASE PERIOD - Process Development and Feasibility**

**1.0 Manufacture of cGMP FDP (lyo-rPA/CpG) and diluent (Milestone 1)**

Within 28 months, complete the release of >2,000 doses of both cGMP FDP (lyo rPA/CpG) and diluent, suitable for use in Phase I clinical trials. Work shall include the following activities and deliverables:

a. Process Development

- Generation of R&D FDP (lyo rPA/CpG) and diluent for analytical development and preliminary stability studies
- Production of development lots
- Production of initial reference standard
- Development of the process steps to produce the bulk FDP (lyo rPA/CpG)
- Formulation and its subsequent aliquoting into vials prior to lyophilization.
- Development of the Iyophilization cycle suitable for manufacturing to the required scale.
- A final report shall be provided to the Project Officer, which shall describe the development activities undertaken, data generated and recommendations for technical transfer and scale up of the process.

b. Technical Transfer of process to FDP (lyo rPA/CpG) manufacturer

- Review audit status, quality agreement and commercial contract. Re-audit, update the quality agreement and contract as required.
- Submit copy of current audit report and quality agreement to the Project Officer for consent prior to placing orders with CMO.
- Transfer of the lyophilization process to the cGMP facility - CMO.
- Establishment and qualification of the required analytical methods at CMO and/or other selected CROs.
- Technical transfer reports summarizing completion of activities shall be submitted to the Project Officer, including analytical qualification reports, prior to GMP manufacture.

c. Production of Master Batch Records (MBRs)

- Master batch records shall be produced by CMO and reviewed and approved by the Contractor's technical and quality functions and by CMO
- Final approved MBRs shall be submitted to the Project Officer prior to production of the demonstration batches

d. Production of two demonstration batches of FDP (lyo rPA/CpG)

- Conduct cGMP manufacturing runs
- Complete release testing of material
- Complete QA review of batch records, including review of non-conformances and disposition of batch



e. Update of Master Batch Records (MBRs)

- Updated Master batch records shall be produced by CMO and reviewed and approved by the Contractor's technical and quality functions and by CMO

f. Production of two clinical batches of cGMP FDP (lyo rPA/CpG)

- Conduct two cGMP manufacturing runs
- Complete release testing of materials
- Complete QA review of batch records, including review of non-conformances and disposition of batch
- Submit copies of the executed BMRs and CoA to Project Officer, within 5 months after manufacture.

g. Clinical batch of cGMP diluent (to be supplied from the Challenge Grant program)

- Conduct a cGMP manufacturing run
- Complete release testing of diluent
- Complete QA review of batch records, including review of non-conformances and disposition of batch
- This work shall be supplied from the existing challenge grant

**2.0 Development and Qualification of Assays (Milestone 2)**

Develop and qualify all assays required for manufacture, stability, non-clinical and clinical. Work shall include the following activities and deliverables:

a. Analytical Development and qualification of Process Assays

- Development and qualification of in-process monitoring and control assays
- Qualification reports shall be produced and submitted to the Project Officer within 14 months of award.

b. Analytical Development and qualification of Product Assays

- Development and qualification of product characterization and release assays
- Qualification reports shall be produced and submitted to the Project Officer within 14 months of award.

c. Analytical Development and qualification of Stability Indicating Assays

- Development and qualification of stability indicating assays
- Qualification reports shall be produced and submitted to the Project Officer within 14 months of award.

d. Development of immuno-potency assay in association with on-going rPA vaccine programme.

- Development of immuno-potency assay
- Development reports shall be produced and submitted to the Project Officer within 24 months of award.



**3.0 Stability (Milestone 3)**

Initiate R&D and cGMP stability trials within 11 months and 26 months respectively of contract award. Work shall include the following activities and deliverables:

a) Set up R&D and cGMP stability trials

***R&D Stability Trials***

- Produce R&D protocol(s) for FDP (Iyo-rPA/CpG) and diluent stability trials
- Initiate the R&D stability trial using the non-GMP FDP (lyo rPA/CpG) and diluent material

***cGMP Stability Trials***

- Review audit status, quality agreement and commercial contract. Re-audit, update the quality agreement and contract as required.
- Submit copy of current audit report and quality agreement to Project Officer prior to placing orders with CRO
- Produce cGMP protocol(s) for FDP (lyo rPA/CpG) and diluent stability trials
- Technical and quality review and approval of protocols
- Initiate stability trial using the cGMP FDP (lyo rPA/CpG) lot and diluent. The stability program shall include real-time and accelerated studies using temperatures of 35 ° C (proposal required temperature) and 55 ° C (accelerated condition).
- cGMP stability protocols shall be submitted to the Project Officer at least 1 month prior to initiation of the study.
- Updated stability data shall be submitted to the Project Officer as part of the Monthly report.
- An end of stability study report shall be submitted to the Project Officer

**4.0 Pre-Clinical Toxicology (Milestone 4)**

Within 12 months of contract award, commence a Good Laboratory Practice (GLP) safety and toxicity study(ies). Work shall include the following activities and deliverables:

a. Confirmation of CRO and Generation of study protocols

- Review audit status, quality agreement and commercial contract. Re-audit, update the quality agreement and contract as required.
- Production of a draft safety and toxicity protocol(s)
- Submit for Project Officer review a draft safety and toxicity protocol(s) (WBS 4.1.2)
- Submit copy of current audit report and quality agreement to Project Officer prior to placing orders with CRO.

b. Conduct Acute Dose Safety and Toxicity Studies

- Finalize set-up with CRO (including supply of materials and animals)
- Complete acute dose toxicity studies
- Technical and quality review and approval of reports
- Submit reports to Project Officer.



c. Conduct Repeat Dose Safety and Toxicity Studies

- Finalize set-up with CRO (including supply of materials and animals)
- Complete repeat dose toxicity studies
- Technical and quality review and approval of reports
- Submit reports to Project Officer.

d. Conduct Safety Pharmacology study

- Finalize set-up with CRO (including supply of materials and animals)
- Complete safety pharmacology study
- Technical and quality review of report
- Submit report to Project Officer.

e. Submission of final reports to CBER

- Submit Acute Dose report to CBER and seek concurrence
- Submit Repeat Dose report to CBER and seek concurrence
- Submit Safety Pharmacology report to CBER and seek concurrence
- Provide documentation to the Project Officer of interactions with the FDA and that concurrence has been received from CBER/FDA.

**5.0 Non-Clinical Development Mouse Model - (Milestone 5)**

Within 8 month of contract award, commence studies in the mouse model. Prior to the initiation of these studies, confirmation of the CRO shall be undertaken.

Upon CRO confirmation the following studies shall be undertaken;

i. Excipient Effects
ii. Immunogenicity studies
iii. Dose Ranging (CpG/rPA ratios)
iv. Adjuvant Requirements

Each of the above studies shall include the following activities and deliverables:

a. Animal Studies Group (ASG) Consultation

- Submission of a draft protocol(s) to ASG and NIH
- Finalize protocol incorporating any comments from ASG
- Provide documentation to the Project Officer in the form of written minutes of interactions with the ASG and that concurrence has been received from ASG.

b. Conduct Studies (i to iv) and Reporting

- Finalize set-up with CRO (including supply of materials and animals)
- Complete studies
- Technical and quality review and approval of report(s)
- Submit report(s) to Project Officer
- Circulate report(s) to ASG



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

   · hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**(u) Grand Totals**



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

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

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



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**FINANCIAL REPORTING INSTRUCTIONS:**

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

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

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

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

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

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

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

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

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

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

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



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**SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT**

(a) Designated Billing Office Name and Address:

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

Bethesda, MD 20892-8500

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

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

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

*DUNS or DUNS+4:
*TIN:

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

(c) Invoice/Financing Request No.:

(d) Date Invoice Prepared:

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

(f) Effective Date:

(g) Total Estimated Cost of Contract/Order.

(h) Total Fixed Fee (if applicable):

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

J) Office of Acquisitions:

(k) Central Point of Distribution:

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

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

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

(Name of (Title)

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



**INCLUSION ENROLLMENT REPORT**

This report format should NOT be used for data collection from study participants

**Study Title:**

**Total Enrollment:** **Protocol Number:**
**Contract Number:**

**PART A. TOTAL ENROLLMENT REPORT:** **Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race**

| Ethnic Category | Sex/Gender: Females | Sex/Gender: Males | Unknown or Not Reported | Total |
|---|---|---|---|---|
| Hispanic or Latino | | | | 0 |
| Not Hispanic or Latino | | | | 0 |
| Unknown (Individuals not reporting ethnicity) | | | | 0 |
| Ethnic Category: Total of All Subjects* | 0 | 0 | 0 | 0 |
| **Racial Categories** | | | | |
| American Indian/Alaska Native | | | | 0 |
| Asian | | | | 0 |
| Native Hawaiian or Other Pacific Islander | | | | 0 |
| Black or African American | | | | 0 |
| White | | | | 0 |
| More than one race | | | | 0 |
| Unknown or not reported | | | | 0 |
| Racial Categories: Total of All Subjects* | 0 | 0 | 0 | 0 |

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)**

| Racial Categories | Females | Males | Unknown or Not Reported | Total |
|---|---|---|---|---|
| American Indian or Alaska Native | | | | 0 |
| Asian | | | | 0 |
| Native Hawaiian or Other Pacific Islander | | | | 0 |
| Black or African American | | | | 0 |
| White | | | | 0 |
| More Than One Race | | | | 0 |
| Unknown or not reported | | | | 0 |
| **Racial Categories: Total of Hispanics or Latinos**** | 0 | 0 | 0 | 0 |

*These totals must agree
**These totals must agree

Inclusion Enrollment Report
October, 2001

ATTACHMENT 3

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## ANNUAL TECHNICAL PROGRESS REPORT FORMAT FOR EACH STUDY

Study Title:
Date:

Provide the number of subject enrolled in the study to date according to the following categories:

| | American Indian or Alaskan Native | Asian or Pacific Islander | Black, not of Hispanic Origin | Hispanic | White, not of Hispanic Origin | Other or Unknown | Total |
|---|---|---|---|---|---|---|---|
| **Female** | | | | | | | |
| **Male** | | | | | | | |
| **Unknown** | | | | | | | |
| **TOTAL** | | | | | | | |

Subpopulations of the minority groups should also be reported, using a similar format.

Annual Technical Progress Report
July 1994

ATTACHMENT 4

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HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2006)

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

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

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

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

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

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

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

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

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

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

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

(End of Clause)

Safety and Health
HHSAR 352.223-70 (1/06) ATTACHMENT 5

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PROCUREMENT OF CERTAIN EQUIPMENT, NIH(RC)-7

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

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

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

NIH(RC)-7 (4/1/84)
OMB Bulletin 81-16 ATTACHMENT 6

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**RESEARCH PATIENT CARE COSTS — NIH(RC)-11**

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

NIC(RC)-4 (4/1/84) ATTACHMENT 7

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

Approved by OMB
0348-0046

**1. Type of Federal Action:**

o a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

**2. Status of Federal Action:**

o a. bid/offer/application
b. initial award
c. post-award

**3. Report Type:**

o a. initial filing
b. material change

**For Material Change Only:**
Year quarter
date of last report

**4. Name and Address of Reporting Entity:**
**o Prime** **o Subawardee**
Tier , *if known*:

**Congressional District**, *if known*: 4c

**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:**

**Congressional District,** *if known*:

**6. Federal Department/Agency:**

**7. Federal Program Name/Description:**

CFDA Number, *if applicable*:

**8. Federal Action Number,** *if known :*

**9. Award Amount,** *if known* :
$

**10. a. Name and Address of Lobbying Registrant**
(*if individual, last name, first name, MI*):

**b. Individuals Performing Services**
(*including address if different from No. 10a*)
(*last name, first name, MI*):

**11.** Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____
Print Name: _____
Title: _____
Telephone No.: _____ Date: _____

**Federal Use Only:**

Authorized for Local Reproduction
Standard Form LLL (Rev. 7-97)

Disclosure of Lobbying Activities, SF-LLL
7/97 ATTACHMENT 8

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

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

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks “Subawardee,” then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., “RFP-DE-90-001.”

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

**Exhibit 10.39**

**EXECUTION COPY**

**SECURITIES PURCHASE AGREEMENT**

THIS AGREEMENT (this "**Agreement**"), dated this 30th day of September, 2008 (the **"Execution Date"**), is entered into by and among PharmAthene, Inc., a Delaware corporation, having its office at One Park Place; Suite #450, Annapolis, MD 21401 (the "**Company**"), and its successors and permitted assigns, and Kelisia Holdings Ltd., a company limited by shares established under the laws of Cyprus, having its office at 29 Theklas Lyssioti Street, Cassandra Centre, 2nd Floor, 3731 Limassol, Cyprus (the "**Investor**"), and its successors and permitted assigns.

**WHEREAS**:

1. The Company is engaged in the business of research development, manufacture and marketing of pharmaceutical formulations and vaccines;

2. The Investor is an indirect wholly-owned Subsidiary (as defined hereinafter) of Panacea Biotec Limited, a public limited company established under the laws of India, having its registered office at Ambala-Chandigarh Highway, Lalru-140501, Punjab, India ("**PBL**"), which has been formed for various purposes, including, but not limited to conducting research, development, manufacturing and marketing of pharmaceutical formulations and vaccines and making strategic investments in entities engaged in related fields; and

3. The Company, PBL and the Investor, desirous of entering into a strategic alliance, the scope, terms and conditions of which are to be mutually agreed upon but may include (x) manufacturing and/or process development services to be provided to the Company by the Investor and/or PBL and (y) marketing of biodefense products manufactured by the Investor and/or PBL in the United States by PIP, wish to provide for the purchase and sale of Shares and a Warrant (both as hereinafter defined) to the Investor, as more specifically set forth hereinafter.

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements herein contained and for other good and valuable consideration, the receipt and sufficiency of which has been acknowledged by the parties, the parties hereto, intending to be legally bound, hereby agree as follows:

**SECTION 1. Authorization of Issuance and Sale of Shares and Warrant.**

Subject to the terms and conditions hereof, the Company has authorized the issuance and sale to Investor on the Closing Date (as defined in Section 3 hereof) of (i) 3,733,334 shares (the "**Shares**") of common stock, having a par value of US$0.0001 per share, of the Company (the "**Common Stock**") at a price of US$3.50 per share and (ii) a warrant to purchase up to 2,745,098 shares of Common Stock (the "**Warrant Shares**") at an exercise price of US$5.10 per share, whether in one or more tranches, subject to adjustment as set forth therein, in the form attached hereto as Exhibit A (the "**Warrant**") (the Shares and the Warrant issuable to the Investor hereunder and the Warrant Shares are collectively sometimes referred to as the "**Securities**").

**SECTION 2. Sale and Delivery of Shares and Warrant.**

2.1 **Agreement to Sell and Purchase the Shares**. Subject to the satisfaction or waiver of the conditions precedent set forth in Section 6 hereof and the other terms and conditions set forth in this Agreement, at the Closing, the Company shall issue and sell to the Investor, and the Investor shall purchase from the Company, at an aggregate purchase price of US$13,066,669.00 (the "**Purchase Price**"): (a) the Shares *and* (b) the Warrant.

2.2 **Delivery of Shares and Warrant**. At the Closing, the Company shall deliver to the Investor (i) a certificate, registered in the name of the Investor, representing the Shares being purchased by the Investor and (ii) the Warrant executed by the Company. The delivery of such certificate and Warrant shall be made against receipt by the Company at the Closing of a wire transfer to the account designated in writing by the Company of immediately available funds in the amount of US$13,066,669.00.

**SECTION 3. The Closing.**

3.1 **Closing**. The closing (the "**Closing**") hereunder, with respect to the transactions contemplated by Section 2 hereof, shall take place on the second Business Day (excluding the date of receipt of notice) following receipt by the Company of written notice (the "**Closing Notice**") from the Investor (such date sometimes being referred to herein as the "**Closing Date**") that the Closing is to occur at the offices of the Company at One Park Place, Suite 450, Annapolis, Maryland 21401; provided that, in the event the Company has not received the Closing Notice by October 18, 2008, the Closing shall occur on October 20, 2008, notwithstanding the absence of a Closing Notice. The Closing may be accomplished by the facsimile or email transmission of executed copies of the documents contemplated hereby to be delivered at the Closing, confirmed by delivery of originally executed copies of such documents within five (5) Business Days of the Closing Date. The term "**Business Day**" shall mean a day, other than Saturday, Sunday or a public holiday, in the country of the Company and the country of the Investor.

**SECTION 4. Representations and Warranties of the Company to the Investor.**

The Company hereby makes the representations and warranties contained herein to the Investor and acknowledges that the Investor has agreed to the transaction described in Section 2 hereof in reliance on such representations and warranties. The representations and warranties shall be deemed to be true and correct as of the date hereof, except as set forth in the disclosure schedules to be delivered to the Investor by the Company on the date hereof (the "Disclosure Schedules"), and to have been relied upon by the Investor and there shall be no obligation on the Company to update such representations, warranties or Disclosure Schedules subsequent to the date hereof. Disclosures made in the Disclosure Schedules shall not be deemed to constitute additional representations or warranties of the Company but set forth disclosures, exceptions and exclusions called for under this Agreement. The Company hereby represents and warrants to the Investor as follows:

4.1 **Organization**. The Company and each Subsidiary (as defined hereinafter) is an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of organization and have all requisite corporate power and authority to own and lease its property and to carry on its respective businesses as presently conducted and as proposed to be conducted as described in the Company Reports (as defined in Section 4.18 below). The Company and each Subsidiary is duly qualified to do business as a foreign corporation under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, or is subject to no material liability or disability by reason of the failure to be so qualified in any such jurisdiction. Neither the Company nor any Subsidiary owns or leases property or engages in any activity in any other jurisdiction that would require its qualification in such jurisdiction and in which the failure to be so qualified would have a Material Adverse Effect. As used in this Agreement, the term "**Material Adverse Effect**" shall mean any event, occurrence, fact, condition, change, development or effect that is materially adverse to the business, operations, properties (including intangible properties), of the Company and its Subsidiaries taken as a whole; or which has the effect of materially increasing the liabilities of the Company and its Subsidiaries taken as a whole; or which has the effect of materially impairing the ability of the Company and its Subsidiaries to perform their obligations hereunder.

4.2 **Capitalization**.

(a) As more fully described in the capitalization table included in the Company's filings with the SEC, but taking due account for changes in the numbers since the dates of such filings, the authorized and outstanding capital stock of the Company immediately prior to the Closing consists of:

(i) 100,000,000 authorized shares of Common Stock, of which:

(A) 22,319,928 shares of Common Stock are validly issued and outstanding, fully paid and non-assessable;

(B) 11,823,863 shares duly reserved for issuance upon conversion or exercise of securities that may be converted into or exercised for Common Stock (not including Option Shares as defined below); and

(C) 3,591,272 shares duly reserved for issuance in connection with options available under the Company's 2007 Long-Term Incentive Compensation Plan (the "**Option Shares**");

(ii) 1,000,000 authorized shares of preferred stock of the Company, par value US$0.0001 per share, none of which have been designated and none of which are issued or outstanding.

(b) As more fully described in the capitalization table set forth in Exhibit B attached hereto, the authorized and outstanding capital stock of the Company immediately following the Closing shall consist of:



(i) 100,000,000 authorized shares of Common Stock, of which:

(A) 26,053,262 shares of Common Stock shall be validly issued and outstanding, fully paid and non-assessable;

(B) 14,568,961 shares shall have been duly reserved for issuance upon conversion or exercise of securities that may be converted into or exercised for Common Stock, including the Warrant Shares (not including Option Shares); and

(C) 3,591,272 shares shall have been duly reserved for issuance in connection with Option Shares.

(ii) 1,000,000 authorized shares of preferred stock of the Company, par value US$0.0001 per share, none of which shall have been designated and none of which shall be issued or outstanding.

Except pursuant to the terms of this Agreement, the Investor Rights Agreement to be executed and delivered on the Closing Date in the form attached hereto as Exhibit C (the "**Investor Rights Agreement**"), and as set forth in Schedule 4.2 attached hereto and the Company Reports (as defined in Section 4.6(b)), there are, and immediately following the Closing there will be, (i) no outstanding warrants, options, rights, agreements, convertible securities or other commitments or instruments pursuant to which the Company is or may become obligated to issue, sell, repurchase or redeem any shares of capital stock or other securities of the Company, (ii) no preemptive, contractual or similar rights to purchase or otherwise acquire shares of capital stock of the Company pursuant to any provision of law, the certificate of incorporation of the Company (the "**Certificate**"), the bylaws of the Company (the "**Bylaws**") or any agreement to which the Company, or to the Company's knowledge, any of its officers, directors or affiliates, is a party or may otherwise be bound, (iii) no restrictions on the transfer of capital stock of the Company imposed by the Certificate or Bylaws of the Company, any agreement to which the Company, or to the Company's knowledge, any of its officers, directors or affiliates, is a party, any order of any court or any Governmental Authority to which the Company, or to the Company's knowledge, any of its officers, directors or affiliates, is subject, or any statute other than those imposed by relevant state and federal securities laws, (iv) no cumulative voting rights for any of the Company's capital stock, (v) no registration rights under the Securities Act of 1933, as amended (the "**Securities Act**"), with respect to shares of the Company's capital stock, (vi) to the Company's knowledge, no options or other rights to purchase shares of capital stock from stockholders of the Company granted by such stockholders and (vii) no agreements, written or oral, between the Company and any holder of its securities, or, to the Company's knowledge, among holders of its securities, relating to the acquisition, disposition or voting of the securities of the Company.

4.3 **Authorization of this Agreement and the Investor Rights Agreement**. The execution, delivery and performance by the Company of this Agreement and the Investor Rights Agreement and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite action on the part of the Company and/or its shareholders. Each of this Agreement and the Investor Rights Agreement has been duly

executed and delivered by the Company and constitutes a valid and binding obligation of the Company, enforceable in accordance with its respective terms. The execution, delivery and performance of this Agreement and the Investor Rights Agreement and the compliance with the provisions hereof and thereof by the Company will not:

(a) violate any provision of law, statute, ordinance, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other Governmental Authority;

(b) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute (with due notice, lapse of time or both) a default (or give rise to any right of termination, cancellation or acceleration) under (i) any agreement, document, instrument, contract, note, indenture, mortgage or lease to which the Company is a party or under which the Company or any of its assets is bound or affected, (ii) the Certificate or (iii) the Bylaws; or

(c) result in the creation of any lien, security interest, charge or encumbrance upon any of the properties or assets of the Company, except to such extent as would not, individually or in the aggregate, have a Material Adverse Effect.

As used in this Agreement, "**Governmental Authority**" shall mean any nation or government; any federal, state, municipal, local, provincial, regional or other political subdivision thereof; and any entity or person exercising executive, legislative, judicial, regulatory or administrative functions of, or pertaining to, government.

4.4 **Authorization of Common Stock, Warrant and Warrant Shares**. The issuance, sale and delivery of the Shares, Warrant and Warrant Shares contemplated hereby have been duly authorized by all requisite action of the Company, and, when issued, sold and delivered in accordance with (i) this Agreement, the Shares will be validly issued and outstanding, fully paid and non-assessable, with no personal liability attaching to the ownership thereof, and not subject to any encumbrances, rights of first refusal, preemptive rights or similar rights of the stockholders of the Company or others except for any such rights of the Investor under the Investor Rights Agreement, and (ii) the Warrant, and upon the exercise thereof in accordance with the terms of the Warrant, the Warrant Shares will be, validly issued and outstanding, fully paid and nonassessable, with no personal liability attaching to the ownership thereof, and not subject to any encumbrances, rights of first refusal, preemptive rights or similar rights of the stockholders of the Company or others except for any such rights of the Investor under the Investor Rights Agreement. The Company has reserved from its duly authorized capital stock the maximum number of the Warrant Shares (subject to adjustment as provided by the terms of the Warrant) that are issuable upon the exercise of the Warrant.

4.5 **Consents and Approvals**. No authorization, consent, license, application, approval or other order of, or declaration to or filing with, any Governmental Authority (other than filings that are required to be made under applicable federal and state securities laws (which filings shall be made by the Company in accordance with applicable federal and/or state securities laws) or any other person, entity or association is required for (a) the valid



authorization, execution, delivery and performance by the Company of this Agreement and the Investor Rights Agreement or (b) the valid authorization, issuance, sale and delivery of the Securities. The Company has obtained all consents that are necessary to permit the consummation of the transactions contemplated hereby and thereby, including, without limitation, any consent required by the Trading Market.

4.6 **The Company**.

(a) Except as set forth in Schedule 4.6(a) attached hereto, the business of the Company and its Subsidiaries (the "**Business**") is described in the Company Reports.

(b) The Company has filed all reports, registration statements, proxy statements and information statements required to be filed by it under the Securities Act and the Exchange Act, including pursuant to Section 13(a) and 15(d) thereof, for the two years preceding the date hereof (collectively, as they have been amended since the time of their filing and including all exhibits thereto, the "**Company Reports**"). As of their respective dates (and, if amended or superseded by a filing prior to the date hereof, then on the date of such filing), (x) the Company Reports filed over the last two years complied as to form in all material respects with the applicable requirements of the Securities Act and the Exchange Act and the rules and regulations of the Securities and Exchange Commission (the "**Commission**") promulgated thereunder, and (y) none of such Company Reports contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Company is in compliance with applicable requirements of the Sarbanes-Oxley Act of 2002 and applicable rules and regulations promulgated by the Commission thereunder in effect as of the date of this Agreement, except where such noncompliance will not have, individually or in the aggregate, a Material Adverse Effect. To the knowledge of the Company, none of the Company Reports currently is the subject of any review or investigation by the Commission or any other Governmental Authority and there is no currently unresolved violation asserted in writing by the Commission or any Governmental Authority with respect to any of the Company Reports. All statutory books, minutes and registers in relation to the Company have been properly recorded and kept by the Company and all documents which the Company is required by applicable law to file with or deliver to a Person have been correctly filed and/or delivered, except where failure to so record, keep, file or deliver will not have, individually or in the aggregate, a Material Adverse Effect.

(c) Except as set forth in Schedule 4.6(c) attached hereto and the Company Reports:

(i) Neither the Company nor any Subsidiary has entered into, and is a party to, and is otherwise bound or affected by, any written or oral contract, agreement, understanding, arrangement, lease, guaranty or other obligation or series of related obligations or transactions in excess of two hundred and fifty thousand U.S. dollars (US$250,000), other than this Agreement;



(ii) Neither the Company nor any Subsidiary is a party to, or, directly or indirectly, bound by, any material indenture, mortgage, deed of trust or other agreement or instrument relating to the borrowing of money, the guarantee of indebtedness or the granting of any security interest, negative pledge or other encumbrance on the assets of the Company; and

(iii) Neither the Company nor any Subsidiary has incurred, and is subject to any, liabilities or obligations, fixed or contingent, matured or unmatured or otherwise that, individually or in the aggregate, could have a Material Adverse Effect.

(d) The financial statements included in the Company Reports, including any notes thereto, reflect all liabilities of the Company as of the date of such financial statements. Since the date of the unaudited balance sheet dated June 30, 2008 (the "**June 30, 2008 Balance Sheet**"), the Company and its Subsidiaries have not incurred any obligation (or series of related obligations) or liability, contingent or otherwise, in excess of two hundred and fifty thousand U.S. dollars (US$250,000) except as set forth in Schedule 4.6(d) attached hereto. The Company has established and maintains internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended; a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP (as defined in Section 4.6(l) below).

(e) Except as set forth in Schedule 4.6(e) attached hereto and the Company Reports, (i) there are no actions, suits, arbitrations, claims, investigations or legal or administrative proceedings pending or, to the Company's knowledge, threatened, against the Company or any Subsidiary, whether at law or in equity, that, if determined adversely to the Company or any Subsidiary, would reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect, (ii) there are no judgments, decrees, injunctions or orders of any court or Governmental Authority entered or existing against the Company or any Subsidiary or any of their assets or properties for any of the forgoing or otherwise and (iii) the Company and its Subsidiaries have not (A) admitted in writing its inability to pay its debts generally as they become due, (B) filed or consented to the filing against it of a petition in bankruptcy or a petition to take advantage of any insolvency act, (C) made an assignment for the benefit of creditors, consented to the appointment of a receiver for itself or for the whole or any substantial part of its property, (D) had a petition in bankruptcy filed against it, (E) been adjudicated bankrupt, or (F) filed a petition or answer seeking reorganization or arrangement under the federal bankruptcy laws or any other laws of the United States or any other jurisdiction.

(f) The Company and its Subsidiaries are in compliance with all obligations, agreements and conditions contained in any evidence of indebtedness or any loan agreement or other contract or agreement (whether or not relating to indebtedness) to which the Company or any Subsidiary is a party or is subject (collectively, the "**Obligations**"), the lack of compliance with which could afford to any person the right to accelerate any indebtedness or terminate any right of or agreement with the Company or any Subsidiary, except for such lack of compliance that would not, individually or in the aggregate, have a Material Adverse Effect. To



the Company's knowledge, all other parties to such Obligations are in compliance with the terms and conditions of such Obligations.

(g) Except for employment and consulting agreements set forth in Schedule 4.6(c) attached hereto and the Company Reports and for agreements and arrangements relating to the Option Shares and except as set forth in Schedule 4.6(g) attached hereto and the Company Reports, this Agreement and the Investor Rights Agreement, there are no agreements, understandings or proposed transactions between the Company and any of its officers, directors or other "affiliates" (as defined in Rule 405 promulgated under the Securities Act), and there are no transactions between any of such persons and the Company of a type required to be disclosed under Rule 404 of Regulation S-K promulgated under the Securities Act, that have not been so disclosed. There are no employment related disputes/monetary claims involving the employees as parties or otherwise affecting their rights and obligations under a relevant employment agreement, pending or, to the Company's knowledge, threatened against the Company.

(h) All of the employees of the Company and its Subsidiaries who have, or are proposed to have, access to confidential and/or proprietary information of the Company or any Subsidiary, are signatories to, and are bound by, agreements with the Company or such Subsidiary relating to nondisclosure, proprietary information and assignment of patent, copyright and other intellectual property rights in substantially the forms provided to the Investor.

(i) The Company's executive officers as of the date hereof, i.e., David P. Wright, Christopher C. Camut, Valerie Riddle, Eric I. Richman, Francesca Cook, Wayne Morges, Joan Fusco, and Jordan P. Karp, are signatories to, and are bound by, agreements with the Company relating to non-competition.

(j) To the Company's knowledge, no employee of, or consultant to, the Company or any Subsidiary is in violation of any term of any employment contract, patent-disclosure agreement or any other contract or agreement including, but not limited to, those matters relating to (i) the relationship of any such employee with the Company or a Subsidiary or to any other party as a result of the nature of the Company's business as currently conducted or (ii) unfair competition, trade secrets or proprietary information.

(k) Neither the Company nor any Subsidiary has a collective-bargaining agreement covering any of its employees or any employee-benefit plans, except as set forth in Schedule 4.6(k) attached hereto and the Company Reports.

(l) Neither the Company nor any Subsidiary is in violation of, or default under, any provision of its Bylaws or Certificate (or any similar organizational documents), or any material contract, instrument, judgment, order, writ or decree to which it is a party or by which it or any of its properties is bound, and the Company and its Subsidiaries are not in violation of any provision of any federal or state statute, rule or regulation applicable to the Company or any Subsidiary.



(m)

(i) Included in the Company Reports is the balance sheet dated December 31, 2007 (the "**2007 Balance Sheet**"), and statements of operation, stockholders' equity and cash flows for the year then ended (collectively, the "**Financial Statements**"), audited by Ernst & Young LLP, independent certified public accountants of the Company, each of which Financial Statements has been prepared in accordance with accounting principles generally accepted in the United States ("**U.S. GAAP**") consistently applied, and fairly present the financial position of the Company as of the date of such financial statements and the results of its operations for the period covered thereby, subject only to the matters described in the accountant's report

attached thereto. Also included in the Company Reports is the June 30, 2008 balance sheet and the statements of operation and cash flows for the period from January 1, 2008, through June 30, 2008 (collectively, the "**Unaudited Financial Statements**"). The Unaudited Financial Statements are complete and correct, are in accordance with the books and records of the Company and present fairly the financial condition and results of operation of the Company, as at the dates and for the periods indicated, and have been prepared in accordance with U.S. GAAP consistently applied, except that the Unaudited Financial Statements may not be in accordance with U.S. GAAP solely because of the absence of footnotes normally contained therein and are subject to normal year-end audit adjustments. Specifically, but not by way of limitation, the June 30, 2008 balance sheet discloses all of the Company's debts, liabilities and obligations of any nature, whether due or to become due, as of their respective dates (including, without limitation, absolute, accrued and contingent liabilities) to the extent such debts, liabilities and obligations are required to be disclosed in accordance with U.S. GAAP.

(ii) Since the date of the June 30, 2008 balance sheet and other than as set forth in the Company Reports, there has not been:

(A) any damage, destruction or loss to any property of the Company or its Subsidiaries, whether or not covered by insurance, that has had, or will have, a Material Adverse Effect;

(B) any waiver by the Company or any Subsidiary of a material right or of a material debt owed to it;

(C) any satisfaction or discharge of any lien, claim or encumbrance or payment of any obligation by the Company or any Subsidiary, except such a satisfaction, discharge or payment made in the ordinary course of business that would not reasonably be expected to have a Material Adverse Effect;

(D) any change or amendment to a material contract or arrangement by which the Company, any Subsidiary or any of their assets or properties is bound or subject;

(E) any material change in any compensation arrangement or agreement with any present or prospective employee, contractor or director of the Company or any Subsidiary;



(F) any loan to any officer, director or shareholder of the Company or any Subsidiary, other than advances in the ordinary course of business and as permitted under the Securities Laws (as hereinafter defined);

(G) any debt, obligation or liability incurred, assumed or guaranteed by the Company, except for those that are immaterial in amount and for current liabilities incurred in the ordinary course of business;

(H) any other event or condition of any character that would have a Material Adverse Effect; or

(I) any agreement by the Company or any Subsidiary to do any of the foregoing.

(iii) Neither the Company nor any Subsidiary has any liabilities, whether actual or contingent, that were not reflected in the June 30, 2008 balance sheet, except for liabilities incurred after the date thereof in the ordinary course of business, which will not have any Material Adverse Effect on the Company.

4.7 **Payment of Taxes**. Neither the Company, any Subsidiary, nor any entity to whose liabilities the Company has succeeded, has filed or been included in a consolidated, unitary or combined tax return with another person. Except as set forth in Schedule 4.7 and the Company Reports, the Company represents and warrants that (a) the Company and each Subsidiary has filed all tax returns and reports required to have been filed by or for it, including but not limited to income tax, sales tax, use tax and payroll tax returns, (b) all material information set forth in such returns or reports is accurate and complete, (c) the Company and each Subsidiary has paid or made adequate provision for all taxes, additions to tax, penalties, and interest payable by the Company and its Subsidiaries, (d) no material unpaid tax deficiency has been asserted against or with respect to the Company or any Subsidiary by any taxing authority, nor has the Company or any Subsidiary received written notice of any such assertion, (e) the Company and each Subsidiary has collected or withheld all amount required to be collected or withheld by it for any taxes, and, to the extent required by law, all such amounts have been paid to the appropriate governmental agencies or set aside in appropriate accounts for future payment when due, (f) the Company and each Subsidiary is in compliance with, and its records contain all information and documents necessary to comply with, all applicable information-reporting and tax-withholding requirements, (g) the June 30, 2008 balance sheet fully and properly reflects, as of the date thereof, the liabilities of the Company and its Subsidiaries for all accrued taxes, additions to tax, penalties, and interest, (h) for periods ending after June 30, 2008, the books and records of the Company and its Subsidiaries fully and properly reflect its liability for all accrued taxes, additions to tax, penalties and interest, (i) the Company and its Subsidiaries have not granted, nor are they subject to, any waiver of the period of limitations of the assessment of tax for any currently open taxable period, (j) the Company and its Subsidiaries have not made or entered into, and holds no asset subject to, a consent filed pursuant to Section 341(f) of the U.S. Internal Revenue Code of 1986, as amended (the "**Code**"), and the regulations thereunder or a "safe harbor lease" subject to former Section 168(f)(8) of the Internal Revenue Code of 1954, as



amended before the Tax Reform Act of 1986, and the regulations thereunder, (k) the Company and its Subsidiaries are not required to include in income any amount for an adjustment pursuant to Section 481 of the Code or the regulations thereunder and (l) the Company and its Subsidiaries are not a party, or obligated under, any agreement or other arrangement providing for the payment of any amount that would be an "excess parachute payment" under Section 280G of the Code.

4.8 **Intellectual Property Rights**. Except as provided in Schedule 4.8, the Company and each Subsidiary owns or possesses adequate rights to use all material patents, patent applications, trademarks, service marks, trade names, trademark registrations, service-mark registrations, copyrights, licenses, know-how, software, systems and technology (including trade secrets and other unpatented or unpatentable proprietary or confidential information, systems or procedures) used or held for use in the conduct of the Business as presently conducted (collectively, the **"Company Intellectual Property Rights"**). To the Company's knowledge, the Company Intellectual Property Rights that comprise registered trademarks or issued patents are valid

and enforceable. To the Company's knowledge, (i) the operation of the business of the Company, and the products or services in development or which are marketed or sold (or proposed to be marketed or sold) by the Company, do not violate any license or, subject to Schedule 4.8, infringe any intellectual property rights of any party and (ii) there is no unauthorized use, infringement or misappropriation by any third party of any Company Intellectual Property Rights owned by or licensed to the Company. Except as set forth in Schedule 4.8, other than with respect to commercially available software products which the Company and its Subsidiaries license under standard end-user object code license agreements, there are no outstanding material options, licenses, agreements, claims, encumbrances or shared ownership interests of any kind relating to any of the material Company Intellectual Property Rights. To the knowledge of the Company, no third party has made a claim that the Company or its Subsidiaries have violated or, by conducting their business, would violate any Intellectual Property rights of any other person or entity and, to the knowledge of the Company, no such claim has been threatened. Each employee, former employee, contract worker, agent, consultant other service provider and contractor who has contributed to or participated in the conception or development of the Company Intellectual Property Rights, other than those licensed by Company from a third party, has assigned or is obligated to assign to the Company all intellectual property rights relating to such Company Intellectual Property Rights. To the knowledge of the Company, all of the Company Intellectual Property Rights which are registered or have been filed for registration with any third party are in good standing and all of the fees and filings due with respect thereto have been duly made. The Company and its Subsidiaries are not or, as a result of the execution or delivery of this Agreement, or the performance of the Company's obligations hereunder, will not be in violation of any license, sublicense, agreement or instrument involving Intellectual Property to which the Company is a party or otherwise bound, nor will the execution or delivery of this Agreement or the consummation of the transactions contemplated hereby, cause the diminution, license, transfer, termination or forfeiture of the Company's rights in any Company Intellectual Property Rights. The Company has taken commercially reasonable measures to protect the proprietary nature of the proprietary Company Intellectual Property Rights owned by the Company and to maintain in confidence all trade secrets and confidential information owned or used by the Company. No proceedings or, to the



Company's knowledge, investigations challenging or threatening the validity, enforceability, effectiveness or ownership by the Company or its Subsidiaries of any Company Intellectual Property Rights have been made or are outstanding. For the purposes of this Section 4.8, "to the Company's knowledge" shall mean actual knowledge, as of the date of this Agreement, of executive officers of the Company.

4.9 **Securities Laws**. Except as disclosed pursuant to this Agreement, neither the Company nor anyone acting on its behalf has offered securities of the Company for sale to, or solicited any offers to buy the same from, or sold securities of the Company to, any person or organization, in any case so as to subject the Company, its promoters, directors or officers to any liability under the Securities Act, the Securities and Exchange Act of 1934, as amended (the "**Exchange Act**"), or any state securities or "blue sky" law and the rules and regulations promulgated thereunder (collectively, the "**Securities Laws**"). None of the offer, grant, sale or issuance of the Securities to the Investor contemplated by this Agreement and the Investor Rights Agreement will be in violation of the Securities Laws when offered, sold and issued.

4.10 **Title to Assets and Properties**. Except as set forth in Schedule 4.10 attached hereto and the Company Reports, the Company and its Subsidiaries have good and marketable title in fee simple to all real property and good and marketable title to all personal property and assets owned by them, in each case free and clear of all liens, encumbrances and defects except such as, in the aggregate, do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company and its Subsidiaries; and any real property and buildings held under lease by the Company and its Subsidiaries are held by them under valid, subsisting and enforceable leases with such exceptions as are not material and do not interfere with the use made and proposed to be made of such property and buildings by the Company and its subsidiaries. All the assets of the Company, whether movable or immovable, including without limitation, equipment and machinery, owned, leased or licensed to or by the Company or employed by it, are in serviceable condition for use thereof in the ordinary course of Business.

4.11 **Investments in Other Persons**. Except and to the extent set forth in Schedule 4.11 attached hereto and the Company Reports, (a) the Company and its Subsidiaries have not made any loan or advance to any person or entity that is outstanding on the date hereof, nor is it committed or obligated to make any such loan or advance, and (b) the Company has never owned or controlled, and do not currently own or control, directly or indirectly, any subsidiaries and has never owned or controlled, and does not currently own or control, any capital stock or other ownership interest, directly or indirectly, in any corporation, association, partnership, trust, joint venture or other entity (except to the extent reflected on Schedule 4.11, each a **"**Subsidiary**"** and collectively the "Subsidiaries").

4.12 **ERISA/Employee Benefit Plans**.

(a) Schedule 4.12 and the Company Reports contain a true and complete list of each material "employee benefit plan" (within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**")) and each other



material employment, stock option, stock purchase, restricted stock or other equity-based, incentive, severance, termination, retention, change of control or other material benefit plans, programs, agreements, contracts, policies or arrangements contributed to, sponsored or maintained by the Company or any of its Subsidiaries (or which the Company or any of its Subsidiaries is obligated to contribute to, sponsor or maintain) as of the date hereof for the benefit of any future, current, former or retired employee, officer, consultant, independent contractor or director of the Company or any of its Subsidiaries (collectively, the "**Company Employees**") or to which the Company or any of its Subsidiaries is a party or with respect to which the Company or any of its Subsidiaries has or would reasonably be expected to have any liability (such plans, programs, policies, agreements and arrangements, including the Company Stock Plans, and including material bonus, vacation, deferred compensation, profit sharing, savings, retirement, retiree medical or life insurance, supplemental retirement, severance and fringe benefit plans contributed to, sponsored or maintained by the Company or any of its Subsidiaries (or which the Company or any of its Subsidiaries is obligated to contribute to, sponsor or maintain) as of the date hereof for the benefit of any Company Employee, collectively, "**Company Plans**").

(b) With respect to each Company Plan, the Company has made available to Investor a current, accurate and complete copy, including any amendments, of (i) each such Company Plan (or, if a plan is not written, a written description thereof) and, to the extent applicable, (ii) any related trust agreement or other funding instrument, (iii) the most recent determination letter received from the Internal Revenue Service (the "**IRS**") for each Company Plan that is intended to be qualified under Section 401(a) of the Internal Revenue Code of 1986, as amended and including any applicable guidance issued or regulations promulgated thereunder (the "**Code**"), (iv) the most recent summary plan description and any summaries of any material modification of such Company Plan, (v) all prospectuses prepared in connection with any such Company Plan, (vi) any material communications to or from any

governmental agency with respect to any ongoing or pending claim or audit or any claim or audit concluded on or after January 1, 2006, and (vii) for the most recent two years (A) the Form 5500 and attached schedules, (B) audited financial statements, and (C) actuarial valuation reports, if any.

(c) Each Company Plan has been established and administered in all material respects in accordance with its terms and in compliance with the applicable provisions of applicable laws, rules and regulations, including ERISA and the Code. No "prohibited transaction," within the meaning of Section 4975 of the Code or Sections 406 or 407 of ERISA, and not otherwise exempt under Section 408 of ERISA, and no breach of fiduciary responsibility, has occurred with respect to any Company Plan, and no event, transaction, fact or condition exists that, to the knowledge of the Company, presents a risk to the Company or any of its Subsidiaries, or after the Closing Date, to the Investor, or any of their respective Affiliates (as such term is defined in the Investor Rights Agreement), of incurring any such liability. All contributions, premiums and other payments required to be made with respect to each Company Plan have been made on or before their due dates under applicable law and the terms of such Company Plan and all amounts properly accrued to date or as of the Effective Time as liabilities of the Company or any of its Subsidiaries which are not yet due have been properly recorded on the books of the Company and, to the extent required by Generally Accepted Accounting



Principles ("**GAAP**"), adequate reserves are reflected on the Financial Statements of the Company or liability thereof was incurred in the ordinary course of business consistent with past practice since December 31, 2007. No Company Plan has an "accumulated funding deficiency" (whether or not waived) within the meaning of Section 412 of the Code or Section 302 of ERISA.

(d) Neither the Company nor any of its Subsidiaries is now contributing to or has, since January 1, 2003, contributed to or had, any liability, contingent or otherwise, with respect to (i) a pension plan (within the meaning of Section 3(2) of ERISA) subject to Section 412 of the Code or Title IV of ERISA; (ii) a multiemployer plan (within the meaning of Section 3(37) or 4001(a)(3) of ERISA); or (iii) a single employer pension plan (within the meaning of Section 4001(a)(15) of ERISA) for which any other person that, together with the Company or any of its Subsidiaries, is or was treated as a single employer under Section 414 of the Code would reasonably be expected to incur liability under Section 4063 or 4064 of ERISA.

(e) No proceedings (other than routine claims for benefits in the ordinary course) are pending or, to the knowledge of the Company, threatened with respect to any Company Plan or against the assets of such Company Plan.

(f) No Company Plan provides post-termination welfare benefits, and neither the Company nor any of its Subsidiaries has any obligation to provide any post-termination welfare benefits, in each case other than health care continuation as required by Section 4980B of the Code.

(g) Each Company Plan which is intended to be qualified under Section 401(a) of the Code has received a favorable determination letter from the IRS covering all tax law changes prior to the Economic Growth and Tax Relief Reconciliation Act of 2001 or is a prototype plan subject to a favorable opinion letter that may be relied on, and, to the knowledge of the Company, no circumstances exist or existed that has or is likely to affect such favorable determination or result in the loss of qualification of such Company Plan under Section 401(a) of the Code. Each outstanding option is a stock right that is exempt from the provisions of section 409A of the Code. Each Company Plan that is a "nonqualified deferred compensation plan" within the meaning of Section 409A(d)(1) of the Code and applicable guidance issued thereunder (a "**Nonqualified Deferred Compensation Plan**") that is subject to Section 409A of the Code has been operated in good faith compliance with Section 409A of the Code since January 1, 2005. No Nonqualified Deferred Compensation Plan that is intended to be exempt from Section 409A of the Code due to the effective date provisions that are applicable to Section 409A of the Code, as set forth in Section 885(d) of the American Jobs Creation Act of 2004, as amended (the "**AJCA**"), has been "materially modified" within the meaning of Section 885(d)(2)(B) of the AJCA after October 3, 2004, based upon a good faith reasonable interpretation of the AJCA.

(h) Neither the execution by the Company of this Agreement nor the consummation of the transactions contemplated hereby will (either alone or upon occurrence of



any additional or subsequent events) (i) constitute an event under any Company Plan or any trust or loan related to any of those plans or agreements that will or may result in any payment, acceleration, forgiveness of indebtedness, vesting, distribution, increase in benefits or obligation to fund benefits with respect to any Company Employee, (ii) result in the triggering or imposition of any restrictions or limitations on the right of the Company to amend or terminate any Company Plan or (iii) result in the failure of any amount to be deductible by reason of Section 280G of the Code.

(i) No Company Plan is under audit or is the subject of an investigation by the IRS, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation, the SEC or any other governmental agency, nor, to the knowledge of the Company, is any such audit or investigation pending or threatened.

(j) All options, equity and equity-based awards under Company Plans have been granted in compliance with the terms of the applicable Company Plans, with applicable laws, and with the applicable provisions of the Articles of Incorporation and Bylaws as in effect at the time of the applicable grant.

(k) No deduction for federal income tax purposes has been or is expected by the Company to be disallowed for remuneration paid by the Company or any of its Subsidiaries by reason of Section 162(m) of the Code, including by reason of the transactions contemplated hereby.

4.13 **Labor Matters**. The Company and its Subsidiaries (i) are in material compliance with all terms and conditions of employment and all employment laws including, pay equity, wages and hours of work, occupational health and safety and have undertaken necessary health and safety risk assessments and have maintained and implemented all necessary manuals and health and safety management policies and systems and (ii) have not and are not engaged in any unfair labor practice and no unfair labor practice complaint, grievance or arbitration proceeding is pending or, to the knowledge of the Company, threatened against the Company or any of its Subsidiaries. No collective bargaining agreement is currently in force or is currently being negotiated by the Company, any Subsidiary, or any other person in respect of the business of the Company, its Subsidiaries or any of the employees. No trade union, council of trade unions, employee bargaining agency or affiliated bargaining agent holds bargaining rights with respect to any of the employees by way of certification, interim certification, voluntary recognition, or succession rights, or has applied or, to the knowledge of the Company, threatened to apply to be certified as the bargaining agent of the employees of the Company and its Subsidiaries. To the knowledge of the Company, there are no threatened or pending

union organizing activities involving any of the employees of the Company or its Subsidiaries. There is no labor strike, dispute, work slowdown or stoppage pending or involving or, to the knowledge of the Company threatened against the Company or its Subsidiaries. There are no charges pending under OHSA in respect of the Company or any Subsidiary. The Company and each Subsidiary has complied in all respects with any orders issued under OHSA and there are no appeals of any orders under OHSA currently outstanding.



4.14 **Permits and Other Rights; Compliance with Laws**. The Company has all material franchises, material permits, material licenses and other material rights and privileges necessary to permit it to own its properties and to conduct the Business as presently conducted (including all certificates, licenses, registrations, applications, authorizations, approvals and permits required under Environmental Laws, the Federal Food, Drug and Cosmetic Act of 1938, as amended (the **"FDCA"**), the Public Health Service Act of 1944, as amended (the **"PHSA**") and the regulations of the U.S. Food and Drug Administration (the **"FDA"**) promulgated thereunder) (collectively, **"Permits"**), and the Company has not received any notice (oral or written) of proceedings relating to the revocation or modification of any Permit. The Company and its Subsidiaries are in full compliance with all laws, including, but not limited to, laws with respect to manufacturing, clinical research and development, submission of applications for review by governmental authorities, marketing, promotion, and sale of all of their products. There are no pending or, to the knowledge of the Company, threatened actions or proceedings by the FDA, U.S. Department of Justice, or any applicable foreign equivalent which would prohibit or impede the sale of any product currently in development, under investigation, or manufactured or sold by the Company or any of its Subsidiaries into any market. The Company is in compliance in all material respects under each, and the transactions contemplated by this Agreement will not cause a violation under any of such Permits. The Company is in compliance in all respects with all material provisions of the laws and governmental rules and regulations applicable to its businesses, properties and assets, and to the products and services under development, investigation, or sold by it, including, without limitation, all such rules, laws and regulations relating to fair employment practices and public or employee safety.

4.15 **Insurance**. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business on terms consistent with the market for the business in which the Company and its Subsidiaries operate. There are currently no proceedings pending against the Company or any Subsidiary under any insurance policies currently in effect and covering the property, business or employees of the Company and its Subsidiary, and all premiums due and payable with respect to the insurance policies maintained by the Company and the Subsidiaries have been paid to date. The Company and its Subsidiaries have in full force and effect fire- and casualty and such other insurance policies issued by insurers of recognized financial responsibility that extend coverage sufficient in amount as are reasonably prudent and customary in the business in which the Company and its Subsidiaries are engaged (subject to reasonable deductibles) to allow it to replace any of its properties that might be damaged or destroyed. Neither the Company nor any Subsidiary is in default with respect to its obligations under any insurance policy maintained by it except for any such defaults as would not reasonably be expected to have a Material Adverse Effect.

4.16 **Investment Company; FIRPTA**. Neither the Company nor any Subsidiary is, an investment company nor is either of them an affiliate of an investment company within the meaning of the Investment Company Act of 1940, as amended. The Company and its Subsidiaries are not a U.S. real property holding corporation within the meaning of the Foreign Investment in Real Property Tax Act of 1980.



4.17 **Board of Directors**. Except as set forth in Schedule 4.17 attached hereto and the Company Reports, the Company has not extended any offer or promise, or entered into any agreement, arrangement, understanding or otherwise, whether written or oral, with any person or entity by which the Company has agreed, to allow such person or entity to participate, in any way, in the affairs of the board of directors of the Company, including, without limitation, the appointment or nomination as a member, or the right to appear at, or receive the minutes of, a meeting of the board of directors of the Company.

4.18 **Environmental Matters**.

(i) All of the current and past operations of the Company, the Subsidiaries and any real property currently owned, operated, used or leased by the Company or any Subsidiary (the **"Real Property"**) comply and have at all times complied with all federal, state and local laws, judgments, decrees, orders, consent agreements, authorizations, permits, licenses, rules, regulations, codes, ordinances, common or decision law (including, without limitation, principles of negligence and strict liability) relating to the pollution, protection, investigation, remediation, monitoring, damages to, or restoration of the environment (including, without limitation, natural resources) or the health or safety matters of humans and other living organisms (the **"Environmental Laws"**), except where the failure to so comply would not have a Material Adverse Effect. To the knowledge of the Company, all real property formerly owned, operated, used or leased by the Company or any Subsidiary (the **"Former Real Property"**) complied at all times during the term of the Company or such Subsidiary's ownership, operation, use or lease thereof with all applicable Environmental Laws, except where the failure to so comply would not have a Material Adverse Effect.

(ii) Except as set forth in Schedule 4.18 and the Company Reports, (A) the Company and the Subsidiaries have no knowledge of any claim, and has not received notice of a complaint, loss order, directive, claim, request for information, violation or citation, and no proceeding has been instituted, nor to the Company's knowledge, threatened, raising a claim against the Company, any Subsidiary or any predecessor thereto or any of their respective Real Property, Former Real Property or other assets indicating or alleging any damage to the environment or any liability or obligation under or violation of any Environmental Laws and (B) the Company and the Subsidiaries are not subject to any order, decree, injunction or other directive of any Governmental Authority.

(iii) Except as set forth in Schedule 4.18 and the Company Reports, (A) the Company and its Subsidiaries have not used and, to the Company's knowledge, no other Person has used any portion of any Real Property or Former Real Property during the term of the Company or its Subsidiaries ownership, operation, use or lease thereof for the generation, handling, processing, treatment, storage or disposal of any Hazardous Materials except in accordance with applicable Environmental Laws; (B) the Company and its Subsidiaries do not own or operate any underground tank and there are no underground tanks or other underground storage receptacles, asbestos-containing materials or other Hazardous Materials located in any portion of any Real Property and (C) the Company, its Subsidiaries nor, to the Company's knowledge, any other person, has not caused or suffered to occur any releases or threatened

releases of Hazardous Materials on, at, in, under, above, to, from or about any Real Property or Former Real Property during the term of the Company and its Subsidiaries ownership, operation, use or lease thereof. The Company and its Subsidiaries have not contractually, by operation of law, including the Environmental Laws, or otherwise assumed or succeeded to any environmental liabilities of any predecessors or any other person or entity. As used herein, the term "**Hazardous Materials**" shall mean any pollutants, contaminants, or toxic or hazardous substances, materials, wastes, constituents, compounds or chemicals, including without limitation petroleum or any by-products thereof, any form of natural gas, asbestos or asbestos-containing materials, polychlorinated biphenyls or polychlorinated biphenyls-containing equipment, radon or other radioactive elements, carcinogenic or mutagenic agents, pesticides, explosives, flammables, corrosives and urea formaldehyde foam insulation, in each case that form the basis of liability, or are subject to regulation, under any Environmental Laws.

4.19 **Litigation**. There is no proceeding pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties which adversely affects or challenges the legality, validity or enforceability of any of the transactions contemplated hereby. None of the Company, the Subsidiaries or, to the Company's knowledge, any director or officer thereof (in his or her capacity as such), is or has been the subject of any proceeding involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the SEC involving the Company, the Subsidiaries or any current or former director or officer of the Company or any Subsidiary (in his or her capacity as such). The SEC has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

4.20 **Listing**. The Company's Common Stock is listed on the American Stock Exchange (the "**Trading Market**"). The Company is in compliance with the terms of its listing agreement with the Trading Market and its rules and standards for continued listing and has complied or will timely comply with such agreement and such rules and standards in connection with the transactions contemplated by this Agreement. No proceeding is pending or, to the Company's knowledge, threatened relating to any unresolved violation of any of such items or delisting of the Common Stock, and the Company has no reason to believe that the Common Stock will not continue to be so listed. The Common Stock has never been delisted or suspended from listing or trading by the Trading Market.

4.21 **Product Warranty; Product Liability**. Each product being manufactured by the Company and its Subsidiaries is being manufactured in conformity with all product specifications. Neither the Company nor any Subsidiary has any liability for damages caused by use of any such products or other damages in connection therewith or any other customer or product obligations.



4.22 **Disclosure**.

(a) Subject to Section 4.22(b), the sum of the disclosure provided to the Investor regarding the Company, the Subsidiaries, their business and the transactions contemplated hereby, including the Company Reports and the Schedules to this Agreement, furnished by or on behalf of the Company, does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. No event or circumstance has occurred or information exists with respect to the Company, the Subsidiaries or their business, properties, prospects, operations or financial conditions, which, under the Securities Laws of the United States, requires public disclosure or announcement by the Company but which has not been so publicly announced or disclosed (assuming for this purpose that the Company's reports filed under the 1934 Act are being incorporated into an effective registration statement filed by the Company under the 1933 Act).

(b) Notwithstanding Section 4.22(a), the Investor acknowledges that the Company has not provided to the Investor certain disclosure as described in Section 26 hereof.

**SECTION 5. Representations, Warranties and Covenants of the Investor to the Company.**

The Investor hereby make the representations, warranties and covenants contained herein to the Company and acknowledge that the Company has agreed to the transaction described in Section 2 hereof in reliance on such representations, warranties and covenants. The representations and warranties shall be deemed to be true and correct as of the date hereof and to have been relied upon by the Company and there shall be no obligation on the Investor to update such representation and warranties subsequent to the date hereof. The Investor represents and warrants to and agrees with the Company as follows:

5.1. **Subsidiary Relationship.** The Investor is an indirect wholly-owned subsidiary of PBL and will remain an indirect majority owned subsidiary of PBL so long as it owns or holds any of the Securities.

5.2 **Restrictions on Transfer**. The Investor shall not transfer, directly or indirectly, through Affiliates or otherwise, any Securities or any rights therein to (i) any individuals or entities whose business purpose, in whole or in substantial part, is competitive with the business of the Company (except to the extent that such transfer is to a direct or indirect wholly-owned subsidiary of PBL), (ii) individuals, entities or organizations (including governments or governmental agencies or organizations) then appearing on the list of Specially Designated National and Blocked Persons maintained by the U.S. Office of Foreign Assets Control ("**OFAC**") or entities or individuals, transfer of such rights to whom might reasonably be expected to have an adverse effect on the ability of the Company to bid for and receive grants or contracts from the United States government, and (iii) entities or organizations then controlled by such individuals or having their registered office, headquarters or primary place of business located in a nation that is then subject to an OFAC sanctions program; provided that non-negotiated *bona fide* sales of Shares on the Trading Market ("**Non-Negotiated Bona Fide**

**Sales**"), which, for the sake of clarity, shall not include negotiated block sales, are excluded from this transfer restriction. In the event of any transfer (other than Non-Negotiated Bona Fide Sales), the transferee shall agree to be bound by all of the terms and conditions imposed on the Investor in this Agreement, the Investor Rights Agreement and under the Warrant.

5.3. **Prior Ownership of Securities.** To the knowledge of the Investor after due inquiry, none of the Investor, its directors, its executive officers and its Affiliates currently own any securities of the Company or any of its affiliates, nor did any of the Investor, its directors, its executive officers and its Affiliates own securities of the Company prior to July 28, 2008, the date on which PBL and the Company entered into that certain Letter of Intent (the "Letter of Intent").

5.4. **Private Placement.**

(a) The Investor is acquiring the Shares and Warrant for its own account, for investment and not with a view to the resale or distribution thereof within the meaning of the Securities Act**.**

(b) The Investor is an "accredited investors" as such term is defined in Rule 501(a) promulgated under the Securities Act.

(c) The Investor agrees that the Company may place a legend on the certificates representing the Securities stating that the Securities have not been registered under the Securities Act and, therefore, cannot be offered, sold or transferred unless registered under the Securities Act or an exemption from such registration is available in the opinion of counsel satisfactory to the Company.

(d) The Investor has such knowledge and experience in business and financial matters and with respect to investments in restricted securities so as to enable it to understand and evaluate the risks of its investment in the Securities and form an investment decision with respect thereto. The Investor is able to bear the risks of an investment in the Securities. The Investor has been afforded the opportunity, during the course of negotiating the transactions contemplated by this Agreement, to ask questions of, and to secure such information from, the Company and its officers and directors as they have deemed necessary to evaluate the merits of entering into such transactions.

(e) On the Closing Date, the Investor shall have an adequate net worth and means of providing for their current needs and personal contingencies to sustain a complete loss of its investment in the Company.

5.5. **Authorization of this Agreement and Investor Rights Agreement.** The execution, delivery and performance by the Investor of this Agreement and the Investor Rights Agreement and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite action on the part of the Investor. This Agreement has been duly executed and delivered by the Investor and constitutes a valid and binding obligation of the Investor, enforceable in accordance with its respective terms. When executed and



delivered by the Investor in accordance with this Agreement, the Investor Rights Agreement will constitute a valid and binding obligation of the Investor, enforceable in accordance with its respective terms. The execution, delivery and performance of this Agreement and the Investor Rights Agreement and the compliance with the provisions hereof and thereof by the Investor will not:

(a) violate any provision of law, statute, ordinance, rule or regulation or any ruling, writ, injunction, order, judgment or decree of any court, administrative agency or other Governmental Authority, as would not, individually or in the aggregate, have a Material Adverse Effect;

(b) conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute (with due notice, lapse of time or both) a default (or give rise to any right of termination, cancellation or acceleration) under (i) any agreement, document, instrument, contract, understanding, arrangement, note, indenture, mortgage or lease to which the Investor is a party or under which the Investor or any of their assets is bound or affected, except for such conflicts, breaches or defaults as would not, individually or in the aggregate, have a material adverse effect on the business or financial condition of the Investor, (ii) the Certificate or (iii) the Bylaws; or

5.6. **Resale Conditions.** The Investor further understands that the exemptions from registration afforded by Rule 144 and Rule 144A (the provisions of which are known to them) promulgated under the Securities Act depend on the satisfaction of various conditions and that, if applicable, Rule 144 may afford the basis for sales only in limited amounts.

5.7. **Organization.** The Investor is duly organized and validly existing and have the power and authority to enter into this Agreement.

5.8. **Consents.**

(a) No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any Governmental Authority on the part of the Investor is required in connection with the consummation of the transactions contemplated by this Agreement.

(b) No consent or approval on the part of any third party to any agreement with the Investor (aside from those already obtained) is required in connection with the transactions contemplated by this Agreement.

**SECTION 6. Documents to be Delivered.**

6.1 **Documents to be Delivered on the Execution Date.** On or prior to the date hereof, the parties agree to take and shall have taken the following actions:



(a) The Company shall have furnished to the Investor a copy of the waivers and consents to be obtained in connection with the transactions contemplated by this Agreement.

(b) The Company shall have furnished to the Investor a copy of all applicable consents, permits, approvals, qualifications and registrations required to be obtained or effected under any applicable Securities Laws.

(c) The Company shall have furnished to the Investor a certificate or certificates, dated as of the Execution Date, of the Secretary of the Company certifying as to (i) the resolutions of the Company's board of directors authorizing the execution and delivery of this Agreement, the issuance to the Investor of the Securities, the execution and delivery of such other documents and instruments as may be required by this Agreement and the consummation of the transactions contemplated hereby, and certifying that such resolutions were duly adopted and have not been rescinded or amended as of said date, and (ii) the name and the signature of the officers of the Company authorized to sign, as appropriate, this Agreement, the Investor Rights Agreement and the other documents and certificates to be delivered pursuant to this Agreement by either the Company or any of its officers.

(d) The Company shall have furnished to the Investor a certificate or certificates, dated as of the Execution Date, of the President of the Company certifying as to the truth, accuracy and completeness of the representations and warranties made by the Company pursuant to this Agreement.

(e) The Company shall have furnished to the Investor a certificate or certificates, dated as of the Execution Date, of the Chief Financial Officer or Treasurer of the Company certifying that, since the date of the Unaudited Financial Statements, there has not been any material adverse change in the financial condition or operations of the Company and that, except as to the extent reflected in the Unaudited Financial Statements and except for liabilities arising in the ordinary course of business, the Company has no material accrued or contingent liabilities arising out of any transaction or state of facts existing prior to the date of this Agreement.

(f) The Company shall have furnished to the Investor a certificate to the effect that the consummation of the transactions contemplated by this Agreement shall not be in violation of any law or regulation, and shall not be subject to any injunction, stay or restraining order.

(g) The Investor shall have furnished to the Company a certificate or certificates, dated as of the Execution Date, of the Director or such other officer of equal ranking of the Investor certifying as to the truth, accuracy and completeness of the representations and warranties made by the Investor pursuant to this Agreement.

(h) The Investor shall have furnished to the Company a certificate to the effect that all waivers and consents to be obtained in connection with the transactions contemplated by this Agreement have been taken or obtained.



(i) The Investor shall have furnished to the Company a copy of all applicable consents, permits, approvals, qualifications and registrations required to be obtained or effected by the Investors under any applicable Securities Laws.

(j) The Investor shall have furnished to the Company a certificate to the effect that the consummation of the transactions contemplated by this Agreement shall not be in violation of any law or regulation, and shall not be subject to any injunction, stay or restraining order.

(k) That certain letter agreement shall have been executed on the date hereof (the "**Letter Agreement**").

6.2 **Closing Conditions—Investor.** Set forth below are the only conditions to the payment by the Investor of the Purchase Price on the Closing Date, as described in Section 2 hereof, and there shall be no other conditions or rights of the Investor not to make such payment as described therein. On or before the Closing Date:

(a) The Company shall have delivered, or caused to have delivered, to the Investor stock certificates representing the Shares as set forth in Section 2.

(b) The Company shall have delivered, or caused to have delivered, to the Investor the Warrant as set forth in Section 2.

(c) The Company shall have delivered the legal opinion of its counsel, in the form attached hereto as Exhibit D, executed by such counsel.

(d) The Letter Agreement shall be in full force and effect as of the Closing Date.

(e) The Company shall have executed the Investor Rights Agreement.

6.3 **Closing Conditions—Company.** Set forth below are the only conditions to the delivery of the certificates representing the Shares and the Warrant to the Investor as described in Section 2 hereof and there shall be no other conditions or rights of the Company not to make such delivery as described therein. On or before the Closing Date:

(a) The Investor shall have delivered the Purchase Price in the manner and to the account specified by the Company in writing.

(b) The Letter Agreement shall be in full force and effect as of the Closing Date.

(c) The Investor shall have executed the Investor Rights Agreement.



6.4 **Further Covenants.**

(a) The Company shall use its best efforts to obtain approval for the listing of the Shares on the Trading Market promptly after the date hereof and shall use its reasonable best efforts to maintain the continuous listing of the Shares on the Trading Market.

(b) The Company agrees to make the requisite entries reflecting the issuance of the Shares and the Warrant in the register of shareholders and register of Warrants of the Company, respectively, and shall furnish copies thereof to the Investor for its records.

**SECTION 7. Reservation and Listing of Warrant Shares.**

7.1 **Reservation of Warrant Shares.** The Company shall maintain a reserve from its fully authorized Common Shares for issuance pursuant to the Warrant in such amount as may be required to fulfill its obligations in full under the Warrant.

7.2 **Listing of Warrant Shares.** The Company shall (i) prepare and timely file with the Trading Market an additional shares listing application covering all of the Warrant Shares issued or issuable under the Warrant, (ii) use its best efforts to cause such Warrant Shares to be approved for listing on the Trading Market as soon as practicable thereafter but in any event no later than 14 days after the issuance and allotment of the Warrant Shares to the Investor, (iii) provide to the Investor evidence of such listing, and (iv) use its reasonable best efforts to maintain the continuous listing of such Warrant Shares on such Trading Market.

**SECTION 8. Expenses and Fees.**

Each of the parties shall pay all costs, fees and expenses incurred or to be incurred by it in negotiating, executing, delivering and preparing the Agreement, the Investor Rights Agreement and the other documents contemplated hereby and thereby and in closing and carrying out the transactions contemplated hereby and thereby, including the Closing.

**SECTION 9. Brokers or Finders.**

Except as set forth on Schedule 9 hereto, the Company represents and warrants to the Investor, and the Investor represents and warrants to the Company, that no person or entity has or will have, as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon the Company or the Investor for any commission, fee or other compensation as a finder or broker because of any act or omission by the Company or the Investor or by any agent of the Company or the Investor.

**SECTION 10. Exchanges; Lost, Stolen or Mutilated Certificates.**

Upon surrender by the Investor to the Company of Securities purchased or acquired by the Investor hereunder, the Company, at its expense, will issue in exchange therefor, and deliver to such Investor, a new certificate or certificates or replacement Warrant, as the case may be, representing such Securities in such denominations as may be requested by such Investor. Upon



receipt of evidence satisfactory to the Company of the loss, theft, destruction or mutilation of any certificate representing any Shares or the Warrant purchased or acquired by the Investor hereunder and, in case of any such loss, theft or destruction, upon delivery of any indemnity agreement satisfactory to the Company, or in case of any such mutilation, upon surrender and cancellation of such certificate or Warrant, the Company, at its expense, will issue and deliver to the Investor a new certificate for such Shares or a replacement Warrant as applicable, of like tenor, in lieu of such lost, stolen or mutilated certificate.

**SECTION 11. Survival of Representations and Warranties.**

The representations and warranties set forth in Sections 4 and 5 hereof shall survive the Closing for a period of 18 months following the Effective Date of the Registration Statement as defined in the Investor Rights Agreement. Notwithstanding the foregoing, the representations and warranties contained in Sections 4.1, 4.2, 4.3, 4.4, 4.7, 4.9, 4.10, 4.14, 5.5, 5.7 and Section 9 shall survive the Closing for the applicable statute of limitations.

**SECTION 12. Indemnification.**

The Company shall indemnify, defend and hold the Investor harmless against any and all liabilities, loss, cost or damage, together with all reasonable costs and expenses related thereto (including reasonable legal and accounting fees and expenses), arising from, relating to and the result of (x) an untruth, inaccuracy or breach of any representations, warranties or covenants of the Company contained herein, or (y) any claim with regard to the items disclosed on Schedule 9 hereto, which amount shall in no event in the aggregate for all claims hereunder exceed the aggregate of the Purchase Price and the consideration paid for the Warrants (to the extent exercised) as specified in Section 1 of this Agreement.

**SECTION 13. Remedies.**

Each party agrees that in event that a settlement of any controversy, claim or dispute is not reached by mutual agreement, such controversy, claim or dispute will be settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association. The place of arbitration will be in London, England and the arbitrator's report will be submitted within six (6) months of the initiation of the arbitration process. The applicable federal or state court shall have jurisdiction to enforce any award or remedy granted in the arbitration. Each party will bear its own costs incurred in the course of arbitration.

**SECTION 14. Successors and Assigns.**

Except as otherwise expressly provided herein, this Agreement shall bind and inure to the benefit of the Company and the Investor and their respective successors and permitted assigns. This Agreement is not assignable except by written consent of each of the parties hereto or by

operation of law. Any purported assignment of this Agreement in violation of this Section shall be null and void. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective permitted successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement

**SECTION 15. Entire Agreement.**

This Agreement, together with the other writings referred to herein or delivered pursuant hereto that form a part hereof, contains the entire agreement among the parties with respect to the subject matter hereof and amends, restates and supersedes all prior and contemporaneous arrangements or understandings, whether written or oral, with respect thereto, including without limitation the Letter of Intent.

**SECTION 16. Notices.**

All notices, requests, consents and other communications hereunder to any party shall be deemed to be sufficient if contained in a written instrument delivered in person, duly sent by first-class registered, certified or overnight mail, postage prepaid, sent by reputable express courier services (such as FedEx., UPS, DHL, etc.) or telecopied with a confirmation copy by regular mail, addressed or telecopied, as the case may be, to such party at the address or telecopier number, as the case may be, set forth below or such other address or telecopier number, as the case may be, as may hereafter be designated in writing by the addressee to the addressor listing all parties:

if to the Company, to:

PharmAthene, Inc.
One Park Place, Suite 450
Annapolis, Maryland 21401
Attention: General Counsel
Telecopier: +1 410 269 2601

with a copy to:

Sonnenschein Nath & Rosenthal LLP
1221 Avenue of the Americas
New York, New York 10020
Attention: Jeffrey A. Baumel, Esq.
Telecopier: +1 212 768 6800



if to the Investor, to:

Kelisia Holdings Limited
C/o Fortis Intertrust Management N.V., Curacao, Geneva Branch
Boulevard des Philosophes 15
1205 Geneva
Switzerland
Postal Address: P.O. Box 3292 - 1211 Geneva 3, Switzerland
Attention: Nicholas Welton
Telecopier: +41 22 317 80 11

with a copy to:

Panacea Biotec Limited
B-1 Extension/ A-27
Mohan Co-op. Industrial Estate
Mathura Road
New Delhi - 110044
INDIA
Attention: Mr. Rajesh Jain
Telecopier: +99 11 2694 0199, 4167 9070

with a copy to:

Foley & Lardner, LLP
500 Woodward Avenue; Suite 2700
Detroit, Michigan 48226
Attention: Daljit S. Doogal, Esq.
Telecopier: (313) 234-2800

All such notices, requests, consents and other communications shall be deemed to have been received (a) in the case of personal delivery or delivery by express courier service, on the date of such delivery, (b) in the case of mailing, on the third Business Day following the date of such mailing, (c) in the case of overnight mail, on the first Business Day following the date of such mailing, and (d) in the case of facsimile transmission, when confirmed by facsimile-machine report.

**SECTION 17. Changes.**

(a) For the purposes of this Agreement and all agreements executed pursuant hereto, no course of dealing between or among any of the parties hereto and no delay on the part of any party hereto in exercising any rights hereunder or thereunder shall operate as a waiver of the rights hereof and thereof. No provision hereof may be waived otherwise than by a written instrument signed by the party or parties so waiving such covenant or other provision as contemplated herein.

(b) No amendment or modification of this Agreement may be made and no provisions hereof may be waived, without the written consent of the Company and Investor.



**SECTION 18. Counterparts.**

This Agreement may be executed in any number of counterparts, and each such counterpart shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement.

**SECTION 19. Headings.**

The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be a part of this Agreement.

**SECTION 20. Nouns and Pronouns; Knowledge.**

Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. As used in this Agreement (except for Section 4.8, with respect to which a different definition applies), the phrase "to the Company's knowledge" shall mean the actual knowledge, as of the date of this Agreement, of executive officers of the Company who because of their office and duties and/or after due care and inquiry knew.

**SECTION 21. Severability.**

Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

**SECTION 22. Governing Law.**

This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding choice-of-law rules thereof.

**SECTION 23. Disclosure.**

Except as otherwise required by law (including the rules of the American Stock Exchange), Investor and the Company agree that they shall make no written or other public disclosures regarding this transaction or regarding the parties hereto to any individual or organization without the prior written consent of the other party hereto (which consent shall not be unreasonably withheld); provided, however, that nothing in this Agreement shall restrict the parties hereto from disclosing information (a) that is already publicly available, (b) to its attorneys, accountants, consultants and other advisors to the extent necessary to obtain their services in connection with Investor's investment in the Company, and (c) in the case of the



Company to other prospective investors, lenders and other potential sources of financing for the Company. If any announcement is required by law to be made by any party hereto, prior to making such announcement such party will deliver a draft of such announcement to the other party and shall give the other party a reasonable opportunity to comment thereon.

**SECTION 24. Integration.**

The Company shall not, and shall use reasonable efforts to ensure that no Affiliate of the Company shall, sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities to the Investor, or that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of the Trading Market with the effect of requiring approval by the Company's stockholders under such rules and regulations.

**SECTION 25. Further Assurances.**

(a) The parties to this Agreement shall from time to time execute and deliver all such further documents and do all acts and things as the other party may reasonably require to effectively carry on the full intent and meaning of this Agreement and/or to complete the transactions contemplated hereunder.

(b) If, for any reason whatsoever, any term contained in this Agreement cannot be performed or fulfilled, the Parties agree to meet and explore alternative solutions depending upon the new circumstances, but keeping in view the spirit and core objectives of this Agreement.

**SECTION 26. Acknowledgement.**

The parties hereto acknowledge that in connection with the transactions contemplated hereby, (i) the Company did not provide information to the Investor or its Affiliates regarding its recombinant Protective Antigen Anthrax vaccine program and the Investor and its Affiliates did not provide information

to the Company regarding their recombinant Protective Antigen Anthrax vaccine program and (ii) the Company did not provide to the Investor or its Affiliates any information, including without limitation information relating to Protexia®, where the provision of such information would have violated applicable U.S. law, rules or regulations.

**SECTION 27. Standstill.**

For a period beginning on the date hereof and ending on the third anniversary of the Closing Date, other than with respect to its purchase of securities from the Company under this Agreement, the Warrant or the Investor Rights Agreement, the Investor agrees that neither it, nor any of its officers, directors or Affiliates will, directly or indirectly, as a member of a group or otherwise, purchase, offer to purchase, enter into any agreement relating to the purchase of, or otherwise engage in any transaction relating to, any securities of the Company whether publicly or privately. Any breach of this Section 27 by the Investor would cause the Company substantial



and irrevocable damage and therefore, in the event of a breach or threatened breach by the Investor of this Section 27, the Company and/or its Affiliates, in addition to such other remedies which may be available, will be entitled to specific performance of this Section 27 and injunctive relief without the necessity of proving actual damages. This Section 27 shall survive any termination of this Agreement.

**SECTION 28. Termination.**

28.1. This Agreement may be terminated and the Transactions contemplated hereby may be abandoned at any time:

(a) By the Investor, if any of the conditions set forth in Section 6.2 shall, on or prior to the Closing Date, not have been fulfilled or have become incapable of fulfillment.

(b) By the Company, if any of the conditions set forth in Section 6.3 shall, on or prior to the Closing Date, not have been fulfilled or have become incapable of fulfillment.

28.2. In the event of the termination of this Agreement pursuant to Sections 28.1 or 28.2., the obligations of the parties under this Agreement shall terminate and there shall be no liability on the part of any party hereto, except for the obligations in the confidentiality provisions hereof, and all of the provisions of this Section 28.2 and Sections 13 and 27; provided, however, that no party hereto shall be relieved or released from any liabilities or damages arising out of its wilful breach of any provision of this Agreement. In the event that this Agreement is terminated by either party pursuant to this Section 28, in addition to such other remedies which may be available to such party, such party will be entitled to specific performance of Sections 2, 3 and 6 hereof and injunctive relief without the necessity of proving actual damages.

*[Remainder of page intentionally left blank; signature page follows]*



**IN WITNESS WHEREOF**, the parties hereto have executed this Securities Purchase Agreement as of the date first above written.

**PharmAthene, Inc.**

By: /s/ David P. Wright

Name: David P. Wright

Title: President and CEO

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT

**Kelisia Holdings Ltd.**

By: /s/ Standguard Limited

Name: Duly represented by Mr. Petros Livanios

Title: Director

[SIGNATURE PAGE TO SECURITIES PURCHASE AGREEMENT]

[LETTERHEAD OF PHARMATHENE, INC.]

September 30, 2008

PANACEA BIOTEC LTD.
B-1 Extn./ G-3, Mohan Co-op. Indl. Estate
Mathura Road, New Delhi - 110 044
India

Attn: Rajesh Jain

**Re: Letter Agreement**

Ladies and Gentlemen:

In connection with the purchase by Kelisia Holdings Ltd.**,** a company limited by shares established under the laws of Cyprus ("**Kelisia**"), an indirect wholly-owned subsidiary of Panacea Biotec Ltd., a public limited company established under the laws of India (together with its affiliates, "**PBL**"), of securities of PharmAthene, Inc., a Delaware corporation ("**PIP**"), pursuant to the Securities Purchase Agreement dated of even date herewith between PIP and Kelisia (the "**Securities Purchase Agreement**") and the Investor Rights Agreement between PIP and Kelisia to be executed in the form attached as an exhibit to the Securities Purchase Agreement (the "**Investor Rights Agreement**"), (i) PBL has agreed to be bound by certain restrictions on its activities with respect to the securities to be acquired, and (ii) both PBL and PIP have agreed to engage in discussions from time to time relating to, among other things, the manufacture and/or process development by PBL of a portion of PIP's proprietary Biodefense Medical Countermeasurers under development (the "**PIP Countermeasures**") and to afford PIP a right of first negotiation respecting the possible commercialization and marketing of certain of PBL's products, as more fully set forth in this letter below. Unless otherwise stated herein, capitalized terms that are not defined in this letter agreement have the meaning set forth in the Securities Purchase Agreement.

***Representations***

PBL represents to PIP that Kelisia is an indirect wholly-owned subsidiary of PBL and agrees that it will remain an indirect majority-owned subsidiary of PBL so long as Kelisia owns or holds, directly or indirectly, any of the Securities. PBL agrees that during such time it will not transfer, directly or indirectly, a substantial part of its ownership in Kelisia or Kelisia's immediate parent company to (i) any individuals or entities whose business purpose in whole or in substantial part is competitive with the business of the Company (except to the extent that such transfer is to a wholly-owned direct or indirect subsidiary of PBL), (ii) individuals, entities or organizations (including governments or governmental agencies or organizations) then appearing on the list of Specially Designated National and Blocked Persons maintained by the U.S. Office of Foreign Assets Control ("**OFAC**") or entities or individuals, transfer of such rights to whom might reasonably be expected to have an adverse effect on the ability of the Company to bid for and receive grants or contracts from the United States government, or (iii) entities or organizations then controlled by such individuals or having their registered office, headquarters or primary place of business located in a nation that is then subject to an OFAC sanctions program; provided that restriction contained in this paragraph shall no longer apply from such time at which the aggregate number of Shares (as defined in the Investor Rights Agreement) owned by Kelisia and that Kelisia may acquire upon exercise of the Warrant is 500,000 or fewer. In the case of any transfer prior to such time, any transferee must, as a condition to such transfer, agree not to transfer, directly or indirectly, a substantial part of its ownership, if any, in Kelisia or Kelisia's immediate parent company to individuals, entities or organizations listed in (i), (ii) or (iii) above.

To the knowledge of PBL after due inquiry, none of PBL, its directors, its executive officers and its Affiliates currently own any securities of the Company or any of its affiliates, nor did any of PBL, its directors, its executive officers and its Affiliates own securities of the Company prior to July 28, 2008, the date on which PBL and the Company entered into that certain Letter of Intent.

For a period beginning on the date hereof and ending on the third anniversary of the Closing Date, other than with respect to Kelisia's purchase of securities from the Company under the Securities Purchase Agreement, the Warrant or the Investor Rights Agreement, PBL agrees that neither it, nor any of its officers, directors or Affiliates will, directly or indirectly, as a member of a group or otherwise, purchase, offer to purchase, enter into any agreement relating to the purchase of, or otherwise engage in any transaction relating to, any securities of PIP whether publicly or privately. Any breach of the covenant in the preceding sentence would cause PIP substantial and irrevocable damage and therefore, in the event of a breach or threatened breach by PBL of such covenant, PIP and/or its Affiliates, in addition to such other remedies which may be available, will be entitled to specific performance of such covenant and injunctive relief without the necessity of proving actual damages. Such covenant shall survive any termination of this letter agreement.



PBL furthermore represents and warrants that, during the period beginning 30 days prior to the date of this letter agreement and ending on the date of this letter agreement, none of the Investor or its Affiliates, or any entity acting under their direction or control, have engaged, directly or indirectly, in any trading of Common Stock, including, without limitation, short sales or hedging of any kind, other than as contemplated by the Securities Purchase Agreement.

PBL acknowledges and agrees that PBL's representations set forth above under the heading "***Representations***" constitute material inducements to PIP to enter into the Securities Purchase Agreement and the Investor Rights Agreement (and the other agreements and documents contemplated thereby) with Kelisia.

***Manufacturing/Process Development Work***

As reasonably requested by either party from time to time, representatives of PIP will meet (whether in person, by telephone, video conference or other means) with authorized PBL personnel to discuss in good faith whether the parties are interested in negotiating and potentially entering into a

manufacturing, process development or other similar arrangement with respect to the PIP Countermeasures (or components thereof), which to the extent permitted by law (including rules and regulations of the U.S. Food and Drug Administration ("**FDA**"), the U.S. Department of Health and Human Services and the International Traffic in Arms Regulations (ITAR)), shall include PIP's Valortim®, Protexia® and SparVax™ product candidates. If as a result of these discussions, PBL and PIP enter into a manufacturing, process development or other arrangement, any such arrangement and the work thereunder will comply in all respects with applicable U.S. laws, rules and regulations, including where applicable the FDA's current Good Manufacturing Practices regulations ("**cGMP**").

If, following their initial discussions, either PBL or PIP determines that it does not have an interest in a manufacturing, process development or similar arrangement with respect to one or more of the PIP Countermeasures or PIP determines that PBL's manufacturing facilities are not being operated in compliance with cGMP, neither party shall be further obligated to engage in discussions in the future. Furthermore, neither PIP nor PBL shall have any legally binding obligation to engage in negotiations with respect to, or to enter into, any manufacturing, process development or other arrangement respecting the PIP Countermeasures. If PBL and PIP enter into negotiations with respect to any such potential arrangement, each of PBL and PIP shall have the right to terminate such negotiations at any time for any reason in its sole discretion (including in the case of PIP a determination on its part that the manufacture of, or process development related to, one or more of the PIP Countermeasures, or components thereof, outside the United States could have the effect of reducing the likelihood that any such PIP Countermeasure would be eligible to win a procurement award) and without any liability to the other party unless a definitive agreement is executed governing manufacturing, process development or other similar arrangement with respect to the PIP Countermeasures (or components thereof).



Nothing in this letter agreement shall be construed as precluding, limiting, restricting or preventing PIP in any way from discussing, negotiating or entering into manufacturing, process development or other arrangements or agreements, including option agreements, respecting the PIP Countermeasures or otherwise with any third party. PIP shall be entitled to enter into any of the foregoing with any third party at any time (even if PIP is still in discussions or negotiations with PBL) without limitation or restriction.

***PIP Right of First Negotiation***

PIP shall have a right of first negotiation with respect to the sales, marketing and distribution of any and all PBL products (whether owned, developed or in-licensed by PBL – except to the extent that a specific license agreement prohibits such grant of first negotiation) that have utility or potential utility as a biodefense product in the United States (but excluding PBL's rPA anthrax vaccine currently under development) ("**PBL Biodefense Products**"). As such, subject to all of the provisions of the existing confidentiality agreements between the parties, PBL shall disclose to PIP all relevant information regarding the PBL Biodefense Products with respect to which PBL has any rights to sell, market, use or develop, and shall provide such additional information, including access to employees, as PIP may reasonably request from time to time. For purposes of this letter agreement, the biodefense products in the United States shall include all biodefense medical countermeasures for "category A, B and C pathogens" as designated by the U.S. National Institutes of Allergy and Infectious Diseases (NIAID) and which may include emerging infectious diseases**.**

From time to time following written notice (the "**Notice**") from PIP, and for five (5) years from the date of this letter agreement, PBL will negotiate with PIP in good faith and on an exclusive basis for sixty (60) days (the "**Exclusivity Period**") to provide for the grant to PIP of exclusive sales, marketing and distribution rights in the United States (including a sub-license to all necessary intellectual property (the "**Necessary Intellectual Property**"), to the extent such sub-license is permitted) of one or more PBL Biodefense Products as identified in the Notice on such commercially reasonable terms as are mutually agreed upon by the parties. During the Exclusivity Period, neither PBL nor any of its officers, directors, employees, consultants and advisors will enter into any discussions, negotiations or legally binding agreements with any third party for the sale, marketing and/or distribution of any PBL Biodefense Product identified in the Notice in the United States. For a period ending on the later of (i) the date that is five (5) years from the date of this letter agreement or (ii) the end of the Exclusivity Period, PBL covenants not to enter into any agreements that would restrict the sub-licensing of Necessary Intellectual Property to PIP.



***Termination***

The parties under this letter agreement hereby agree that in the event that the Securities Purchase Agreement is terminated by either party pursuant to Section 28 of the Securities Purchase Agreement, that this letter agreement shall be rendered null and void.

***Other Terms***

Unless otherwise agreed to in the relevant agreement, any manufacturing, process development or similar arrangement with respect to the PIP Countermeasures and any arrangement with respect to the sales, marketing and distribution of any and all PBL Biodefense Products is subject to termination at PIP's or PBL's option, respectively, following an acquisition or other transaction, by a third party, which would result in change of control of PBL or PIP.

Information exchanged by the parties under this letter agreement will be subject to, and governed by, the terms and conditions of the confidentiality agreement executed between the parties and effective on 4th April, 2008.

Each party agrees that in event that a settlement of any controversy, claim or dispute is not reached by mutual agreement, such controversy, claim or dispute will be settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association**.** The place of arbitration will be in London, England and the arbitrator's report will be submitted within six (6) months of the initiation of the arbitration process. The applicable federal or state court shall have jurisdiction to enforce any award or remedy granted in the arbitration. Each party will bear its own costs incurred in the course of arbitration.

This letter agreement embodies the entire agreement and understanding between the parties hereto and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. This letter agreement and the rights and obligations of each party hereto may not be assigned or delegated without the prior written consent of the other parties hereto. This letter agreement shall not be modified or amended except by an

instrument in writing signed by or on behalf of the parties hereto. This letter agreement may be executed in one or more counterparts each of which will be deemed an original, but all of which together shall constitute one and the same instrument.

Sincerely,

**PHARMATHENE, INC.**

By: /s/ David P. Wright
David P. Wright, CEO



AGREED AND ACCEPTED:

**PANACEA BIOTEC LTD.**

By: /s/ Rajesh Jain
Name: Rajesh Jain
Title: Joint Managing Director

Date: September 30, 2008

[SIGNATURE PAGE TO PIP-PBL LETTER AGREEMENT]

**Exhibit 10.41**

**EXECUTION COPY**

**PHARMATHENE, INC.**

**INVESTOR RIGHTS AGREEMENT**

**THIS INVESTOR RIGHTS AGREEMENT** (the "**Agreement**") is entered into as of October 10, 2008, by and among PHARMATHENE, INC., a Delaware corporation having its office at One Park Place; Suite #450, Annapolis, MD 21401 (the "**Company**"), and its successors and permitted assigns, and Kelisia Holdings Ltd., a company limited by shares established under the laws of Cyprus having its office at 29 Theklas Lyssioti Street; Cassandra Centre, 2nd Floor; 3731 Limassol; Cyprus (the "**Investor**"), an indirect wholly owned subsidiary of Panacea Biotec Limited, a public limited company established under the laws of India, having its registered office at Ambala-Chandigarh Highway, Lalru-140501, Punjab, India and its successors and permitted assigns.

**RECITALS**

WHEREAS, on the date hereof, the Company has sold and issued (i) 3,733,334 shares of its Common Stock having par value of US$0.0001 per share, of the Company at a price of US$3.50 per share ("**Common Stock**"), and (ii) a warrant (the "**Warrant**") to purchase up to 2,745,098 shares of its Common Stock at an exercise price of US$5.10 per share, in each case to the Investor pursuant to the Securities Purchase Agreement, dated September 30, 2008, between the Company and the Investor (the "**Securities Purchase Agreement**");

WHEREAS, as a condition of purchasing the shares of Common Stock and the Warrant, the Investor has requested that the Company extend to it registration rights and pre-emptive rights as set forth below;

NOW, THEREFORE, in consideration of the mutual promises, representations, warranties, covenants and conditions set forth in this Agreement and the investment of the Investor in the Common Stock and the Warrant, the parties mutually agree as follows:

**SECTION 1. GENERAL**

**1.1 Definitions.** (a) Capitalized terms that are not otherwise defined in this Agreement have the meanings given such terms in the Securities Purchase Agreement, and (b) the following terms shall have the meanings indicated:

***"Affiliate"*** means with respect to any Person, any Person that directly or indirectly, Controls, is Controlled by, or is under common Control with, such Person.

"***Common Stock***" means the common stock, par value $0.0001 per share, of the Company.

***"Control"*** (including with correlative meaning, Controlled by and under common Control with) shall mean, with respect to any Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by Contract or otherwise, provided that in all events

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(and in addition to the above), the direct and indirect ownership of more than 50% of the paid-up and issued voting capital of a Person shall be deemed to constitute control over such Person.

"***Equity Percentage***" shall mean, as to the Investor or a transferee of the Investor, that percentage figure that expresses the ratio that (a) the number of Shares owned by such Person and which such Person may acquire upon exercise of the Warrant (subject to the limitation described in the definition of Shares below) bears to (b) the aggregate number of shares of issued and outstanding Common Stock on the date hereof immediately after giving effect to the issuance of the Shares.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Form S-3***" means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC that permits inclusion or incorporation of substantial information by reference to other documents filed by the Company with the SEC.

"***Person***" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or agency or subdivision thereof) or other entity of any kind, whether incorporated, registered or not.

"***Piggy-Back Registration Statement***" means a Registration Statement filed with respect to a registration described in Section 2.3 hereof.

"***Register***," "***registered***" and "***registration***" refer to a registration effected by preparing and filing a registration statement in compliance with the Securities Act, and the declaration or ordering of effectiveness of such registration statement or document.

"***Registrable Securities***" means (a) the Shares and (b) any common stock of the Company issued as (or issuable upon the conversion or exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, such Shares. Notwithstanding the foregoing, "Registrable Securities" shall not include any securities sold by a person or eligible for sale without restriction to the public pursuant to a registration statement or Rule 144 under the Securities Act or sold in a private transaction in which the transferor's rights under Section 2 of this Agreement are not expressly assigned.

"***Registrable Securities then outstanding***" shall be the number of shares determined by calculating the total number of shares of Common Stock that are Registrable Securities and either (a) are then issued and outstanding or (b) are issuable pursuant to then exercisable or convertible securities.

"***Registration Expenses***" shall mean all expenses incurred by the Company in complying with Sections 2.2 hereof, including, without limitation, all registration and filing fees, printing expenses, fees and disbursements of counsel for the Company, blue-sky fees and expenses.

"***Registration Statement***" means the Shelf Registration Statement or the Piggy-Back Registration Statement, as applicable.

"***SEC***" or "***Commission***" means the U.S. Securities and Exchange Commission.

"***Securities Act***" shall mean the Securities Act of 1933, as amended.

"***Selling Expenses***" shall mean all underwriting discounts and selling commissions applicable to the sale.

"***Shares***" shall mean (i) the shares of Common Stock issued to the Investor pursuant to the Securities Purchase Agreement, and (ii) the shares of Common Stock issued or issuable upon exercise of the Warrant to purchase up to 2,745,098 shares of Common Stock, dated October 10, 2008, issued by the Company to the Investor (the "**Warrant**"); provided that, for the purposes of calculating the number of shares issuable upon exercise of the Warrant, consideration is given, and such amount is limited to, the maximum amount that could be exercised after consideration of the limitation contained in Section 2(d) of the Warrant.

"***Trading Day***" means (a) any day on which the Common Stock is listed or quoted on the Trading Market, or (b) if the Common Stock is not then listed or quoted on a Trading Market, then any Business Day.

**SECTION 2. REGISTRATION; RESTRICTIONS ON TRANSFER**

**2.1 Restrictions on Transfer.**

(a) Investor and each transferee, if any, agrees not to make any disposition of all or any portion of the Shares or other Registrable Securities unless and until:

(i) There is then in effect (and not suspended pursuant to Section 2.4(b) hereof) a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with such registration statement (including without limitation the method of disposition set forth therein); or

(ii) Such disposition is made pursuant to and in compliance with (A) Rule 144 or a successor rule thereof (as amended from time to time) or (B) any other applicable exemption from registration under the Securities Act (in which case the Investor shall have notified the Company of the disposition and, if requested by the Company, Investor shall have



furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, that such disposition will not require registration of such shares under the Securities Act); or

(iii) (A) Any proposed transferee has agreed in writing to be bound by the terms of this Agreement by executing a counterpart signature page hereto (which shall not be deemed to be an amendment hereto), (B) Investor shall have notified the Company of the disposition, and (C) if requested by the Company, Investor shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, that such disposition will not require registration of such shares under the Securities Act.

(b) Each certificate representing Shares or other Registrable Securities shall (unless otherwise permitted by the provisions of this Agreement) be stamped or otherwise imprinted with a legend substantially similar to the following (in addition to any legend required under applicable state securities laws):

> THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR WITH THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933 (THE "**ACT**") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS.

(c) Within fifteen (15) days of written request, the Company shall be obligated to reissue unlegended certificates at the request of any holder of Shares or other Registrable Securities if such holder shall have obtained an opinion of counsel (which counsel may be counsel to the Company) reasonably acceptable to the Company to the effect that the applicable securities may lawfully be so disposed of without registration.

(d) Any legend that may be endorsed on an instrument pursuant to applicable state securities laws and the stop-transfer instructions with respect to such securities shall be removed upon receipt by the Company of an order of the appropriate blue-sky authority authorizing such removal.

(e) Notwithstanding the foregoing provisions of this Section 2.1, the restrictions imposed by this Section 2.1 upon the transferability of any Shares or other Registrable Securities shall cease and terminate when (i) any such Shares or other Registrable Securities are sold or otherwise disposed of in accordance with a registration statement (including without limitation the method of disposition set forth therein); (ii) the holder of such Shares or other Registrable Securities has met the applicable requirements for transfer of such

Shares or other Registrable Securities, as the case may be, pursuant to subparagraph (b) of Rule 144 under the Securities Act or a successor rule thereof (as amended from time to time)("**Rule 144**") or (iii) any such Shares or other Registrable Securities are sold or otherwise disposed of by such other method contemplated by this Section 2.1 that does not require that the securities transferred bear the legend set forth in this Section 2.1. Whenever the restrictions imposed by this Section 2.1 have terminated, a holder of a certificate for Shares or other Registrable Securities as to which such restrictions have terminated shall be entitled to receive from the Company, without expense, a new certificate not bearing the restrictive legend set forth in this Section 2.1 and not containing any other reference to the restrictions imposed by this Section 2.1.

(f) The Company covenants that, to the extent it does not qualify as a "reporting issuer" as defined under Rule 144(c) during the period ending with the termination of the transferability restrictions as described in Section 2.1(e) above, it will take such action in connection with the furnishing of information as the Investor may reasonably request, all to the extent required from time to time to enable the Investor to sell Registrable Securities without registration under the Securities Act within the limitations of the exemption provided by Rule 144.

(g) The Investor represents and warrants that, during the period beginning 30 days prior to the date of this Agreement and ending on the date of this Agreement, none of the Investor or its Affiliates, or any entity acting under their direction or control, have engaged, directly or indirectly, in any trading of Common Stock, including, without limitation, short sales or hedging of any kind, other than as contemplated by this Agreement.

**2.2 Shelf Registration.** (a) The Company shall, within 45 days from the date of this Agreement (the "**Filing Date**"), file a registration statement (as amended or supplemented from time to time, the "**Shelf Registration Statement**") under the Securities Act covering all of the Registrable Securities then outstanding, and shall use its best efforts to cause the Shelf Registration Statement to become effective as promptly as practicable thereafter (provided that in the event the Company receives notice from the SEC that it will not "review" the Shelf Registration Statement and that the Company can request acceleration of effectiveness, the Company shall cause the Shelf Registration Statement to become effective within ten (10) days of receipt of such notice), and shall use its best efforts to keep such Shelf Registration Statement continuously effective under the Securities Act until the earlier of (i) the date on which all Registrable Securities are eligible for sale under Rule 144 without volume, manner of sale or other restrictions under such rule and (ii) the date on which all Registrable Securities covered by such Shelf Registration Statement have been sold (the "**Effectiveness Period**"). Such Shelf Registration Statement shall be on Form S-3 (except if the Company is not eligible to register for resale the Shelf Registrable Securities on Form S-3, then such registration shall be on such other appropriate form as the Company may reasonably select), and shall contain (unless otherwise directed by the Investor) the "Plan of Distribution" attached hereto as Annex A.



(b) The amount of Registrable Securities required to be included in the initial Shelf Registration Statement as described in Section 2.2(a) shall be not less than the maximum amount of Registrable Securities which may be included in a Registration Statement without exceeding registration limitations imposed by the SEC pursuant to Rule 415 under the Securities Act (the "**Rule 415 Amount**"). In the event that less than all of the Registrable Securities are included in the Shelf Registration Statement as a result of the limitation described in this Section 2.2(b), then the Company will file additional Shelf Registration Statements each registering the Rule 415 Amount, seriatim, until all of the Registrable Securities have been registered.

**2.3 Piggy-Back Registration**.

(a) If the Company proposes to register (including for this purpose a registration effected by the Company for stockholders other than the Investor) any of its Common Stock under the Securities Act in connection with the public offering of such securities solely for cash (other than (i) a registration on Form S-8 (or similar or successor form) relating solely to the sale of securities to participants in a Company stock plan or to other compensatory arrangements to the extent includable on Form S-8 (or similar or successor form), (ii) a registration on Form S-4 (or similar or successor form), (iii) a shelf registration statement covering the offer and sale of securities from time to time in one or more offerings or (iv) unless a Registration Statement has not already been filed for the Registrable Securities, a registration in connection with a rights offering to existing securityholders of the Company), the Company shall, at such time, give the Investor written notice of such registration. Upon the written request of the Investor received by the Company within twenty (20) Trading Days after mailing of such notice by the Company, the Company shall use its best efforts to cause to be registered under the Securities Act all of the Registrable Securities that the Investor has requested to be registered; provided that the right of the Investor to have such Registrable Securities so registered shall be subordinated in all respects to the rights of any other holders of registration rights, whether now existing or to be granted in the future. The Company may grant any registration rights, including registration rights that are superior in priority to the piggy-back registration rights granted to the Investor pursuant to this Section 2.3, to third parties, as it deems to be in its best interest. Except as otherwise required pursuant to this Agreement, the Company shall have no obligation under this Section 2.3 to make any offering of its securities, or to complete an offering of its securities that it has proposed to make. The Investor may withdraw its written notice of registration at any time, but such notice may not be reinstated if the twenty (20) day Trading Day period referred to above has expired.

(b) Subject to the provisions of Section 2.3(c) hereof, the amount of Registrable Securities required to be included in the initial Piggy-Back Registration Statement as described in Section 2.3(a) shall be not less than the lesser of (a) the amount of Registrable Securities that the Investor has requested to be so registered and (b) the maximum amount of Registrable Securities which may be included in a Registration Statement without exceeding the Rule 415 Amount.



(c) In the event that any registration pursuant to this Section 2.3 shall be, in whole or in part, an underwritten public offering of securities of the Company, the number of shares of Registrable Securities to be included in such underwriting may be reduced by the managing underwriter if and to the extent that the managing underwriter shall be of the opinion that such inclusion would adversely affect the marketing of the securities to be sold by the Company therein; provided, however, that the Company shall notify the Investor in writing of any such reduction. Notwithstanding the foregoing provisions, the Company may withdraw or delay or suffer a delay of any registration statement referred to in this Section 2.3 without thereby incurring any liability to the Investor or its Affiliates.

**2.4 Expenses of Registration**. Except as specifically provided herein, all Registration Expenses incurred in connection with any registration, qualification or compliance pursuant to Sections 2.2 or 2.3 shall be borne by the Company. All Selling Expenses incurred in connection with any registrations hereunder shall be borne by the holders selling the securities.

**2.5 Shelf Registration Procedures**. In connection with the Company's registration obligations hereunder with respect to the Shelf Registration Statement, the Company shall:

(a) Not less than ten (10) Trading Days prior to the filing of the Shelf Registration Statement or any related prospectus ("**Prospectus**") or any amendment or supplement thereto, the Company shall (i) furnish to the Investor and its counsel ("**Investor Counsel**") copies of such documents proposed to be filed, which documents will be subject to the review of Investor and Investor Counsel, and (ii) cause its officers and directors, counsel and independent certified public accountants to respond to such inquiries as shall be necessary, in the reasonable opinion of respective counsel, to conduct a reasonable investigation within the meaning of the Securities Act. The Company shall not file such Shelf Registration Statement or any related Prospectus, amendments or supplements thereto to which the Investor and Investor Counsel shall reasonably object.

(b) (i) Prepare and file with the SEC such amendments, including post-effective amendments, to the Shelf Registration Statement and the Prospectus used in connection therewith as may be necessary to keep such Shelf Registration Statement continuously effective as to the applicable Registrable Securities for the Effectiveness Period; (ii) cause the related Prospectus to be amended or supplemented by any required Prospectus supplement, and as so supplemented or amended to be filed pursuant to Rule 424 under the Securities Act; (iii) respond as promptly as reasonably possible, and in any event within twenty (20) Trading Days, to any comments received from the Commission with respect to the Shelf Registration Statement or any amendment thereto and promptly thereafter provide copies of such response to the Investor; and (iv) comply in all material respects with the provisions of the Securities Act and the Exchange Act with respect to the disposition of all Registrable Securities covered by the Shelf Registration Statement during the applicable period in accordance with the intended methods of disposition by the Investor set forth in the Shelf Registration Statement as so amended or in such Prospectus as so supplemented.



(c) Notify the Investor within three (3) Trading Days of receipt, and if requested by the Investor, confirm such notice in writing within three (3) Trading Days thereafter, of any of the following events: (i) the Commission notifies the Company of whether it plans to "review" the Registration Statement; (ii) the Commission comments in writing on the Registration Statement (in which case the Company shall deliver to the Investor a true and complete copy of such comments within three (3) Trading Days of receipt, a timeline relating to the proposed drafting of responses within six (6) Trading Days of receipt and of all such written responses); (iii) the Registration Statement or any post-effective amendment thereto is declared effective; (iv) the Commission or any other Federal or state governmental authority requests any amendment or supplement to the Registration Statement or Prospectus or requests additional information related thereto; (v) the Commission issues any stop order suspending the effectiveness of the Registration Statement or if the Company receives notice that the Commission initiates any Proceedings for that purpose; (vi) the Company receives notice of any suspension of the qualification or exemption from qualification of any Registrable Securities for sale in any jurisdiction, or the initiation or threat of any Proceeding for such purpose; or (vii) the financial statements included in the Registration Statement become ineligible for inclusion therein or any statement made in the Registration Statement or related Prospectus or any document incorporated or deemed to be incorporated therein by reference is untrue in any material respect or any revision to the Registration Statement, related Prospectus or other document is required so that it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(d) Use its best efforts to avoid the issuance of or, if issued, obtain the withdrawal of (i) any order suspending the effectiveness of the Registration Statement or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, at the earliest practicable moment.

(e) Furnish to the Investor and Investor Counsel, without charge, copies of the Registration Statement and each amendment thereto, including financial statements and schedules, and all exhibits to the extent and in such quantity as requested by such Person (excluding those previously furnished or incorporated by reference) within three (3) Trading Days after the filing of such documents with the Commission.

(f) Promptly upon request, deliver to the Investor and Investor Counsel without charge, as many copies of the Prospectus or Prospectuses (including each form of prospectus) related to the Registration Statement and each amendment or supplement thereto as such Persons may reasonably request. The Company hereby consents to the use of such Prospectus and each amendment or supplement thereto by the Investor in connection with the offering and sale of the Registrable Securities covered by such Prospectus and any amendment or supplement thereto. Furthermore, the Company hereby agrees that the Investor is permitted to use such Prospectuses including any amendment and each supplement thereto, if required for the purposes of any report or public announcements or disclosures to be submitted to, or made pursuant



to the requirements of, any governmental or regulatory body in India/Cyprus/Netherlands (as the case may be) and/or if required to comply with any law applicable to the Investor at the Investor's expense and to the extent reasonably practicable.

(g) In the time and manner required by the Trading Market, if at all, prepare and file with such Trading Market an additional shares listing application covering all of the Registrable Securities; (ii) take all steps necessary to cause such Registrable Securities to be approved for listing on the Trading Market as soon as reasonably practicable thereafter; (iii) to the extent available to the Company, provide to the Investor evidence of such listing; and (iv) maintain the listing of such Registrable Securities on each such Trading Market.

(h) Prior to any public offering of Registrable Securities pursuant to the Registration Statement, use its best efforts to register or qualify or cooperate with the Investor and Investor Counsel in connection with the registration or qualification (or exemption from such registration or qualification) of such Registrable Securities for offer and sale under the securities or Blue Sky laws of such jurisdictions within the United States as the Investor reasonably requests in writing, to keep each such registration or qualification (or exemption therefrom) effective during the Effectiveness Period, and to do any and all other acts or things necessary or advisable to enable the disposition in such jurisdictions of the Registrable Securities covered by the Registration Statement.

(i) Cooperate with the Investor to facilitate the timely preparation and delivery of certificates representing Registrable Securities to be delivered to a transferee pursuant to the Registration Statement, which certificates shall be free, to the extent permitted by this Agreement, of all restrictive legends, and to enable such Registrable Securities to be in such denominations and registered in such names as the Investor may request.

(j) Upon the occurrence of any event described in Section 2.5(c)(vii), as promptly as reasonably possible, prepare a supplement or amendment, including a post-effective amendment, to such Registration Statement or a supplement to the related Prospectus or any document incorporated or deemed to be incorporated therein by reference, and file any other required document so that, as thereafter delivered, neither the Registration Statement nor its related Prospectus will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(k) Cooperate with any due diligence investigation undertaken by the Investor in connection with the sale of Registrable Securities pursuant to the Registration Statement, including without limitation by making available any documents and information at the facilities of the Company during normal business hours and upon reasonable notice.

(l) In the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement with the underwriter(s), in usual and customary



form, including, without limitation, by providing customary legal opinions, comfort letters and indemnification and contribution obligations.

(m) Comply with all applicable rules and regulations of the Commission.

(n) Notwithstanding the above, the Company may suspend the effectiveness of the Registration Statement, suspend the use of any Prospectus included therein, and shall not be required to amend or supplement the Registration Statement, any related Prospectus or any document incorporated therein by reference for a period of time not to exceed 60 consecutive days and in no event to exceed more than an aggregate of 90 days during any rolling 12-month period (the "**Pending Event Suspension Period**"), if (i) an event or circumstance occurs and is continuing that has not been publicly disclosed and, if not disclosed in the Registration Statement, any related Prospectus or any document incorporated therein by reference as then amended or supplemented, would, in the Company's good-faith judgment, after consultation with its outside securities counsel, result in the Registration Statement, any related Prospectus or any such document containing an untrue statement of a material fact or omitting to state a material fact required to be stated therein, or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and (ii) in the good faith judgment of the board of directors of the Company (the "**Board**"), after consultation with its outside securities counsel, the Company has a *bona fide* business purpose for not then disclosing the existence of such event or circumstance (only to the extent such event or circumstance is material non-public information).

In the event of the occurrence of any Pending Event Suspension Period, the Company shall promptly upon such occurrence, notify the Investor in writing. The Company will also provide written notice to the Investor of the end of each Pending Event Suspension Period. The Investor agrees to cease all public disposition efforts under the Registration Statement with respect to the Registrable Securities then held by the Investor immediately upon receipt of notice of the beginning of any Pending Event Suspension Period and until the Investor receives notice of the end of such Pending Event Suspension Period.

**2.6 Piggy-Back Registration Procedures**. In connection with the Company's registration obligations hereunder with respect to a Piggy-Back Registration Statement in which Registrable Securities held by the Investor are in fact included, the Company shall:

(a) Not less than three (3) Trading Days prior to the filing of each Piggy-Back Registration Statement or any related Prospectus or any amendment or supplement thereto (i) furnish to the Investor and Investor Counsel copies of all such documents proposed to be filed (and thereafter include in the Piggy-Back Registration Statement all reasonable comments received by the Investor or Investor Counsel on disclosure relating to the Investor), and (ii) cause its officers and directors, counsel and independent certified public accountants to respond to such inquiries as shall be necessary, in the reasonable opinion of respective counsel or the Investor, as the case may be, to conduct a reasonable investigation within the meaning of the Securities Act.



(b) (i) Cause the related Prospectus to be amended or supplemented by any required Prospectus supplement, and as so supplemented or amended to be filed pursuant to Rule 424 and (ii) comply in all material respects with the provisions of the Securities Act and the Exchange Act with respect to the disposition of all Registrable Securities covered by a Piggy-Back Registration Statement during the offering.

(c) Promptly notify the Investor and Investor Counsel, and (if requested by any such Person) confirm such notice in writing, of any of the following events: (i) the Commission notifies the Company whether it intends to "review" any Piggy-Back Registration Statement; (ii) the Commission comments in writing on any Piggy-Back Registration Statement (in which case the Company shall deliver to the Investor a copy of such comments and of all written responses thereto); (iii) any Piggy-Back Registration Statement or any post-effective amendment thereto is declared effective; (iv) the Commission or any other Federal or state governmental authority requests any amendment or supplement to a Piggy-Back Registration Statement or related Prospectus or requests additional information related thereto; (v) the Commission issues any stop order suspending the effectiveness of any Piggy-Back Registration Statement or initiates any Proceedings for that purpose; (vi) the Company receives notice of any suspension of the qualification or exemption from qualification of any Registrable Securities for sale in any jurisdiction, or the initiation or threat of any Proceeding for such purpose; or (vii) the financial statements included in any Piggy-Back Registration Statement become ineligible for inclusion therein or any statement made in any Piggy-Back Registration Statement or related Prospectus or any document incorporated or deemed to be incorporated therein by reference is untrue in any material respect or any revision to a Piggy-Back Registration Statement, related Prospectus or other document is required so that it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(d) Furnish to the Investor and Investor Counsel, without charge, copies of each Piggy-Back Registration Statement and each amendment thereto, including financial statements and schedules, and all exhibits to the extent and in such quantity requested by such Person (excluding those previously furnished or incorporated by reference) promptly after the filing of such documents with the Commission.

(e) Promptly upon request, deliver to the Investor and Investor Counsel, without charge, as many copies of the Prospectus or Prospectuses (including each form of prospectus) and each amendment or supplement thereto as such Persons may reasonably request. The Company hereby consents to the use of such Prospectus and each amendment or supplement thereto by the Investor in connection with the offering and sale of the Registrable Securities covered by such Prospectus and any amendment or supplement thereto.

(f) Cooperate with the Investor to facilitate the timely preparation and delivery of certificates representing Registrable Securities to be delivered to a transferee pursuant



to a Piggy-Back Registration Statement, which certificates shall be free, to the extent permitted by this Agreement, of all restrictive legends, and to enable such Registrable Securities to be in such denominations and registered in such names as the Investor may request.

(g) Comply with all applicable rules and regulations of the Commission.

**2.7 Furnishing Information.** It shall be a condition precedent to the obligations of the Company to take any action pursuant to Section 2.2 or 2.3 that the Investor shall have furnished to the Company such information regarding itself, the Registrable Securities held by it and the intended method of disposition of such securities and such other information as shall be reasonably requested by the Company to effect the registration of the Registrable Securities.

**2.8 Indemnification.** In the event any Registrable Securities are included in a Registration Statement:

(a) To the extent permitted by law, the Company will indemnify and hold harmless the Investor and its Affiliates and each of the directors, officers, employees and agents of the Investor and its Affiliates (all of the foregoing, the "**Investor Indemnified Parties**"), against any losses, claims, damages, or liabilities (joint or several) to which they may become subject under the Securities Act, the Exchange Act or other U.S. federal or state law, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (any of the foregoing, a "**Violation**") by the Company or its officers, directors, employees or agents: (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto, (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading, and the Company will pay as incurred to each such Investor Indemnified Party for any legal or other expenses reasonably incurred by such Investor Indemnified Party in connection with investigating or defending any such loss, claim, damage, liability or action (subject to recoupment if this indemnification is judicially determined to be inapplicable by a final, non-appealable order or finding of any Court of competent jurisdiction sitting in the United States); *provided, however*, that the indemnity agreement contained in this Section 2.8(a) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable in any such case for any such loss, claim, damage, liability or action to the extent that it arises out of or is based upon a Violation that occurs in reliance upon and in conformity with written information furnished specifically for use in connection with such Registration Statement by the Investor Indemnified Party or, if the Company has fulfilled its obligations set forth in Section 2.5(f), results from the failure to deliver a Prospectus as required by the Securities Act.



(b) To the extent permitted by law, the Investor will, if Registrable Securities held by the Investor are included in the securities as to which such registration, qualification or compliance is being effected, indemnify and hold harmless the Company, its Affiliates and each of the directors, officers, employees and agents of the Company and its Affiliates (all of the foregoing, the **"Company Indemnified Parties"**), against any losses, claims, damages or liabilities (or actions in respect thereto) to which any one or more of the Company Indemnified Parties may become subject under the Securities Act, the Exchange Act or other U.S. federal or state law, insofar as such losses, claims, damages or liabilities (or actions in respect thereto) arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation occurs in reliance upon and in conformity with written information furnished by the Investor or any other Investor Indemnified Party under an instrument duly executed by such Investor Indemnified Party and stated to be specifically for use in connection with such registration or, if the Company has fulfilled its obligations set forth in Section 2.4, including without limitation Section 2.4(e), results from the failure to deliver a prospectus as required by the Securities Act; and each such Investor will pay as incurred any legal or other expenses reasonably incurred by the Company Indemnified Parties in connection with investigating or defending any such loss, claim, damage, liability or action if it is judicially determined by a final, non-appealable Order or finding of any Court of competent jurisdiction sitting in the United States that there was such a Violation; *provided, however*, that the indemnity agreement contained in this Section 2.8(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without the consent of the Investor, which consent shall not be unreasonably withheld.

(c) Within five (5) Trading Days, after receipt by an indemnified party under this Section 2.8 of notice of the commencement of any action (including any governmental action), such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.8, deliver to the indemnifying party a written notice of the commencement thereof, and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel satisfactory to the Company; *provided, however*, that an indemnified party shall have the right to retain its own counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if the indemnifying party is otherwise unaware of such action and such failure is materially prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.8, but the omission so to deliver written notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.8.

(d) The obligations of the Company and Investor under this Section 2.8 shall survive completion of any offering of Registrable Securities in a Registration Statement and the termination of this Agreement. No indemnifying party, in the defense of any such claim or litigation, shall, except with the consent of each indemnified party, consent to entry of any judgment or enter into any settlement that does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

**2.9 Assignment of Registration Rights.** The rights to cause the Company to register Registrable Securities pursuant to this Section 2 may be assigned by the Investor; provided that the Investor may not assign its registration rights under this Section 2 in whole or in part to (a) any individuals or entities whose business is competitive, in whole or in substantial part, with the business of the Company (except to the extent such transfer is to PBL or any of its direct or indirect wholly-owned subsidiaries), (b) individuals, entities or organizations (including governments or governmental agencies or organizations) then appearing on the list of Specially Designated National and Blocked Persons maintained by the U.S. Office of Foreign Assets Control ("**OFAC**") or entities or individuals, transfer of such rights to whom might reasonably be expected to have an adverse effect on the ability of the Company to bid for and receive grants or contracts from the United States government, and (c) entities or organizations then controlled by such individuals or having their registered office, headquarters or primary place of business located in a nation that is then subject to an OFAC sanctions program; provided that assignment of registration rights in connection with non-negotiated *bona fide* sales of Shares on the Trading Market ("**Non-Negotiated Bona Fide Sales**"), which, for the sake of clarity, shall not include negotiated block sales, are excluded from this restriction on assignment. In the event of any assignment (except in connection with Non-Negotiated Bona Fide Sales), the assignee shall agree to be bound by all of the terms and conditions imposed on the Investor under Section 2 of this Agreement and Section 27 of the Securities Purchase Agreement and under the Warrant.

**2.10 Amendment of Registration Rights.** Any provision of this Section 2 may be amended, and the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the Investor. Any amendment or waiver effected in accordance with this Section 2.10 shall be binding upon the Investor and the Company.

**SECTION 3. PRE-EMPTIVE RIGHTS**

**3.1 Subsequent Offerings.** For a period of three (3) years from the date of this Agreement, the Investor shall have the pre-emptive right to purchase its Equity Percentage of all Equity Securities that the Company may, from time to time, propose to sell and issue in any sale that is exempt from registration under the Securities Act after the date of this Agreement, other than the Equity Securities excluded by Section 3.5 hereof. The term "**Equity Securities**" shall mean (i) any Common Stock or preferred stock of the Company ("**Preferred Stock**"), (ii) any security convertible, with or without consideration, into any Common Stock or Preferred Stock



(including any option to purchase such a convertible security) or (iii) any option, warrant or right to acquire an Equity Security.

**3.2 Exercise of Rights.** If the Company proposes to issue any Equity Securities in any sale that is exempt from registration under the Securities Act, it shall give the Investor written notice of its intention, describing the Equity Securities, the price and the terms and conditions upon which the Company proposes to issue the same. The Investor shall have twenty (20) days from the giving of such written notice to agree to purchase up to its Equity Percentage of the Equity Securities for the price and upon the terms and conditions specified in the Company's notice by giving notice to the Company and stating therein the quantity of Equity Securities (up to an amount not to exceed Investor's Equity Percentage) it agrees to purchase. If the Investor decides to waive its pre-emptive rights with respect to any such transaction, and the Company does not enter into an agreement for the sale of the Equity Securities within ninety (90) days of such waiver, or if such agreement is not consummated within sixty (60) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such Equity Shares shall not be offered unless first reoffered to the Investor in accordance herewith.

**3.3 No Termination Upon Waiver of Pre-Emptive Rights.** The pre-emptive rights established by this Section 3 shall not terminate nor be deemed to be waived with respect to any subsequent private placement transactions if the Investor or its assignees do not exercise their rights as provided in Section 3.2 to purchase Equity Securities offered to them pursuant to Section 3.1. The provisions of this Section 3 may be amended or waived only by the agreement of the Company and the Investor.

**3.4 Transfer of Pre-Emptive Rights.** The Investor may assign its pre-emptive rights under this Section 3 in whole or in part provided that (i) each such assignment shall be in connection with a transfer to one individual or entity of a minimum of 500,000 Shares issued pursuant to the Securities Purchase Agreement and (ii) the Investor may not assign its pre-emptive rights under this Section 3 in whole or in part to (a) any individuals or entities whose business is competitive, in whole or in substantial part, with the business of the Company (except to the extent such transfer is to PBL or any of its direct or indirect wholly-owned subsidiaries), (b) individuals, entities or organizations (including governments or governmental agencies or organizations) then appearing on the list of Specially Designated National and Blocked Persons maintained by the U.S. Office of Foreign Assets Control ("**OFAC**") or entities or individuals, transfer of such rights to whom might reasonably be expected to have an adverse effect on the ability of the Company to bid for and receive grants or contracts from the United States government, and (c) entities or organizations then controlled by such individuals or having their registered office, headquarters or primary place of business located in a nation that is then subject to an OFAC sanctions program. In the event of any such assignment, the assignee shall agree to be bound by all of the terms and conditions imposed on the Investor under Section 3 of this Agreement, Section 27 of the Securities Purchase Agreement and under the Warrant.



**3.5 Excluded Securities.** The pre-emptive rights established by this Section 3 shall have no application to any of the following Equity Securities:

(a) shares of Common Stock, options, warrants or other Common Stock purchase rights issued or to be issued pursuant to the 2007 Long-Term Incentive Compensation Plan of the Company, as amended from time to time.

(b) stock issued pursuant to rights or agreements after the date of this Agreement; *provided* that the pre-emptive rights established by this Section 3 applied with respect to the initial sale or grant by the Company of such rights or agreements;

(c) any Equity Securities issued for consideration other than cash pursuant to a merger, consolidation, acquisition or similar business combination;

(d) shares of Common Stock issued in connection with any stock split, stock dividend or recapitalization by the Company;

(e) any Equity Securities issued upon the exercise or conversion of any instrument, security, note, warrant, option or other right outstanding on the date of this Agreement;

(f) any Equity Securities issued pursuant to or in connection with any equipment-leasing or other capital or operating lease arrangement, or debt financing from a bank, similar financial institution or other lender, in which the issuance of the Equity Securities was secondary to such transaction;

(g) any Equity Securities issued in connection with strategic alliances involving the Company or any of its subsidiaries; and

(h) any Equity Securities issued in a public offering.

**SECTION 4. MISCELLANEOUS**

**4.1 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding choice-of-law rules thereof.

**4.2 Remedies.** Each party agrees that in event that a settlement of any controversy, claim or dispute is not reached by mutual agreement, such controversy, claim or dispute will be settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association. The place of arbitration will be in London, England and the arbitrator's report will be submitted within six (6) months of the initiation of the arbitration process. The applicable federal or state court shall have jurisdiction to enforce any award or remedy granted in the arbitration. Each party will bear its own costs incurred in the course of arbitration.



**4.3 Successors and Assigns.** Except as otherwise expressly provided herein, this Agreement shall bind and inure to the benefit of the Company and the Investor and their respective permitted successors and assigns; *provided, however*, that, any proposed transfers of Investor's rights under this Agreement shall be subject to the other provisions of Sections 2.7 and 3.4 of this Agreement and prior to the receipt by the Company of adequate written notice of the transfer of any Registrable Securities specifying the full name and address of the transferee, the Company may deem and treat the person listed as the holder of such Registrable Securities in its records as the absolute owner and holder of such Registrable Securities for all purposes, including the payment of dividends or any redemption price.

**4.4 Entire Agreement.** This Agreement and any schedules hereto, the Securities Purchase Agreement and the other documents delivered pursuant thereto, constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof, including without limitation that certain Letter of Intent entered into by the Company and Panacea Biotec Ltd. and dated July 28, 2008.

**4.5 Severability.** Any provision of this Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

**4.6 Changes.**

(a) For the purposes of this Agreement, no course of dealing between or among any of the parties hereto and no delay on the part of any party hereto in exercising any rights hereunder shall operate as a waiver of the rights hereof. No provision hereof may be waived otherwise than by a written instrument signed by the party or parties so waiving such covenant or other provision as contemplated herein.

(b) Except as otherwise expressly provided, no amendment or modification of this Agreement may be made without the written consent of the Company and the Investor.

**4.7 Notices and Consents.** All notices and consents required or permitted hereunder must be in writing and shall be deemed effectively given in the manner specified in the Securities Purchase Agreement.

**4.8 Headings.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be a part of this Agreement.

**4.9 Counterparts.** This Agreement may be executed in any number of counterparts, and each such counterpart shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement.



[*Remainder of page intentionally left blank; signature page follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

| | |
|---|---|
| PHARMATHENE, INC. | KELISIA HOLDINGS LTD. |
| By: /s/ David P. Wright | By: /s/ Standguard Limited |
| Name: David P. Wright | Name: Duly represented by Mr. Paulos Paulou |
| Title: President and CEO | Title: Director |

[SIGNATURE PAGE TO INVESTOR RIGHTS AGREEMENT]

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Annex A

**Plan of Distribution**

The selling stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

The selling stockholders may also engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.



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The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after the Company has filed an amendment to the registration statement or supplement to the prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of the prospectus and may sell the shares of common stock from time to time under the prospectus after the Company has filed an amendment to the registration statement or supplement to the prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under the prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

The Company is required to pay all fees and expenses incident to the registration of the shares of common stock, including the fees and disbursements of counsel to the selling stockholders. The Company has agreed to indemnify the selling stockholders against certain losses, claims, damages

and liabilities, including liabilities under the Securities Act.

The selling stockholders have advised the Company that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If the Company is notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, the Company will file a supplement to the prospectus. If the selling stockholders use the prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of the Company's common stock and activities of the selling stockholders.

THESE SECURITIES HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**SECURITIES ACT**") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS.

COMMON STOCK PURCHASE WARRANT

To Purchase up to 2,745,098 Shares of Common Stock of

PHARMATHENE, INC.

THIS COMMON STOCK PURCHASE WARRANT (the "**Warrant**") certifies that, for value received, Kelisia Holdings Ltd., a company limited by shares established under the laws of Cyprus, having its office at 29 Theklas Lyssioti Street; Cassandra Centre, 2nd Floor; 3731 Limassol; Cyprus (together with any permitted transferee, the "**Holder**"), an indirect wholly owned subsidiary of Panacea Biotec Limited, a public limited company established under the laws of India, having its registered office at Ambala-Chandigarh Highway, Lalru-140501, Punjab, India ("**PBL**"), is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time after the date hereof (the "**Initial Exercise Date**") and on or prior to 5:00 p.m. U.S. Eastern Time on the first anniversary following the Initial Exercise Date (the "**Termination Date**") but not thereafter, to subscribe for and purchase from PharmAthene, Inc, a Delaware corporation (the "**Company**"), up to 2,745,098 shares (the "**Warrant Shares**") of common stock, par value US$0.0001 per share, of the Company (the "**Common Stock**"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions.

**"Affiliate"** means with respect to any Person, any Person that directly or indirectly, Controls, is Controlled by, or is under common Control with, such Person.

"**Business Day**" means a day other than a Saturday or Sunday or a day on which banks in Delaware are authorized or required by law to close.

**"Control"** (including with correlative meaning, Controlled by and under common Control with) shall mean, with respect to any Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by Contract or otherwise, provided that in all events (and in addition to the above), the direct or indirect ownership of more than 50% of the paid-up and issued voting share capital of a Person shall be deemed to constitute control over such Person.

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"**Person**" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind, whether incorporated, registered or not.

Section 2. Exercise.

(a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by (i) delivery to the Company of a duly executed facsimile copy of the Notice of Exercise annexed hereto (the "**Notice of Exercise**") (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of such Holder appearing on the books of the Company); (ii) surrendering this Warrant to the Company; and (iii) making payment to the Company of the aggregate Exercise Price (as defined below) for the shares thereby purchased by wire transfer to an account designated by the Company of same-day funds or cashier's check drawn on a United States bank. The Company shall deliver any objection to any Notice of Exercise within three Business Days of receipt of such notice. In the event of any dispute or discrepancy, the records of the Company shall be controlling and determinative in the absence of manifest error.

(b) Exercise Price. The per share exercise price for the Warrant Shares shall be US$5.10, subject to adjustment hereunder (the "**Exercise Price**").

(c) Mechanics of Exercise.

(i) Authorization of Warrant Shares. The Company covenants that all Warrant Shares that may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges or any encumbrance of any nature whatsoever in respect of the issue thereof.

(ii) Delivery of Certificates Upon Exercise. Certificates for shares purchased hereunder shall be transmitted by the transfer agent of the Company to the Holder by physical delivery to the address specified by the Holder in the Notice of Exercise within five (5) Business Days following receipt by the Company of a duly executed Notice of Exercise, this Warrant and the aggregate Exercise Price as set forth above ("**Warrant Share Delivery Date**"). This Warrant shall be deemed to have been exercised, the Warrant Shares shall be deemed to have been issued, and the Holder shall be deemed to have become a holder of record of such shares for all purposes, on the date the Exercise Price is received by the Company (the "**Exercise Date**").

(iii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of the Holder and upon surrender of this Warrant certificate, at the time of delivery of the certificate or certificates representing Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall, in all other respects, be identical to this Warrant.

(iv) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share that the Holder would otherwise be entitled to purchase upon such exercise, the Company shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price.

(v) Charges, Taxes and Expenses. Issuance of certificates for Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such certificate, all of which taxes and expenses shall be paid by the Company, and such certificates shall be issued in the name of the Holder.

(vi) Closing of Books. The Company will not close its stockholder books or records in any manner that prevents the timely exercise of this Warrant pursuant to the terms hereof.

(d) Maximum Exercise. The Holder shall not be entitled to exercise the Warrant for any amount of Warrant Shares that, if issued, would result on any such Exercise Date in the aggregate number of shares that the Holder would otherwise receive pursuant to the exercise of the Warrant, together with the 3,733,334 shares of Common Stock the Holder purchased pursuant to the Securities Purchase Agreement, dated September 30, 2008, between the Company and the Holder (the "**Securities Purchase Agreement**"), and any other shares beneficially owned by PBL, Kelisia Holdings Ltd. and any holder of Warrant Shares or shares of Common Stock issued pursuant to the Securities Purchase Agreement, and of their respective officers, directors and Affiliates, equaling or exceeding twenty percent (20%) of the number of shares of Common Stock outstanding on the date of the Securities Purchase Agreement or on such Exercise Date.

Section 3. Certain Adjustments.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company pursuant to this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues, by reclassification of shares of the Common Stock, any shares of capital stock of the Company, then, in each case, the Exercise Price shall be adjusted by multiplying the Exercise Price immediately prior to such adjustment by a fraction the numerator of which shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or reclassification.



(b) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(c) Voluntary Adjustment by Company. The Company may, at any time during the term of this Warrant and with the prior written approval by the Holder, reduce the then-current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

(d) Notice to Holder.

(i) Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to this Section 3, the Company shall within five (5) Business Days mail to the Holder a notice setting forth the Exercise Price after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

(ii) Notice to Allow Exercise by Holder. If any of the events specified in Section 3(a)(i), (ii), (iii) or (iv) occurs, then, in each case, the Company shall cause to be mailed to the Holder at its last address as it shall appear upon the Warrant Register of the Company a notice setting forth the record date or the effective date for such event.

(e) Further Negotiations. If at any time beginning thirty (30) trading days after the Closing Date, the weighted average closing price of the common stock of the Company on the American Stock Exchange or any successor exchange during the preceding twenty (20) consecutive trading days was below US$3.50 per share, the Holder may request that the Company attend a meeting to discuss an amendment to this Warrant that could result in an adjustment to the Exercise Price. Representatives of the Company shall agree to meet with the Holder and will have such meeting at a time that is mutually convenient, but in no event more than twenty (20) days after such request is made in writing by the Holder. The Company is under no obligation to agree to any such adjustment and this provision does not modify or limit the restrictions provided for in Section 2(d) of this Warrant.

Section 4. Transfer of Warrant.

(a) Transferability. This Warrant and all rights hereunder may be transferred to third parties; provided that this Warrant and any rights hereunder may not be transferred, directly or indirectly, through Affiliates or otherwise, to (a) any individuals or entities whose business purpose is competitive, in whole or in substantial part, with the business of the Company (except to the extent such transfer is to PBL or any of its direct or indirect wholly-owned subsidiaries), (b) individuals, entities or organizations (including governments or governmental agencies or organizations) then appearing on the list of Specially Designated National and Blocked Persons maintained by the U.S. Office of Foreign Assets Control ("**OFAC**") or entities or individuals, transfer of such rights to whom might reasonably be expected to have an adverse effect on the ability of the Company to bid for and receive grants or contracts from the United States government, and (c) entities or organizations then controlled by

such individuals or having their registered office, headquarters or primary place of business located in a nation that is then subject to an OFAC sanctions program. In the event of any such transfer, the transferee shall agree to be bound by all of the terms and conditions imposed on the Investor under this Warrant, the Investor Rights Agreement of even date herewith, between the Company and Kelisia Holdings Ltd. (to the extent applicable to holders of Warrant Shares) and Section 27 of the Securities Purchase Agreement.

(b) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "**Warrant Register**"), in the name of the Holder hereof and upon receipt of written notice from Holder of any permitted transfer, the Company shall update the Warrant Register to reflect the current registered holder. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes.

Section 5. Miscellaneous.

(a) No Rights as Shareholder Until Exercise. This Warrant does not entitle the Holder to any voting rights or other rights as a shareholder of the Company prior to the exercise hereof. Upon the surrender of this Warrant and the payment of the aggregate Exercise Price, the Warrant Shares so purchased shall be, and be deemed to be, issued to such Holder as the record owner of such shares as of the close of business on the later of the date of such surrender or payment.

(b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that, upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and, in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will, in lieu of such Warrant or stock certificate, make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation.

(c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall be a Saturday, Sunday or a legal holiday, then such action may be taken or such right may be exercised on the next succeeding day not a Saturday, Sunday or legal holiday.

(d) Authorized Shares. The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation.

Except and to the extent as waived or consented to by the Holder in writing, the Company shall not by any action, including, without limitation, amending its certificate of



incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of the Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be reasonably necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

(e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Securities Purchase Agreement.

(f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant will have restrictions upon resale imposed by state and federal securities laws and that the certificate(s) representing such Warrant Shares will contain a legend stating that the Warrant Shares have not been registered under the Securities Act and, therefore, cannot be offered, sold or transferred unless registered under the Securities Act or an exemption from such registration is available in the opinion of counsel satisfactory to the Company or unless registered in accordance with the Investor Right Agreement executed by and between the Holder and the Company as of the date hereof.

(g) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Securities Purchase Agreement.

(h) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant or purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(i) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of, and be binding upon, the successors of the Company and the successors and permitted assigns of the Holder. The provisions of this Warrant are intended to be for the benefit of all holders from time to time of this Warrant and shall be enforceable by any such holder or holder of Warrant Shares.

(j) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(k) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but, if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(l) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

(m) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, excluding choice-of-law rules thereof.

(n) Remedies. Each party agrees that in event that a settlement of any controversy, claim or dispute is not reached by mutual agreement, such controversy, claim or dispute will be settled by arbitration administered in accordance with the Commercial Arbitration Rules of the American Arbitration Association. The place of arbitration will be in London, England and the arbitrator's report will be submitted within six (6) months of the initiation of the arbitration process. The applicable federal or state court shall have jurisdiction to enforce any award or remedy granted in the arbitration. Each party will bear its own costs incurred in the course of arbitration.

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized.

Dated: October 10, 2008

**PHARMATHENE, INC.**

By: /s/ David P. Wright
Name: David P. Wright
Title: President and CEO



**NOTICE OF EXERCISE**

TO: PHARMATHENE, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant, and tenders herewith payment of the exercise price in full, not including transfer taxes, if any.

Following the proposed exercise of this Warrant, the total beneficial ownership of Common Stock held by the Holder and its officers, directors and Affiliates will be: _____ shares of Common Stock.

(2) Payment shall be made by (check applicable box):

o wire transfer to an account designated by the Company

o cashier's check drawn on a United States bank

in lawful money of the United States.

(3) Please issue a certificate or certificates representing said Warrant Shares in the name of the undersigned.

The Warrant Shares shall be delivered to the following address:

_____

_____

_____

**Exhibit 10.43**

DATED [ · ] 2008

**DEED OF CONFIDENTIALITY**

**PHARMATHENE UK LIMITED**

**(1)**

**and**

[**INSERT EMPLOYEE'S NAME**]

**(2)**

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**THIS DEED** is made the [ · ] day of [ · ] 2008

**BETWEEN**:

(1) PHARMATHENE UK LIMITED (No. 06534363) (the "**Company**"); and

(2) [INSERT EMPLOYEE'S NAME] of [ · ] (the "**Employee"**).

**IT IS HEREBY AGREED** as follows:

**1. CONFIDENTIAL INFORMATION**

**1.1** During the Appointment the Employee will inevitably receive highly confidential information. The Employee shall not either during his Appointment (other than in the proper course of his duties and for the benefit of the Company) or after his employment has ended for any reason whatsoever:

1.1.1 use, disclose or communicate to any person any Confidential Information which the Employee shall have come to know or have received or obtained at any time (before or after the date of this Agreement) by reason of or in connection with the Employee's service with the Company; or

1.1.2 copy or reproduce in any form or by or on any media or device or allow others access to or to copy or reproduce recorded information whether or not in documentary form ("**Documents**") containing or referring to Confidential Information.

**1.2** All Documents containing or referring to Confidential Information at any time in the Employee's control or possession are and shall at all times remain the absolute property of the Company or its clients, and the Employee undertakes, both during his employment and afterwards:

1.2.1 to exercise due care and diligence to avoid any unauthorised publication, disclosure or use of Confidential Information and any Documents containing or referring to it;

1.2.2 to deliver up any Confidential Information (including all copies of all Documents whether or not lawfully made or obtained) or to delete Confidential Information from any re-useable medium; and

1.2.3 to do such things and sign such documents at the expense of the Company as shall be reasonably necessary to give effect to this Clause and/or to provide evidence that it has been complied with.

**1.3** The restrictions in Clause 1.1 will not apply to Confidential Information which is or which comes into the public domain otherwise than as a result of an unauthorised disclosure by the Employee or any other person who owes the Company an obligation of confidentiality in relation to the information disclosed or which may be required to be disclosed to the extent required by law or any competent regulatory authority.

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**1.4** The Employee agrees that the restrictions set out in this Clause 1 are without prejudice to any other duties of confidentiality owed to the Company whether express or implied and are to survive the termination of the Employee's employment.

**1.5** For the purposes of this Clause 1, "**Confidential Information**" means information which may be imparted in confidence or be of a confidential nature relating to the business or prospective business or internal affairs of the Company, and in particular all information relating to the performance, structure, operation, provision and marketing or sales of any past, present or future product or services of the Company (including lists of clients and potential clients, suppliers, names and addresses of marketing contacts, service and product information including details of any formats, programs, concepts or ideas, creations, outlines, treatments, processes, data, programs, computer models, network information, software or other systems utilised by the Business), know-how, trade secrets, unpublished information relating to the intellectual property of the Company and any other commercial, financial or technical information relating to the Business or to any other client or supplier, officer or employee of the Business.

**1.6** Nothing in this Clause 1 will prevent the Employee from making a protected disclosure under the Public Interest Disclosure Act 1998.

**2. INVENTIONS AND IMPROVEMENTS**

**2.1** The Employee agrees that he has a special obligation to further the interests of the Company and its Associated Companies with respect to any Inventions created or discovered by him in the course of his employment with the Company.

**2.2** If the Employee creates or discovers or participates in the creation or discovery of any Inventions during his employment with the Company or any Associated Company, the Employee shall promptly give to the Secretary of the Company full details of such Inventions and, if such Inventions relate to or are capable of being used in the business for the time being carried on by the Company or any Associated Company, such Inventions shall be the absolute property of the Company or the relevant Associated Company and the Employee shall forthwith and from time to time both during his employment and thereafter at the request and expense of the Company or the relevant Associated Company:

2.2.1 give and supply all such information, data, drawings and assistance as may be necessary to enable the Company or the relevant Associated Company to exploit such Inventions to the best advantage; and

2.2.2 execute all documents and do all things which may be necessary or desirable for obtaining patent or other protection for the Inventions in such parts of the world as may be specified by the Company and for vesting the same in the Company or the relevant Associated Company or as it may direct.

**2.3** The Employee irrevocably appoints the Company to be his attorney in his name and on his behalf to sign, execute or do any such instrument or thing and generally to use his name for the purpose of giving to the Company or the relevant Associated Company (or its nominee) the full benefit of the provisions of this Clause and in favour of any third party a certificate in writing signed by any

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Director or the Company Secretary of the Company that any instrument or act falls within the authority conferred by this Clause shall be conclusive evidence that such is the case.

**2.4** If the Employee creates or discovers or participates in the creation or discovery of any Inventions during his employment under this Agreement which do not relate to or are not capable of being used in the business for the time being carried on by the Company or any Associated Company, the Company shall subject only to the provisions of the Patents Act 1977 have the right to acquire for itself or its nominee the Employee's rights in the Inventions within three months after disclosure pursuant to Clause 2.2 on fair and reasonable terms to be agreed or settled by a single arbitrator as appointed by the Company.

**2.5** The Employee waives all of his Moral Rights as defined in the Copyright Designs and Patents Act 1988 in respect of any acts of the Company or any Associated Company or any acts of third parties done with the Company's authority in relation to the Inventions which are the property of the Company or any Associated Company by virtue of Clause 2.2 hereof.

**2.6** Rights and obligations under this Clause shall continue in force after the termination of this Agreement in respect of Inventions made or discovered during the Employee's employment under this Agreement and shall be binding upon his representatives.

**2.7** In this Clause "Inventions" includes letters patent, trade marks, service marks, designs, utility models, copyrights, design rights, applications for registration or any of the foregoing and the right to apply for them in any part of the world, moral rights, inventions, improvements to procedures, confidential information, know-how and rights of like nature arising or subsisting anywhere in the world, in relation to all of the foregoing, whether registered or unregistered.

**3. GOVERNING LAW**

The terms of this Deed are governed by laws of England and the parties hereto submit to the non-exclusive jurisdiction of the English Courts. The Company may however enforce the Deed in any other courts of competent jurisdiction.

**4. INTERPRETATION**

In this Deed the following words and expressions shall have the following meanings:

| | |
|---|---|
| "Associated Company" | a company which is from time to time a subsidiary or a holding company of the Company or a subsidiary (other than the Company) of a holding company of the Company; |
| "subsidiary" and "holding company" | the meanings respectively ascribed thereto by section 736 of the Companies Act 1985. |

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**EXECUTED** as a Deed for and on behalf of )

**PHARMATHENE UK LIMITED** by )

_____

Director

_____

Director / Company Secretary

_____

Date

**EXECUTED** as a Deed by )

**[EMPLOYEE'S NAME]** )

_____

In the presence of: )

_____

Witness' name

_____

_____

Witness' address

_____

Witness' occupation

_____

Date

**SECOND AMENDMENT TO OFFICE LEASE**

THIS SECOND AMENDMENT TO OFFICE LEASE (this "**Second Amendment**") is made as of Sept. 16th 2008, by and between Park Place Trust, a Maryland business trust ("**Landlord**") and PharmAthene, Inc., a Delaware corporation ("**Tenant**").

**WITNESSETH:**

WHEREAS, Landlord and Tenant entered into that certain Office Lease dated September 14, 2006 (the "**Original Lease**").

WHEREAS, Landlord and Tenant entered into that certain First Amendment to Office Lease dated January 22, 2007 (the "**First Amendment**" and, together with the Original Lease, the "**Lease**").

WHEREAS, pursuant to the Lease, Landlord has leased to Tenant and Tenant has leased from Landlord certain space (the "**Premises**"), consisting of approximately twelve thousand five hundred twenty-seven (12,527) rentable square feet of office space located on the fourth (4th) floor of the building known as Park Place Office Building One and located at West Street and Taylor Avenue, Annapolis, Maryland (the "**Building**"), as more particularly described in the Lease.

WHEREAS, Landlord has agreed to lease to Tenant, and Tenant has agreed to lease from Landlord, approximately 9,329 square feet of additional rentable area on the fifth (5th) floor of the Building (the "**Fifth Floor Expansion Space**") as shown on Exhibit A-2 attached hereto.

WHEREAS, Landlord and Tenant desire to amend the Lease upon the terms and conditions set forth in this Second Amendment.

WHEREAS, except as otherwise defined herein, all terms used in this Second Amendment that are defined in the Lease shall have the same meaning as set forth in the Lease.

NOW, THEREFORE, in consideration of the sum of Ten Dollars ($10.00) cash in hand paid, the mutual covenants hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Landlord hereby leases the Fifth Floor Expansion Space to Tenant, and Tenant hereby leases the Fifth Floor Expansion Space from Landlord. With the addition of the Fifth Floor Expansion Space, the Demised Premises (as so expanded, the "**Demised Premises Expanded**") shall contain approximately 21,856 rentable square feet.

   The Monthly Rent for the Fifth Floor Expansion Space ("**Fifth Floor Expansion Space Monthly Rent**") from and after the Fifth Floor Expansion Space Commencement Date (as defined below) shall be as follows:

| Period | Fifth Floor Expansion Space Monthly Rent | Rate Per Square Foot |
|---|---|---|
| Fifth Floor Expansion Space Commencement | | $ 31.93 |
| Date through end of the Second Lease Year (ending May 31, 2009) | $ 24,822.91 | |
| Third Lease Year | $ 25,569.23 | $ 32.89 |
| Fourth Lease Year | $ 26,338.88 | $ 33.88 |
| Fifth Lease Year | $ 27,131.84 | $ 34.90 |
| Sixth Lease Year | $ 27,948.13 | $ 35.95 |
| Seventh Lease Year | $ 28,787.74 | $ 37.03 |
| Eighth Lease Year | $ 29,650.67 | $ 38.14 |
| Ninth Lease Year | $ 30,536.93 | $ 39.28 |
| Tenth Lease Year (ending May 31, 2017) | $ 31,454.28 | $ 40.46 |

   With the addition of the Fifth Floor Expansion Space, Tenant's Share of Operating Expenses shall be increased from 7.81% to 13.86%, Tenant's Share of Operating Costs shall be increased from 8.24% to 16.33% and Tenant's Share of Real Estate Taxes shall be increased from 7.81% to 13.86%, with such increased amounts pro rated to reflect partial year tenancy with respect to the Fifth Floor Expansion Space from the Fifth Floor Expansion Space Commencement Date through the end of that calendar year.

2. Letter of Credit

   Landlord and Tenant acknowledge that Tenant has provided a Security Deposit Letter of Credit (the "**Letter of Credit**") in the amount of $183,588.00 pursuant to the First Amendment and Section 6(B) of the Lease and that Tenant had the right to reduce the Letter of Credit by $61,196.00 on the last day of the first Lease Year, which right was not exercised by Tenant. Landlord and Tenant agree that given Tenant's right to terminate this Second Amendment pursuant to the Fifth Floor Expansion Space Termination Option as provided in Section 4 hereof, and in consideration of Landlord's willingness to not require an increase in the Letter of Credit immediately upon execution of this Second Amendment,

Tenant hereby waives it right to reduce the Letter of Credit until after the exercise or expiration of the Fifth Floor Expansion Space Termination Option.

If Tenant properly exercises the Fifth Floor Expansion Space Termination Option pursuant to Section 4 hereof and this Second Amendment is terminated pursuant thereto, Tenant shall be entitled to take an immediate reduction in the Letter of Credit of



$61,196.00 and further reductions on the last day of the second, third and fourth Lease Year as outlined in the First Amendment.

If Tenant does not terminate this Second Amendment pursuant to the Fifth Floor Expansion Space Termination Option, on the Fifth Floor Expansion Space Commencement Date, the Letter of Credit shall be increased pro rata from One Hundred Eighty-Three Thousand Five Hundred Eighty-Eight Dollars ($183,588.00) to Three Hundred Twenty Thousand Three Hundred Six Dollars ($320,306.00) and Tenant shall simultaneously be permitted to take a reduction of One Hundred Six Thousand Seven Hundred Sixty-Eight Dollars ($106,768.00), which pro rata increase and reduction shall be evidenced by an amendment to the Letter of Credit to be delivered by Tenant to Landlord on such date, such that on the Fifth Floor Expansion Space Commencement Date the Letter of Credit shall be in the amount of Two Hundred Thirteen Thousand Five Hundred Thirty-Eight Dollars ($213,538). The Letter of Credit Reduction chart contained in Section 6(C) of the Lease shall be deemed deleted and replaced with the following:

| Reduction Date | Security Deposit Reduction Amount | Security Deposit Remaining After Reduction |
|---|---|---|
| Last day of the second Lease Year | $ 53,384.33 | $ 160,152.99 |
| Last day of the third Lease Year | $ 53,384.33 | $ 106,768.66 |
| Last day of the fourth Lease Year | $ 53,384.33 | $ 53,384.33 |

3. Term

(A) The term of the Lease with respect to the Fifth Floor Expansion Space shall commence on the Fifth Floor Expansion Space Commencement Date and shall expire on and be coterminous with the Expiration Date of the Lease, May 31, 2017. The term of the Lease with respect to the Fifth Floor Expansion Space shall also include any properly exercised renewal or extension of the Lease.

(B) The "**Fifth Floor Expansion Space Commencement Date**" shall be the earlier of (i) the date on which Tenant commences business operations in the Fifth Floor Expansion Space or (ii) the date on which the Fifth Floor Expansion Space Leasehold Work (as defined in Exhibit B-1 attached hereto) is substantially complete (as determined in accordance with Paragraph 10 of Exhibit B-1 attached hereto). Notwithstanding the foregoing, Tenant shall not have any right to commence business operations in the Fifth Floor Expansion Space unless the same are vacant and delivered to Tenant by Landlord and during any period Tenant is in breach of any of its obligations under the Lease. Promptly after the Fifth Floor Expansion Space Commencement Date is ascertained, Landlord shall provide and Tenant shall execute a certificate confirming the Fifth Floor Expansion Space Commencement Date in the form of Exhibit D-2 attached hereto.



(C) It is presently anticipated that the Fifth Floor Expansion Space will be delivered to Tenant with the Fifth Floor Expansion Space Leasehold Work substantially complete, except as hereinafter provided, on or about February 15, 2009; provided, however, that if Landlord does not deliver possession of the Fifth Floor Expansion Space by such date, Landlord shall not have any liability whatsoever, and except as set forth in the sentence next following, this Second Amendment shall not be rendered void or voidable, as a result thereof. The foregoing notwithstanding, in the event the Fifth Floor Expansion Space Commencement Date has not occurred by June 15, 2009 (as such date may be extended by force majeure and Tenant Delay, as defined in Exhibit **B),** then Tenant shall have the right to terminate this Second Amendment without penalty upon notice to Landlord given prior to the Fifth Floor Expansion Space Commencement Date. If so terminated, the Lease shall thereafter continue in full force and effect without reference to this Second Amendment.

Except as herein set forth the Fifth Floor Expansion Space shall be deemed part of the Demised Premises Expanded and the Lease shall apply to the Fifth Floor Expansion Space in the same manner it applies to the space originally demised.

4. Prior to the Fifth Floor Expansion Space Commencement Date, Tenant shall have the option to terminate this Second Amendment (the "**Fifth Floor Expansion Space Termination Option**") by providing Landlord with written notice and payment, along with such notice, of the applicable Fifth Floor Expansion Space Termination Fee as follows:

| Notice of Termination | Fifth Floor Expansion Space Termination Fee Per Square Foot | Total Fifth Floor Expansion Space Termination Fee |
|---|---|---|
| Prior to December 1, 2008 | $ 15.00 | $ 139,935.00 |
| Between December 1, 2008 and December 31, 2008 | $ 40.00 | $ 373,160.00 |

This Fifth Floor Expansion Space Termination Option shall, if not thereto exercised, expire upon the earlier of (A) the date Tenant takes possession of the Fifth Floor Expansion Space or (B) 5:00pm EST on December 31, 2008. In the event this Second Amendment is so terminated, the Lease shall continue in full force and effect in accordance with its terms and without reference to this Second Amendment.

5. Any and all references in the Lease to "200 Park Place" are hereby deleted and replaced with "One Park Place."

6. Landlord's address in Section 1 of the Lease, and Landlord's notice address in Paragraph 41 of the Lease, are hereby deleted and replaced with the following: "c/o Jerome J. Parks Companies, One Park Place, Suite 400, Annapolis, Maryland 21401, Attn: Jerome J. Parks."



7. By virtue of the leasing of the Fifth Floor Expansion Space, Tenant shall be entitled to an allocation of two (2) additional contracts for reserved spaces, such contracts to be made available pursuant to Section 8 of the Lease.

8. This Second Amendment shall be binding upon and inure to the benefit of the parties hereto, their successors and assigns.

9. This Second Amendment may be executed in multiple counterparts, each of which shall be an original, but all of which shall constitute one and the same Second Amendment. Faxed signatures shall have the same binding effect as original signature, and a faxed Second Amendment containing the signatures (original or faxed) of the parties shall be binding.

10. In all other respects the Lease shall continue in full force and effect in accordance with its terms.

[Signatures contained on the following page]



IN WITNESS WHEREOF, Landlord and Tenant have caused this Second Amendment to be executed under seal as of the date first above written.

**LANDLORD:**

PARK PLACE TRUST,
a Maryland business trust

By: JBJ/Carlyle Park Place LP, a Delaware limited partnership, as Trustee

By: JBJ Management Company, Inc., a Maryland limited liability company, Managing General Partner

By: /s/ J. Parks [SEAL]
Name: J. Parks
Date: 9/16/08

**TENANT:**

PHARMATHENE, INC.,
a Delaware corporation

By: /s/ Christopher C. Camut [SEAL]
Name: Christopher C. Camut
Title: VP, Chief Financial Officer

EXHIBIT A-2

FIFTH FLOOR EXPANSION SPACE

(Attached)

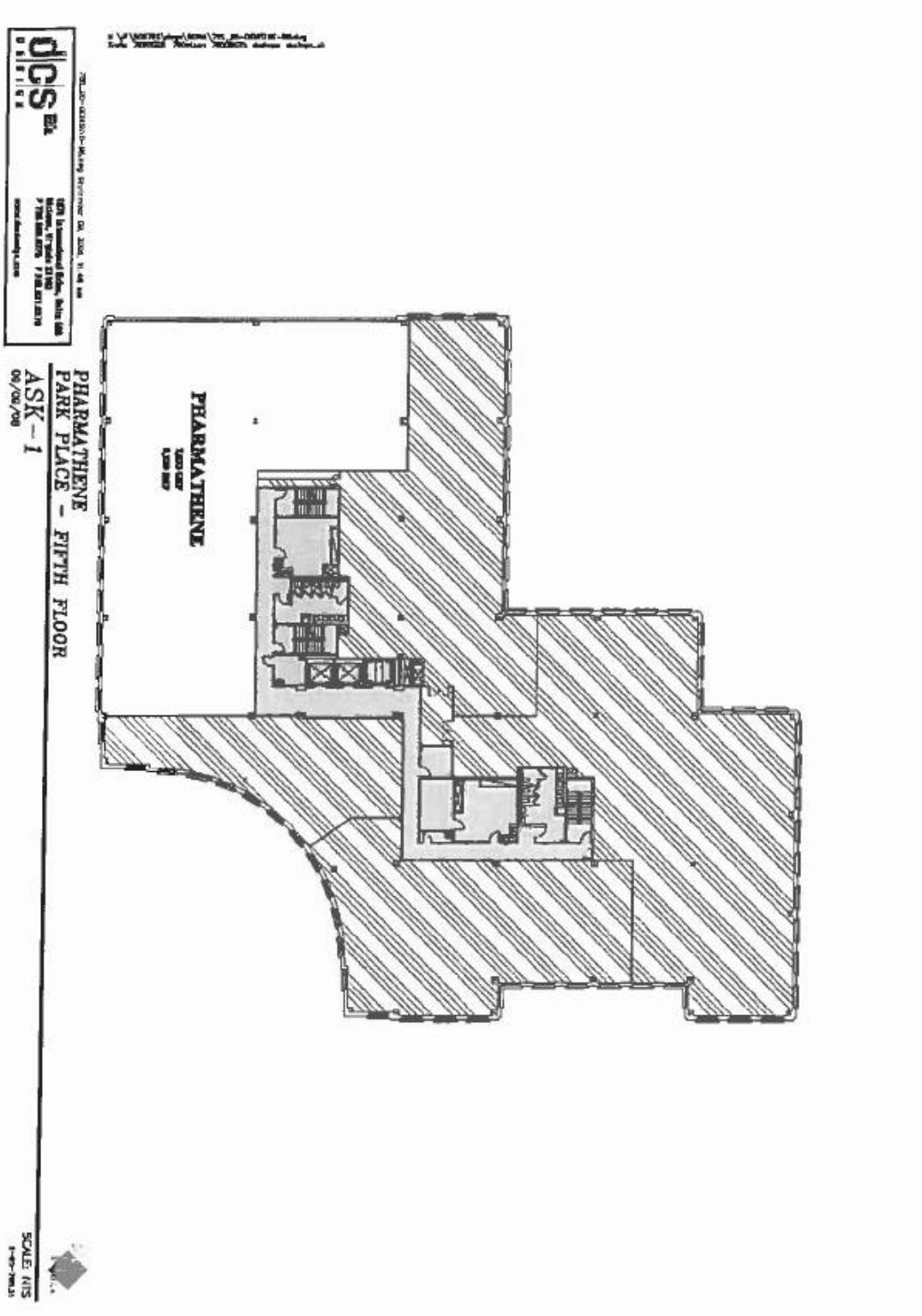


EXHIBIT B-1

WORK AGREEMENT

This Exhibit B-1 is attached to and made a part of that certain Second Amendment to Office Lease dated as of _____, 2008 (the **"Second Amendment"**), between Park Place Trust (**"Landlord"**) and PharmAthene, Inc. (**"Tenant").** Capitalized terms used herein which are not defined in this Work Agreement shall be deemed to have the meanings given such terms in the Lease.

1. Authorized Representatives.

(a) Tenant designates Chris Camut (**"Tenant's Authorized Representative"**) as the person authorized to approve in writing all plans, drawings, specifications, change orders, charges and approvals pursuant to this Exhibit (and the act of either of the aforenamed persons shall be sufficient to bind Tenant). Tenant may designate a substitute Tenant's Authorized Representative by written notice to Landlord. Landlord shall not be obligated to respond to any instructions, approvals, changes, or other communications from anyone claiming to act on Tenant's behalf other than Tenant's Authorized Representative. All references in this Exhibit to actions taken, approvals granted, or submissions made by Tenant shall mean that such actions, approvals or submissions have been taken, granted or made, in writing, by Tenant's Authorized Representative acting for Tenant.

(b) Landlord designates Robert Sudol (**"Landlord's Authorized Representative"**) as the person authorized to approve in writing all plans, drawings, specifications, change orders, charges and approvals pursuant to this Exhibit (and the act of either of the aforenamed persons shall be sufficient to bind Landlord). Landlord may designate a substitute Landlord's Authorized Representative by written notice to Tenant. Tenant shall not be obligated to respond to any instructions, approvals, changes, or other communications from anyone claiming to act on Landlord's behalf other than Landlord's Authorized Representative. All references in this Exhibit to actions taken, approvals granted, or submissions made by Landlord shall mean that such actions, approvals or submissions have been taken, granted or made, in writing, by Landlord's Authorized Representative acting for Landlord.

2. Fifth Floor Expansion Space Leasehold Work. Landlord shall construct the initial leasehold improvements in the Fifth Floor Expansion Space approved by Landlord in accordance with this Exhibit (the **"Fifth Floor Expansion Space Leasehold Work"**) in substantial conformity with the Fifth Floor Expansion Space Leasehold Work Plans.

3. Architect and Engineers. Landlord shall employ Davis, Carter, Scott Ltd. (the **"Fifth Floor Expansion Space Leasehold Architect"**) to prepare the Fifth Floor Expansion Space Leasehold Plans (as hereinafter defined). Landlord shall employ Metropolitan Engineering Inc. (the **"Fifth Floor Leasehold Engineers"),** to prepare the engineering drawings relating to the Fifth Floor Expansion Space Leasehold Work.

4. Reserved.

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5. Plans for Fifth Floor Expansion Space Leasehold Work. Tenant shall provide its space plan to Landlord for Landlord's approval prior to the date shown on the Construction Schedule attached hereto as Schedule B-II (the **"Construction Schedule").** Landlord's approval thereof shall not be unreasonably withheld. Landlord shall cause the Fifth Floor Expansion Space Leasehold Architect and the Fifth Floor Expansion Space Leasehold Engineers to prepare final construction documents for the Fifth Floor Expansion Space Leasehold Work, consistent with the approved space plan no later than the date shown on the Construction Schedule. The construction documents for the Fifth Floor Expansion Space Leasehold Work that have been submitted by Tenant and approved by Landlord shall be referred to herein as the **"Fifth Floor Expansion Space Leasehold Plans."**

6. Reserved.

7. Cost of Fifth Floor Expansion Space Leasehold Work.

(a) Landlord shall select the contractor(s) who will be employed to perform the Fifth Floor Expansion Space Leasehold Work (the **"Fifth Floor Expansion Space Leasehold Contractor"),** based upon the recommendations of Jerome J. Parks Companies, Landlord's Fifth Floor Expansion Space Project Manager (the **"Fifth Floor Expansion Space Project Manager").** Landlord shall cause the contractor to perform the Fifth Floor Expansion Space Leasehold Work in a professional, workmanlike and first class manner consistent with industry standards.

(b) The cost of the design and construction of the Fifth Floor Expansion Space Leasehold Work from shell condition (see Schedule B-I), including all "soft" costs and a construction management fee payable to the Fifth Floor Expansion Space Project Manager in an amount equal to four percent (4%) of the construction bid (collectively, the **"Fifth Floor Expansion Space Leasehold Cost"),** up to the amount of the Fifth Floor Expansion Space Improvements Allowance described in Paragraph 8 below shall be borne by Landlord. Any portion of the Fifth Floor Expansion Space Leasehold Cost that is in excess of the Fifth Floor Expansion Space Improvements Allowance shall be borne by Tenant and is referred to herein as **"Fifth Floor Expansion Space Tenant's Expenses."** In the event the Fifth Floor Expansion Space Leasehold Cost is expected to (based upon the bid) exceed the amount of the Fifth Floor Expansion Space Improvement Allowance, Landlord shall bill to Tenant the projected excess amount in three (3) equal installments, and one-third of the Fifth Floor Expansion Space Improvement Allowance (less any amounts paid to Tenant in connection with the Fifth Floor Expansion Space Leasehold Plans, as more particularly set forth in Paragraph 8(a) below) shall be applied by Landlord to each installment. The installments shall be due as follows: the first installment to be made at the beginning of construction of the Fifth Floor Expansion Space Leasehold Work, the second installment at approximately the mid-point of its construction, and the third upon substantial completion of construction of the Fifth Floor Expansion Space Leasehold Work. Landlord shall notify Tenant in writing as each installment is credited and notify Tenant of any excess amounts due and owing, and Tenant shall, within fifteen (15) days after receipt of said notice, pay to Landlord the applicable portion of Fifth Floor Expansion Space Tenant's Expenses. All amounts payable by Tenant pursuant to this Exhibit shall be considered additional rent and subject to the provisions of the section of the Lease entitled "LATE CHARGES." Following the Fifth Floor Expansion Space Commencement Date,

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Landlord and Tenant shall promptly complete a true up of the Fifth Floor Expansion Space Tenant's Expenses and thereafter Landlord shall pay to Tenant, or Tenant shall pay to Landlord, any amount thereby owing.

8. Fifth Floor Expansion Space Improvements Allowance.

(a) Landlord hereby agrees to grant Tenant an allowance (the **"Fifth Floor Expansion Space Improvements Allowance")** in an amount equal to the product of (a) Twenty-Five Dollars ($25.00), multiplied by (b) the number of rentable square feet in the Fifth Floor Expansion Space, to be applied toward the Fifth Floor Expansion Space Leasehold Cost. Tenant may begin drawing funds from the Fifth Floor Expansion Space Improvements Allowance following execution and delivery of the Second Amendment to pay architectural, engineering, construction management and project management costs theretofore or thereafter incurred by Tenant with respect to the Fifth Floor Expansion Space Leasehold Plans. Tenant shall furnish a written requisition for any portion of the Fifth Floor Expansion Space Improvements Allowance that is to be applied toward such expenses, which requisition shall be accompanied by appropriate invoices from the Fifth Floor Expansion Space Leasehold Architect, the Fifth Floor Expansion Space Leasehold Engineers, the Fifth Floor Expansion Space Project Manager, as applicable, along with any release of liens reasonably required by Landlord. Provided such requisition and invoices are received by Landlord no later than the twenty-fifth (25th) day of a calendar month, Landlord shall pay the amount of such requisition (up to the amount of the Fifth Floor Expansion Space Improvements Allowance) by the twentieth (20th) day of the immediately-succeeding calendar month.

(b) Any portion of the Fifth Floor Expansion Space Improvements Allowance, up to Two and 50/100 Dollars ($2.50) per square foot, that is not applied against the Fifth Floor Expansion Space Leasehold Cost may be applied by Tenant toward the cost of voice and data cabling to be installed in the Fifth Floor Expansion Space. Tenant shall furnish a written requisition for any portion of the Fifth Floor Expansion Space Improvements Allowance that is to be applied toward such expenses, which requisition shall be accompanied by appropriate invoices and release of liens from Tenant's suppliers or consultants. Provided such requisition and invoices are received by Landlord no later than the twenty-fifth (25th) day of a calendar month, Landlord shall pay

the amount of such requisition (up to the amount of the Fifth Floor Expansion Space Improvements Allowance) by the twentieth (20th) day of the immediately-succeeding calendar month.

(c) Any portion of the Fifth Floor Expansion Space Improvements Allowance that remains unapplied after application as set forth in Paragraphs 8(a) and (b) above shall be waived and forfeited.

9. Tenant's Change Orders. If, after preparation and review of the Fifth Floor Expansion Space Leasehold Plans, Tenant requests any change or addition to the work and materials to be provided pursuant to the Fifth Floor Expansion Space Leasehold Plans, then such change order shall require Landlord's approval only if it has an impact on the base building construction, exterior appearance, base-building systems, or structural integrity of the Building, in which event Landlord's decision shall be controlling, provided that Landlord shall in good faith endeavor to resolve such dispute in a manner reasonably satisfactory to Tenant. Tenant

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shall be responsible for any delay in completion of the Fifth Floor Expansion Space Leasehold Work resulting from any change order requested by Tenant. In the event a change order requested by Tenant with respect to the Fifth Floor Expansion Space Leasehold Plans causes the Fifth Floor Expansion Space Leasehold Cost to exceed the amount of the Fifth Floor Expansion Space Improvements Allowance, then all additional expenses attributable to any such change or addition requested by Tenant and approved by Landlord, shall be payable by Tenant, within ten (10) days after the Fifth Floor Expansion Space Project Manager's submission to Tenant of a statement of the additional expenses actually incurred and attributable to such change order, as additional rent. Landlord may cause Tenant to make reasonable substitutions (i.e., by substituting materials of comparable quality, cost and performance specifications) for materials specified in the Fifth Floor Expansion Space Leasehold Plans if any materials specified in the Fifth Floor Expansion Space Leasehold Plans cannot reasonably be obtained at the job site in time to be incorporated into the Fifth Floor Expansion Space Leasehold Work in the normal progression and diligent prosecution of the Fifth Floor Expansion Space Leasehold Work. Landlord and Tenant shall endeavor in good faith to identify all Long Lead Items prior to construction. No material substitutions shall be made without Tenant's prior approval; however, if Tenant withholds its approval, any delay in obtaining and incorporating the originally specified materials (and any consequent delay in completing other work that appropriately must follow incorporation of such delayed materials into the Fifth Floor Expansion Space Leasehold Work) shall be deemed a Tenant Delay.

10. Substantial Completion.

(a) Except as provided in Paragraph 10(b) below, the Fifth Floor Expansion Space Leasehold Work shall be deemed to be substantially complete when the Fifth Floor Expansion Space Leasehold Work (except for punch list items and Long Lead Items (as hereinafter defined)) has been completed in substantial conformity with the Fifth Floor Expansion Space Leasehold Plans as evidenced by the Fifth Floor Expansion Space Leasehold Architect's issuance of a certificate of substantial completion (the issuance thereof not to be unreasonably withheld) and issuance by the appropriate governmental authority(ies) of a certificate of occupancy for the Fifth Floor Expansion Space (or Landlord's certification that all governmental inspections necessary for the issuance thereof have been successfully completed, and that an application therefor has been submitted).

(b) Notwithstanding the foregoing, if Landlord shall be delayed in completing the Fifth Floor Expansion Space Leasehold Work as a result of: (i) Tenant's failure to comply with any deadline specified in this Exhibit or the Construction Schedule attached hereto as Schedule II, (ii) Tenant's request for changes to the Fifth Floor Expansion Space Leasehold Plans subsequent to the date that such plans or construction documents were prepared and reviewed where such changes result in an actual delay as reasonably determined by Landlord and agreed to by the Fifth Floor Expansion Space Project Manager, (iii) Tenant's failure to pay when due any portion of the Fifth Floor Expansion Space Tenant's Expenses or any other sums payable by Tenant pursuant to this Exhibit, (iv) Tenant's request for materials, finishes or installations as part of the Fifth Floor Expansion Space Leasehold Work which constitute Long Lead Items, (v) any delay in obtaining a building permit with respect to the Fifth Floor Expansion Space Leasehold Work caused by the act or omission of Tenant, or (vi) the performance (or failure thereof) of any work by any person or firm employed or retained by

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Tenant, then for purposes of determining the Fifth Floor Expansion Space Commencement Date, the work and materials to be provided by Landlord pursuant to this Exhibit shall be deemed to have been substantially completed on the date that they would have been substantially completed if such delay or delays (each of which is referred to herein as a "**Tenant Delay**") had not occurred. Landlord agrees to use good faith reasonable efforts to counter the effect of any Tenant Delay, including but not limited to employing overtime labor, provided that Landlord shall notify Tenant in writing prior to incurring additional expenses of the estimated amount of such expenses and the amount, if any, by which Landlord anticipates such additional expenses to exceed the Fifth Floor Expansion Space Improvements Allowance; however, Landlord shall not be obligated to expend any additional amounts in such efforts (e.g., by employing overtime labor) unless Tenant agrees in advance to bear any incremental cost associated with such efforts (whether or not such efforts are ultimately successful).

(c) The term "**Long Lead Item**" shall mean any item or material element of the Fifth Floor Expansion Space Leasehold Work identified during the design or award process that, due to circumstances beyond the reasonable control of Landlord (including, without limitation, long lead times necessary for fabrication or delivery) will not be at the Fifth Floor Expansion Space in time to be completed and installed prior to the anticipated occupancy date (i.e., January 1, 2009).

1 1. Punchlist and Possession. Prior to the Fifth Floor Expansion Space Commencement Date, Landlord shall schedule a mutually agreeable time with Tenant to walk through the Fifth Floor Expansion Space and prepare a punchlist setting forth any defects or incomplete work. Tenant's taking of possession of the Fifth Floor Expansion Space shall constitute Tenant's acknowledgement that the Fifth Floor Expansion Space is in good condition and that all work and materials are satisfactory, except as to any items set forth in such punchlist and except as to latent defects discovered by Tenant within three hundred thirty (330) days following the Fifth Floor Expansion Space Commencement Date. Landlord will endeavor in good faith and use commercially reasonable efforts to correct and complete those defects and incomplete items described in such punchlist within sixty (60) days after the Fifth Floor Expansion Space Commencement Date, and will promptly correct any latent defects timely brought to Landlord's attention by Tenant.

12. As-Built Drawings. Upon completion of the Fifth Floor Expansion Space Leasehold Work, Tenant shall cause the Fifth Floor Expansion Space Leasehold Contractor to furnish a set of "as-built" drawings to the Fifth Floor Expansion Space Leasehold Architect, who shall prepare the record set of "as-built" legends, schedules and plans in Mylar-reproducible form and in CADD form, all of which shall be at Tenant's cost and expense subject to application of the Fifth Floor Expansion Space Improvements Allowance. Such "as built" drawings and CADD files shall be delivered to Landlord within sixty (60) days following the Fifth Floor Expansion Space Commencement Date.

**EXHIBIT "B-1"**
**SCHEDULE B-I**

**PARK PLACE**
**OFFICE BUILDING ONE**

BUILDING SHELL DEFINITION (2nd -5th Floors)

**Structure:** Composite metal deck with 3.5" Concrete, on steel frame, 100-lbs/sq. ft. with 80-lbs/ sq. ft. live load and 20-lbs/sq. ft. dead load capacity.

**Exterior:** Architectural finish precast concrete, face brick, exterior insulation finish system and low-e glass in fixed aluminum frame systems.

**Lobby:** Main lobby with entrance from West Street. Lobby features polished stone flooring, wood paneling with all glass doors. Main Elevator Lobby with stone at walls and stainless steel elevator doors and frames.

**Column Spacing:** Approximately thirty feet by forty five feet (30' by 45') column spacing.

**Roof:** Modified Bituminous Roofing System with insulation board.

**Slab to Slab Height:** Twelve feet four inches (12'-4")

**Finish Ceiling Height:** Nine feet (9'-0")

**Perimeter Walls:** Exterior perimeter walls or premises shall be sheetrocked, taped, spackled and ready to receive standard paint finishes under tenant improvements.

**HVAC System:** An air-conditioned shell with sheet metal trunk ductwork in place, supplied from the floor air handling system as described below or its functional equivalent. The system will be designed in accordance with the following temperature design criteria:

Building HVAC design criteria shall be:

Indoor Conditions:

Summer – 75 degrees F. db, +/- 2 degrees and 50% RH, +/- 5%

Winter - 70 degrees F. db, +/- 2 degrees and 30% RH, +/- 5%

The above indoor conditions will be maintained based on following:
Outdoor Conditions:

Summer – 95 degrees F. db / 78 degrees F. wb.



Winter – 10 degrees F. db.

Light colored blinds, fully extended with slats at a 45 degree angle, or draperies fully closed, coincident with peak sun load.

Space electrical load of 8 watts per sf, consisting of 2.5 watts/sf for lighting and 5.5 watts/sf for office equipment.

People density based on one person per 150 sf.

Outside air for ventilation will be provided at the rate of 20 cfm per person, based on the people density noted above, consistent with the current ASHRAE Guidelines for acceptable indoor air quality and current Codes.

Winter humidification will be provided utilizing package electric steam humidifiers.

Each floor will be served by two self-contained VAV air-conditioning units with waterside economizer coil for free cooling. Conditioned air will be delivered through medium pressure ductwork to VAV terminal units for zone control.

Fan powered type VAV terminal unit will be provided for every 500 sf (approximate) of perimeter zone and a shut-off type VAV terminal unit will be provided for every 1000 sf (approximate) of interior zone.

All medium pressure ductwork up to the VAV terminal units and all the VAV terminal units will be provided under base building work.

All low pressure ductworks, diffusers and flexible ductwork will be provided under tenant improvement work.

Outside air riser for tenant's conference rooms and other high occupancy space will be provided with the maximum capacity of 800 CFM per floor.

Condenser water risers serving each floor will be provided under Base Building Work and will be available to the tenants for the twenty four (24) hour operation of tenant supplied air conditioning units.

**Electrical System:** A single electrical service entrance, with vault mounted transformers outside of building, will supply three phase, four-wire, and 480/277 Volt service. Transient Voltage Surge Suppression (TVSS) will be provided at the electrical service entrance. Typical building electrical distribution system will include 480V plug-in bus risers with step down dry type, K- rated transformers for 120/208V for Tenant power distribution at each

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floor. 5.5 watts per square foot is available for Tenant receptacle and equipment use and 2.5 watts per square foot is provided for Tenant lighting. Power systems/capacities are up-gradable for Tenant flexibility.

**Life Safety:** Fire standpipe and base building fire alarm system will be installed per building code. The building's main sprinkler risers and loop system will be sized to support a sprinkler head density of 130 sq. ft. per head. Upturned sprinkler heads will be provided with the base building at a spacing of one head per 225 sq. ft. The addition and relocation of sprinkler heads and branch lines will be at Tenant's cost.

All necessary life-safety systems required by current codes in the Common Areas shall be installed, which shall include, but not be limited to, Building standard voice communication speakers, fire pull stations, fire alarm strobe lights, smoke detectors, exit lights, fire extinguishers and cabinets. Life-safety devices within Tenant's Premises will be at Tenant's cost.

**Plumbing:** Four inch (4") capped sanitary connections and two inch (2") capped vent connections are available at lavatory and water cooler waste stacks (four locations).

One inch (1") capped cold water connections are available at water closet and water cooler supply risers (four locations).

**Window Coverings:** One-inch slat venetian blinds will be installed under the base building at office spaces.

**Energy Management:** Automated, direct digital, base building energy management system.

**Elevators:** 2 traction passenger high speed elevators, with 3,500 lb. capacity and 1 traction passenger/freight high speed elevator, with 4,000 lb. capacity.

**Rest Rooms:** Women and Men's restrooms will be fully finished on each floor with base building. Restroom finishes will include granite/stone countertops, ceramic tile floors and base, and 6'0" ceramic tile wainscot on wet walls. Remaining walls will receive wall covering. Ceilings will be painted drywall.

**Access System:** Kastle, or compatible perimeter and elevator key card entry system.

**Telephone/Data Risers:** Sleeves for future vertical risers are provided on each floor of the building.

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**EXHIBIT "B-1"**
**SCHEDULE B-II**

**TENANT WORK CONSTRUCTION SCHEDULE**

**EXHIBIT "B"**

**SCHEDULE B-I1**

**TENANT WORK CONSTRUCTION SCHEDULE**
PHARMATHENE – 9,329 rsf on 5th Floor

| | Target Date | Duration (cd's) | Responsibility | |
|---|---|---|---|---|
| | | | Tenant | Landlord |
| Lease Execution | 15-Sep-08 | 0 | X | X |
| Prepare and Submit Space Plan | 29-Sep-08 | 14 | X | |
| Tenant Approval of Space Plan | 1-Oct-08 | 2 | X | |
| Prepare and Submit Construction Documents | 29-Oct-08 | 28 | | X |
| Tenant Approval of Construction Documents | 3-Nov-08 | 5 | X | |
| Building Permit Process | 15-Dec-08 | 42 | X | |
| Bidding/Pricing of Construction Documents | 1-Dec-08 | 28 | | X |
| Tenant Approval of Build-out Cost | 4-Dec-08 | 3 | X | |
| Start Construction of Tenant Sapce | 14-Dec-08 | 10 | | X |
| Space Ready for Occupancy | 15-Feb-09 | 63 | X | X |
| | | 153 | cal. Days | |
| | | 22 | weeks | |

**EXHIBIT "D-2"**

**DECLARATION AS TO DATE OF DELIVERY
AND ACCEPTANCE OF POSSESSION OF
THE FIFTH FLOOR EXPANSION SPACE**

Attached to and made a part of the Second Amendment to Office Lease (the **"Second Amendment"),** dated the _____ day of _____, 2008, entered into by and between Park Place Trust, as Landlord and PharmAthene, Inc., as Tenant.

Landlord and Tenant do hereby declare and evidence that possession of the Fifth Floor Expansion Space was accepted by Tenant on the ____ day of _____, 20__. The Second Amendment is now in full force and effect. For the purpose of this Second Amendment, the Fifth Floor Expansion Space Commencement Date is established as the ____ day of _____, 20__ As of the date of delivery and acceptance of possession of the Fifth Floor Expansion Space as herein set forth, there is no right of set off against rents claimed by Tenant against Landlord.

LANDLORD:

PARK PLACE TRUST, a Maryland Business Trust

By: JBJ/Carlyle Park Place LP, a Delaware limited partnership, as Trustee

By: JBJ Management Company, Inc., a Maryland limited liability company, its Managing General Partner

By: _____

Name: _____

Title: _____

TENANT:

PHARMATHENE, INC., a Delaware corporation

By: _____

Name: _____

Title: _____

**Exhibit 31.1**

**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, 2008;

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 14, 2008

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

**Exhibit 31.2**

**Certification of Principal Financial Officer**

**Pursuant to SEC Rule 13a-14(a)/15d-14(a)**

I, Christopher C. Camut certify that:

1. I have reviewed this Form 10-Q of PharmAthene, Inc. for the quarter ended September 30, 2008;

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 14, 2008

/s/ Christopher C. Camut

Name: **Christopher C. Camut**
Title: **Chief Financial Officer**

**Exhibit 32.1**

**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, 2008, 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 Act of 1934; and

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 14, 2008

**Exhibit 32.2**

**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, 2008, as filed with the Securities and Exchange Commission (the "Report"), I, Christopher C. Camut, 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 of 1934; and

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

/s/ Christopher C. Camut

**Christopher C. Camut**
**Chief Financial Officer**
November 14, 2008