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

FORM 10-K

(Mark One

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

For the fiscal year ended December 31, 2008

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

For the transition period from to

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on Which Registered:**
Common Stock, par value $0.0001 per share	NYSE Amex
Warrants to purchase shares of Common Stock	NYSE Amex

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.	Yes o	No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.	Yes o	No x
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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.	Yes o	No x

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. (Check one):

o	Large Accelerated Filer	o	Accelerated Filer	o	Non-Accelerated Filer	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

The aggregate market value of voting stock held by non-affiliates of the registrant was $29,247,869 based upon the closing price on the American Stock Exchange (now the NYSE Amex) on the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2008).

The number of shares of the registrant's Common Stock, par value $0.0001 per share, outstanding as of March 27, 2009 was 28,428,377.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement to be delivered to stockholders in connection with the Annual Meeting of Stockholders to be held on or about May 20, 2009.

TABLE OF CONTENTS

Table of Contents

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K 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 (the "Exchange Act"). 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 following:

- *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 our development programs, including without limitation our bid related to SparVax™ under the Department of Health and Human Services 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/verification 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 under the caption "Risk Factors" in this Report on Form 10-K and in our other reports filed with the U.S. Securities and Exchange Commission (the "SEC") from time to time hereafter. 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," the negative of these words, other variations on these words, or comparable terminology. Such statements include, but are not limited to, the following:

- *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") in April 2008.*

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.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this document. Except to the extent required by applicable laws and regulations, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this document or to reflect the occurrence of unanticipated events. 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.

All forward-looking statements included herein are expressly qualified in their entirety by the cautionary statements contained or referred to elsewhere in this Annual Report. Unless otherwise indicated, the information in this annual report is as of December 31, 2008.

PART I

Item 1. Business.

Background of PharmAthene, Inc.

PharmAthene, Inc. was incorporated under the laws of the State of Delaware as Healthcare Acquisition Corp. ("HAQ") on April 25, 2005, a blank check company 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 a Delaware corporation which at the time was known as "PharmAthene, Inc." ("Former PharmAthene"), pursuant to an Agreement and Plan of Merger, dated as of January 19, 2007 (the "Merger Agreement"), 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." Effective February 27, 2009, PharmAthene US Corporation was merged with and into PharmAthene, Inc., with PharmAthene, Inc. being the surviving corporation. Our executive offices are located at One Park Place, Suite 450, Annapolis, Maryland 21401 and our telephone number is 410-269-2600. Our stock trades on the NYSE Amex (formerly the NYSE Alternext US or the American Stock Exchange) under the symbol "PIP."

Unless the context otherwise requires, all references in this report to the "Company", "PharmAthene", "we", "us" or "our" refers to the business of the combined company after the Merger and to the business of Former PharmAthene prior to the Merger, and "HAQ" refers to the business of Healthcare Acquisition Corp. and its subsidiaries, as a combined entity, prior to the Merger. Unless the context otherwise requires, the information contained in this report gives effect to the consummation of the Merger of August 3, 2007 and the change of our name from "Healthcare Acquisition Corp." to "PharmAthene, Inc."

Overview

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

- SparVax™ - a second generation recombinant Protective Antigen ("rPA") anthrax vaccine,
- Valortim® - a fully human monoclonal antibody 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.

Products

We acquired our lead product candidate, SparVax™, as part of our purchase of the biodefense vaccines business of Avecia in April 2008. 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 *Bacillus anthracis* (the anthrax bacterium). Phase I and Phase II clinical trials involving over 700 healthy adult human subjects have been completed 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 and rabbits against a lethal aerosol challenge of Ames strain anthrax spores.

On February 29, 2008, the Department of Health and Human Services ("DHHS") issued a formal Request for Proposal (RFP-BARDA-08-15) for an "Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile", which includes a requisition for 25 million doses of an rPA anthrax vaccine. We submitted a response to this solicitation on July 31, 2008.

Valortim®, our second most advanced product candidate, is a fully human monoclonal (an identical population of highly specific antibodies produced from a single clone) antibody designed to protect against and treat human inhalational anthrax, the most lethal form of infection caused by the *Bacillus anthracis* bacterium. We are 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 inhalational anthrax infection. We 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 us 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 National Institute of Allergy and Infectious Diseases ("NIAID") and the Biomedical Advanced Research and Development Authority ("BARDA") awarded to us a $13.9 million contract for the advanced development of Valortim® as an anti-toxin therapeutic to treat inhalation anthrax infection. We have recognized revenue of $1.4 million through December 31, 2008 under this contract, which we expect will continue to be funded in installments through fiscal year 2011. BARDA has indicated that it plans to provide an additional $2 million to us under the existing NIAID contract, bringing the total amount to $15.9 million. In addition, in March 2009, BARDA issued a Broad Agency Announcement ("BAA") for the Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures, which included an advanced development solicitation for proposals covering anthrax anti-toxins. In response, we submitted an initial proposal providing for further development of Valortim® and are awaiting a response.

Protexia®, our nerve agent countermeasure, is a recombinant form of human butyrylcholinesterase, a naturally occurring enzyme ("BChE"). 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 ("IND") with the FDA in the third quarter of 2008 and began a Phase I clinical trial in humans in October 2008. We expect this trial to be completed during the second half of 2009.

Table of Contents

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 prophylactic treatment of chemical nerve agent poisoning, which we submitted in November 2005. In September 2006, we were 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. We believe the DoD will make a decision in this regard by the end of the fourth quarter of 2009, following completion of the on-going Phase I human clinical trial for Protexia® and its review of the data from that trial and our manufacturing scale-up efforts. 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). We have recognized revenue of $35.5 million through December 31, 2008 under this contract.

RypVax™, which we acquired as part of the Avecia Acquisition, 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 Phase I clinical trials involving a total of 139 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 protect against a lethal aerosol challenge.

In 2004, Avecia was awarded a multi-year contract, under which it could receive up to approximately $50.7 million from 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 December 31, 2008, PharmAthene recognized revenue of $2.7 million 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, which we acquired as part of the Avecia Acquisition, 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 SNS. In particular, we 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 ("AVA")), which was initially licensed by the FDA in 1970, has an approved dosing regimen of five doses over a period of 18 months and is required to be stored at between 2º and 8º C.

Two grants from the U.S. National Institutes of Health ("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 initial development of our third generation anthrax vaccine candidate. On September 25, 2008, we were awarded a contract by 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, we could receive up to approximately $83.9 million over a nine year period (including the base period and the $13.2 million disclosed above) under this contract, which includes a cost reimbursement component and a fixed fee component payable upon achievement of

Table of Contents

certain milestone events. Of this amount, we have recognized revenue of $0.1 million through December 31, 2008.

Biodefense Market

The worldwide biodefense market can generally be divided into three segments: U.S. civilian, U.S. military, and non-U.S. markets. U.S. government funding represents the vast majority of the worldwide market. According to the UPMC Center for Biosecurity, U.S. government biodefense military and civilian spending peaked in fiscal year 2005 at over $8 billion and has averaged around $5.4 billion in fiscal years 2007 and 2008. Funding in fiscal year 2009 is expected to increase again to nearly $8 billion. The U.S. civilian market includes funds to protect the U.S. population from biowarfare agents and is largely funded by the Project BioShield Act of 2004. Project BioShield is the U.S. government's largest biodefense initiative. The DoD is responsible for the development and procurement of countermeasures for the military segment which focuses on providing biowarfare protection for military personnel and civilians who are on active duty. Non-U.S. markets address protection against biowarfare agents for both civilians and military personnel in foreign countries. It is expected that foreign countries will want to procure biodefense products as they are developed and validated by procurement by the U.S. government.

Primary Customers

For the next several years, we believe our main customers will be national governments, primarily the U.S. government. Currently, our primary customers are the DoD, NIAID, BARDA and the NIH. For the years ended December 31, 2008 and 2007, contract revenues from the DoD and NIAID related to Protexia® and Valortim® comprised 64% and 100%, of total revenues, respectively. Contract revenues related to SparVax™ and RypVax™, acquired during fiscal year 2008, represented 36% of total revenues for the year ended December 31, 2008.

Currently, the U.S. government may, at its discretion, purchase critical biodefense products for the SNS prior to FDA approval based on Emergency Use Authorization ("EUA") 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. Due to the current economic downturn, the accompanying fall in tax revenues and the U.S. government's efforts to stabilize the economy, the U.S. government may be forced or choose to reduce or delay spending in the biodefense field, which could decrease the likelihood of future government

contract awards, the likelihood that the government will exercise its right to extend any of its existing contracts and/or the likelihood that the government would procure products from us. 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 Dependence on U.S. Government Contracts — 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.

Table of Contents

Avecia Acquisition

On March 20, 2008, we entered into a Sale and Purchase Agreement (the "Purchase Agreement") with Avecia for the acquisition of all of the assets related to Avecia's biodefense vaccines business, which included a second generation rPA anthrax vaccine (SparVax™), a recombinant dual antigen plague vaccine (RypVax™), and a third generation rPA anthrax vaccine program. The Avecia Acquisition closed on April 2, 2008.

At closing, PharmAthene paid to Avecia initial consideration of $10 million in cash and provided a letter of credit in the amount of $7 million as security for the deferred consideration in that same amount, 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) October 2, 2009. Additional amounts may become payable to Avecia assuming certain milestones are achieved as follows:

(i) $3 million upon the entry by PharmAthene into a multi-year funded contract or series of contracts with the U.S. or UK governments (or subcontractors thereof) for the further development of Avecia's pneumonic and bubonic plague vaccine (RypVax™) with a total committed aggregate value in excess of $30 million; and

(ii) $10 million upon the entry by PharmAthene into a multi-year funded contract with the U.S. government (or subcontractors thereof) for the further development

Table of Contents

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

(iii) $5 million upon the entry by PharmAthene into a multi-year funded development contract to be issued by BARDA (part of DHHS) under solicitation number RFP-BARDA-08-15 for the further development of Avecia's anthrax vaccine (SparVax™); and

(iv) $5 million upon the entry by PharmAthene into a contract or contracts for the supply of SparVax™ into the SNS; and

(v) 2.5% of PharmAthene net sales of SparVax™ to the U.S. government within the period of ten years from the closing of the Avecia Acquisition after the first 25 million doses; and

(vi) 1% of PharmAthene net sales of third generation anthrax vaccine to the U.S. government within the period of ten years from the closing of the Avecia Acquisition.

In addition to the potential milestone payments described above, for a period of 10 years following our first purchase of Drug Substance, if we purchase bulk drug substance for the anthrax and plague vaccines ("Drug Substance") from a supplier other than Avecia, we may be obligated to make the following payments to Avecia in certain circumstances (the "Manufacturing IP Consideration"):

(i) where (A) a national government or agency after award of a contract specifies that production of Drug Substance must be sourced from a supplier other than Avecia or (B) Avecia is unable to fulfill our demand for Drug Substance, 3.75% of the amounts that would have been payable to Avecia had Avecia produced the Drug Substance; and

(ii) where we elect to source Drug Substance from any supplier other than Avecia in all other circumstances, 7.5% of the amounts that would have been payable to Avecia had Avecia produced the Drug Substance.

In no event, however, are we obligated to pay Manufacturing IP Consideration if we terminate our supply arrangements with Avecia as a result of Avecia's unremedied material breach of its obligations to us under our supply agreement with them.

Table of Contents

March 2009 Public Offering

On March 27, 2009, we closed on the public sale of an aggregate of 2,116,055 newly issued shares of our common stock at $2.60 per share and warrants to purchase an aggregate of 705,354 shares of our common stock at an exercise price of $3.00 per share, resulting in aggregate gross proceeds of $5,501,743. The warrants will be exercisable beginning on September 27, 2009 and will expire on September 27, 2014, five years from the date they become exercisable.

Equity Investment by Panacea Biotec

In October 2008 a subsidiary of Panacea Biotec Ltd. ("Panacea Biotec") made an equity investment in us, providing gross proceeds of approximately $13.1 million. Under the financing, Panacea Biotec subsidiary Kelisia Holdings Ltd. ("Kelisia") purchased 3,733,334 shares of our common stock at $3.50 per share. In addition, Panacea Biotec's subsidiary received 12-month warrants to purchase up to 2,745,098 additional shares of our common stock at an exercise price of $5.10 per share, subject to a stock ownership cap, following any warrant exercise, of 19.99% of our issued and outstanding common stock. For three years following the closing on this sale of securities, Panacea Biotec has agreed not to purchase additional shares of our stock without our prior written consent. Panacea Biotec's subsidiary has certain limited rights to participate in future private financings by us to maintain its then current ownership level.

Business Concept and Strategy

Our goal is to become the premier company worldwide specializing in the discovery, development and commercialization of prophylactic and therapeutic drugs for defense against

Table of Contents

bioterrorism and, eventually, to leverage our biodefense capabilities for non-biodefense products in broader commercial markets. Our strategy to achieve this objective includes the following elements:

- **Maximize the value of our current product candidate portfolio as well as products that we may acquire in the future**. Our products target areas that the U.S. government has identified as having critical biodefense needs and preclinical data supports the potential of these products to meet those needs. We intend to develop these products aggressively while fulfilling the requirements of the U.S. government's contracting processes. Development and contracting requirements of biodefense products are unique, and we continue to build capabilities to meet the requirements while developing our products.

- **Continue to build and leverage core capabilities in biodefense**. We have developed and will continue to develop unique biodefense product development and contracting capabilities. Development of the capabilities has required a substantial investment, which we anticipate will be leveraged by acquiring additional biodefense product candidates through licensing and mergers and acquisitions. We believe that product opportunities will come primarily from companies focused on commercial markets that wish to see their products or technologies exploited in biodefense.

- **Where applicable, expand use of our products from biodefense into commercial markets**. Some of our product candidates may be useful for preventing or treating diseases or conditions outside of biodefense. For example, Protexia® may be useful to treat overdoses of cocaine or heroin. Additionally, after products are FDA approved, it may be possible to market biodefense products through commercial channels. We will evaluate and develop these opportunities as warranted.

Biodefense Industry

Market Overview

The worldwide biodefense market can generally be divided into three segments: U.S. civilian, U.S. military, and non-U.S. markets. U.S. government funding represents the vast majority of the worldwide market. According to the UPMC Center for Biosecurity, U.S. government biodefense military and civilian spending peaked in fiscal year 2005 at over $8 billion and has averaged around $5.4 billion in fiscal years 2007 and 2008. Funding in fiscal year 2009 is expected to increase again to nearly $8 billion.

- ***U.S. Civilian***: The U.S. civilian market includes funds to protect the U.S. population from biowarfare agents and is largely funded by the Project BioShield Act of 2004. Project BioShield, the U.S. government's largest biodefense initiative, governs and funds with $5.6 billion the procurement of biodefense countermeasures for the SNS for the period from July 2004 through 2013. Of the $5.6 billion, $3.4 billion was made available through fiscal year 2008, and the remaining $2.2 billion becomes available in fiscal year 2009. Of the $3.4 billion, $1.9 billion was awarded in procurement contracts through 2008. A total of $3.7 billion remains in the Project BioShield Special Reserve Funds. This amount includes $1.5 billion which was unspent from the initial $3.4 billion traunch and the $2.2 billion that became available in fiscal year 2009.

- ***Military***: The DoD is responsible for the development and procurement of countermeasures for the military segment which focuses on providing biowarfare protection for military personnel and civilians who are on active duty. The President's request for funding in fiscal year 2009 was $1.5 billion compared to annual spending of $1.02 billion for 2008, and $1.2 billion to $1.8 billion from 2005 to 2007. We anticipate that annual funding for the programs through 2013 will continue in a comparable range.

Table of Contents

- ***Non-U.S. Markets***: Non-U.S. markets address protection against biowarfare agents for both civilians and military personnel in foreign countries. We anticipate that foreign countries will want to procure biodefense products as they are developed and validated by procurement by the U.S. government.

Project BioShield

Project BioShield, established under the Project BioShield Act of 2004 and the U.S. government's largest biodefense initiative, is focused on acquiring products with low technology risk that will be available for purchase in the near term. The U.S. government has identified the following threats as priorities: anthrax, smallpox, botulinum toxin, radiation, and nerve agent exposure. To evaluate and select the best products for these threats, the DHHS typically issues Requests for Information ("RFI") followed by Requests for Proposals ("RFP"). RFPs detail product and procurement requirements including treatment types, numbers of doses and delivery timeframes. To qualify for Project BioShield funding, products must demonstrate product efficacy in an animal model and initial product safety in Phase I clinical trials, and companies must show that they can provide sufficient manufacturing capability. As of December 31, 2008, 11 awards have been made under Project BioShield, including those for anthrax, radiation and botulinum toxin.

In addition to the threats identified as priorities under Project BioShield, the DoD requires recombinant bioscavengers for prophylaxis against nerve agent exposure faced by combat troops. We are pursuing the development of products for prophylaxis against and treatment of anthrax, nerve agent exposure, and plague.

Anthrax

The three general modes of infection by *Bacillus anthracis* ("*B. anthracis*"), the bacterium which causes anthrax infection, are by inhalation, ingestion or skin contact with anthrax spores. Inhalation is the form of infection most likely to be lethal. Inhalation anthrax occurs when anthrax spores become airborne and enter a person's body through the lungs. Persons suffering from inhalation anthrax will experience a series of symptoms consisting of fever, muscle aches, fatigue and cough, which last an average of four days. Following this period, there is rapid onset of severe respiratory distress, low blood oxygen and low blood pressure, which generally culminates in death. Inhalation anthrax is usually fatal if left untreated, and has approximately a 50% mortality rate in patients treated aggressively with antibiotics and supportive care. Persons infected by *B. anthracis* that is ingested will suffer from gastrointestinal anthrax; those whose skin comes into contact with anthrax will suffer from cutaneous anthrax. Gastrointestinal anthrax often presents with serious gastrointestinal difficulty, vomiting of blood, severe diarrhea, acute inflammation of the intestinal tract and loss of appetite. Gastrointestinal anthrax has a 25% to 60% mortality rate if left untreated. Cutaneous anthrax generally causes skin infections within a week or two after exposure. Cutaneous anthrax is the least fatal. Without treatment, up to 20% of all skin infection cases are fatal. Treated cutaneous anthrax is rarely fatal.

B. anthracis is a spore forming bacterium that has potential use as a bioterror weapon, especially when delivered in an aerosolized form. Following germination of the spores, the bacteria replicate and produce three toxins. The first of the toxins, Anthrax Protective Antigen ("PA"), polymerizes and attaches to the outside of healthy cells in the infected person, and then facilitates the entry of the two additional destructive toxins, referred to as Lethal Factor and Edema Factor, into the cells.

The DoD estimates that up to ten countries may possess anthrax weapons and an undetermined number of individuals and terrorist groups could have access to anthrax. Anthrax is an effective

Table of Contents

bioterrorism agent because the spores are stable, can be milled to a fine powder and may be dispersed widely with readily available instruments and machinery. The World Health Organization estimates that 50 kilograms of *B. anthracis* spores released upwind of a city of 500,000 people could result in up to 95,000 fatalities, with an additional 125,000 persons being incapacitated.

As the congressionally mandated report of the Commission on the Prevention of WMD Proliferation and Terrorism, entitled "World at Risk", noted when issued in December 2008, unless the world acts quickly, it is likely that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013, with biological weapons identified as the most likely type of weapon to be used during that time. Among the recommendations in the report is the need to "enhance the nation's capabilities for rapid response to prevent biological attacks from inflicting mass casualties".

We believe that currently available treatment for inhalation anthrax is limited and suboptimal. Following exposure, but prior to the onset of symptoms, antibiotics like ciprofloxacin, doxycycline or penicillin can be used as post-exposure prophylaxis with the goal of preventing progression of the disease. To be fully effective when used in this way, the recommended antibiotic treatment must be continued for 60 days. We believe that both compliance and side effects are problematic for anyone asked to take antibiotics for such an extended period of time. Products like our two rPA-based anthrax vaccine candidates, which are designed to be effective in two or three doses, and our monoclonal human antibody treatment, Valortim®, with a prolonged half-life, might allow for less frequent dosing to achieve adequate post-exposure prophylaxis.

Chemical Weapons and Nerve Agents

Chemical weapons use the toxic properties of chemical substances to produce physiological effects on an enemy. Classic chemical weapons, such as chlorine and phosgene, were employed during World War I and consisted primarily of commercial chemicals used as choking and blood agents, to cause respiratory damage and asphyxiation. Nerve agents, one of the most lethal forms of chemical weapons, were developed in the 1930s in the years leading up to World War II.

Nerve agents function by binding to acetylcholinesterase, an enzyme that normally causes termination of the activity of the neurotransmitter acetylcholine. Nerve agents block the activity of acetylcholinesterase, allowing the activity of acetylcholine to continue unchecked. As a result, nerve impulses are continually transmitted, causing muscle contractions that do not stop. This effect is referred to as a "cholinergic crisis" and results in a loss of muscle control, respiratory failure, paralysis and convulsions. Nerve agent exposure that does not cause death after a short period can lead to permanent brain damage.

Nerve agents, which are liquids at room temperature, are generally lethal far more quickly and in far lower quantities than classic chemical weapons, and are effective both when inhaled and when absorbed through the skin. These agents can be delivered through explosive devices, spray tanks or most liquid or gas dispersion devices and machinery.

There currently is only one FDA approved pre-treatment for nerve agents, pyridostigmine bromide ("PB"). PB is only approved for the pre-treatment of exposure to the nerve agent soman. It confers no protection on its own but enhances the protection conferred by post-exposure treatment. The standard of care for post-exposure treatment involves repeated doses of a cocktail of drugs including atropine, reactivators including the oxime 2-PAM and anti-convulsants. However, this type of care acts primarily on the symptoms of nerve agents, not their underlying cause. We believe available pre-and post-treatment options are inadequate and that there is a need for more efficacious countermeasures,

Table of Contents

especially as evidence mounts that modified, more toxic forms of organophospates nerve agents may be used in future attacks.

Plague

The Centers for Disease Control and Prevention classify *Yersinia pestis* ("*Y. pestis*") as a Category A bioterrorism agent, the highest threat category ranked by the CDC. Plague is a disease caused by the bacterium *Y. pestis* found endemically in rodents and flea populations in certain parts of the world. The World Health Organization reports an estimated 1,000 to 3,000 human cases of plague worldwide every year. More than a dozen cases occur annually in the western United States, most often in rural and semi-rural areas. There are two primary forms of the disease, bubonic and pneumonic. The majority of cases are of the bubonic form, which is transmitted through the bite of an infected flea or upon exposure to infected material through a break in the skin. Symptoms include swollen, tender lymph glands called buboes. If bubonic plague is not treated, the bacteria can spread through the bloodstream and infect the lungs, causing a secondary case of pneumonic plague. Pneumonic plague affects the lungs and can be transmitted from person to person when an individual breathes in *Y. pestis* particles in through the air. Naturally occurring pneumonic plague is uncommon, although small outbreaks do occur.

Y. pestis used in an aerosol attack could cause an outbreak of the pneumonic form of plague shortly after infection. Once pneumonic disease is established in a human host, the bacteria can be readily transmitted between individuals. The extended time between exposure to the bacteria and diagnosis increases the opportunity to transmit the bacteria over a vast area, making containment a challenge. Creating a bioweapon carrying *Y. pestis* is highly feasible as the bacterium occurs readily in nature and could easily be isolated and grown in quantity in a laboratory.

To prevent a high risk of death, particularly for pneumonic plague, antibiotics must be given within 24 hours of the first symptoms. However, given the rapid onset of the disease and the difficulty diagnosing pneumonic plague, it can rapidly prove fatal in untreated individuals or in a situation where treatment is delayed. Currently, no vaccine is commercially available.

PharmAthene's Product Candidates

SparVax™: Recombinant Protective Antigen (PA)-based Anthrax Vaccine

SparVax™ is a second generation, rPA anthrax vaccine designed to protect against inhalation anthrax, the most lethal form of B. anthracis infection in humans. The vaccine has been shown to induce anti-PA antibodies in healthy human volunteers and in animal models of inhalation anthrax. These antibodies are believed to function by targeting Protective Antigen, a protein component necessary to initiate the toxic cascade and cell entry of toxins produced by the bacterium. SparVax™ has been shown to be protective in rabbit and non-human primate models when animals are vaccinated and then exposed to lethal inhalation doses of anthrax spores. One Phase I and two Phase II clinical trials have been completed in over 700 individuals. Data from these trials demonstrated that SparVax™ is well tolerated and immunogenic.

SparVax™ is being developed for two indications: post-exposure prophylaxis ("PEP") in conjunction with antibiotics and general use prophylaxis ("GUP"). In a PEP setting, the vaccine would be used following a suspected exposure to augment the natural immune response and provide protection once antibiotics are discontinued. In the GUP setting, the vaccine is administered in advance of any

Table of Contents

exposure and is intended to induce an immune response that will be protective should there be an exposure.

Pre-clinical Studies

Prior to filing an IND with the FDA, SparVax™ underwent safety testing in rodents and non-human primates. Single dose acute toxicity testing was conducted in mice and rats, while repeat dose toxicity studies were conducted in mice, rats, rabbits and Cynomolgus monkeys. Sparvax™ was well tolerated with no deaths and no behavioral or clinical signs observed in any species. All of the toxicology studies were compliant with Good Laboratory Practices ("GLP") and the data were used to support the IND and allow for the initiation of clinical trials of SparVax™. In the future, as a part of its development program, we will conduct additional animal studies to demonstrate the safety of the vaccine for use in women of childbearing potential (reproductive toxicology).

Non-clinical Studies

SparVax™ is being developed utilizing the Animal Rule (21 CFR 609.1(a)(1-4)) which allows for efficacy testing in appropriate animal models in lieu of clinical efficacy trials. To date, animal model development and efficacy studies in both rabbits and non-human primates for both GUP and PEP indications using SparVax™ have been sponsored by NIAID and conducted by a commercial research organization ("CRO") for us through contract with NIAID. Future studies will be sponsored by us and conducted by this CRO. Data from the studies conducted to date have shown that SparVax™ is immunogenic in both rabbits and non-human primates; protection has been demonstrated in vaccinated animals subjected to aerosol challenge with Ames strain spores.

Clinical Studies

The Phase I trial was a dose escalation study designed to evaluate a range of dose levels administered in two different schedules. Doses ranged from 5 µg to 100 µg given intramuscularly on either a 0, 21 day regimen or a 0, 28 day regimen. A comparator arm using the currently licensed anthrax vaccine was also included. The results demonstrated that the vaccine was safe, well-tolerated and immunogenic. There were no vaccine related serious adverse events ("SAEs") and no vaccine-related changes in blood chemistries, vital signs, or electrocardiograms ("ECGs"). A minority of subjects reported injection site irritation. The incidence, severity, and causality of adverse events were similar across all dose groups. Both regimens produced similar levels of immunogenic response with the peak antibody titer for the 0, 28 day regimen occurring earlier after vaccination as compared to that produced by the 0, 21 day regimen.

The Phase II program was designed to include larger subject numbers and a three-dose schedule at the two highest dose levels tested in Phase I (50 and 100 µg rPA). Two Phase II trials were conducted, both of which used different 3-dose priming schedules to study the effect of different dose levels and different dosing schedules.

The Phase IIa trial compared two regimens (0, 7, 14 day vs. 0, 14, 28 day dosing) at two dose levels (50 and 100 µg). This study also incorporated an antigenic challenge dose (i.e., a dose to show that the initial series of doses adequately "primed" the immune system to respond to natural infection by producing antibody due to immunologic memory) at either day 182 or day 365; the dose was the same as the dose the subject received in the priming series. SparVax™ was well tolerated with no vaccine-related SAEs or changes in blood chemistries, vital signs, or ECGs reported. Further, SparVax™ was immunogenic in this study with the 0, 14, 28 day schedule producing far better antibody titers as

Table of Contents

compared to the 0, 7, 14 day schedule, regardless of the dose administered. The results from the antigenic challenge dose demonstrate that immunologic memory was induced by the priming series.

The Phase IIb trial compared a longer dosing regimen (0, 28, 56 day dosing) at two different dose levels (50 and 100 µg) with a smaller control group who received the currently licensed anthrax vaccine, AVA. This study also incorporated an antigenic challenge dose at either day 182 or day 365 in the SparVax™ groups; the dose was the same as the dose the subject received in the priming series. Here, too, SparVax™ was well-tolerated with no vaccine-related SAEs or changes in blood chemistries, vital signs or ECGs reported. At least one vaccine-related adverse event was reported in approximately 40% of the SparVax™ subjects at each dose and approximately 80% of the subjects in the AVA group. These were predominantly local injection site reactions, thus the local tolerability of SparVax™ was somewhat better than AVA in this study. The immunogenicity data showed that a good level of response was achieved with both vaccines and with both doses of SparVax™. The antibody titers were comparable between the two SparVax™ dose levels and the AVA arm. The results from the antigenic challenge dose administered to the SparVax™ groups demonstrated that immunologic memory was induced by the priming series.

Future studies will seek to confirm the dose and schedule of SparVax™ that induces antibody levels in humans which are comparable to those shown to be protective in the animal models, demonstrate the acceptability of using SparVax™ in conjunction with antibiotics, and confirm the safety of SparVax™ in a sufficient number of human subjects (as agreed to with FDA).

Funding

To date, funding for the development of SparVax™ has occurred under two contracts from the NIH originally made in 2002 and 2003 which provided for aggregate funding of approximately $118.0 million. Through December 31, 2008, PharmAthene recognized revenue of $9.2 million under these contracts.

On February 29, 2008, the Department of Health and Human Services ("DHHS") issued a formal Request for Proposal (RFP-BARDA-08-15) for an "Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile", which includes a requisition for 25 million doses of an rPA anthrax vaccine. We submitted a response to this solicitation on July 31, 2008.

Valortim®: Anthrax Monoclonal Antibody

Valortim® is a fully human monoclonal antibody designed to protect against and treat human inhalational anthrax, the most lethal form of infection caused by the *Bacillus anthracis* bacterium.

Valortim® functions by targeting PA, a protein component of the bacterium that attaches to and facilitates the entry of the destructive toxins Lethal Factor (LF) and Edema Factor (EF) into healthy cells in the infected person. Valortim® is designed to bind to PA and protect the cells from damage by the anthrax toxins. In preclinical

studies, Valortim® protected animals against infection, and when administered after exposure, facilitated recovery and survival in animals exposed to lethal inhalation doses of anthrax spores.

Anthrax spore challenge studies in animals have demonstrated protection by Valortim® both when given early following challenge (post-exposure prophylaxis) as well as when given up to 48 hours after challenge (therapeutic intervention). Valortim® binds to a novel site of PA, permitting protection after toxins have already attached to the cell. We believe potency and the unique mechanism of action of

Table of Contents

Valortim® differentiate it from competing products. In the initial Phase I clinical trial in healthy human volunteers, Valortim® was well-tolerated with no drug-related serious adverse events reported.

Medarex Collaboration and Development Timeline

We are developing Valortim® in collaboration with Medarex, Inc. (a bipharmaceutical company that specializes in developing fully human antibody-based therapeutic products) pursuant to a collaboration agreement entered into in November 2004. Under the terms of the collaboration agreement, we made an initial $2.0 million payment to Medarex to fund planned development activities in 2004, and we are responsible for funding all research and development and commercialization activities that exceed current and future government funding. The collaboration agreement provides that Medarex and PharmAthene will share operating profits according to a formula that establishes our share of the profits at between 20% and 60%, generally as follows: (i) upon execution of the collaboration agreement and the $2.0 million initial payment, our profit share was 20%; (ii) to maintain our 20% profit share we are required to contribute funding in an amount equivalent to the funding provided by the U.S. government to Medarex via grants awarded to fund Valortim® development work (approximately $7.2 million); (iii) our share of operating profits will increase to 50% if a contract for the procurement of Valortim® is entered into with the U.S. government and we have satisfied our obligation to fund the additional $7.2 million; and (iv) our share of the operating profits can increase by 10% for every $5 million of funding we provide over and above the initial payment of $2.0 million and the amount that we provide as funding in excess of the $7.2 million in matching funds provided to Medarex. Our aggregate share of the operating profits is capped at 50% if the condition under clause (iii) is not satisfied and 60% if it is satisfied. Should the parties enter into a contract for the procurement of Valortim® with the U.S. government prior to our satisfying our obligation under clause (ii) above, we are required to make a milestone payment to Medarex in an amount up to $1.5 million in order to achieve a 50% profit share in the program. Prior to distribution of operating profits, each party is entitled to reimbursement of research and development expenses incurred that were not otherwise covered by government funding.

Additional animal model development and testing of Valortim® for therapeutic efficacy in African green monkeys is being carried out under a Collaborative Research and Development Agreement with the U.S. Army Medical Research Institute of Infectious Diseases. In October 2008, we announced results from a pilot study, funded by NIH, designed to attempt to refine a rabbit model as a predictive therapeutic model for anthrax inhalation disease and which showed that Valortim® enhanced survival as compared to a control group in this animal model.

Valortim® has received Fast Track designation from the FDA, which generally indicates that the FDA will facilitate the development and expedite the regulatory review of the product depending on the FDA's resources. However, we can provide no assurance that the review will be successful. In addition, the FDA may withdraw its approval of a Fast-Track product on a number of grounds, including the sponsor's failure to conduct any required post-approval study with due diligence and failure to continue to meet criteria for designation. Valortim® has also been granted orphan drug status, a designation for drugs developed for diseases which affect less than 200,000 persons in the United States and provides for reduced fees to the FDA, market exclusivity for seven years, and other FDA-related privileges.

We conducted an end-of-Phase I meeting with the FDA in October 2007 during which the FDA agreed that the African green monkey model (described below) is acceptable as one of the two required species for licensure of Valortim® under the Animal Rule (21 CFR 314 Subpart I).

Table of Contents

Clinical and Preclinical Studies

Valortim® is being developed for two indications: (i) as a post-exposure prophylaxis; and (ii) as a post-exposure therapy.

Clinical Phase I Studies

PharmAthene and Medarex have completed dosing in a Phase I open-label, dose-escalation clinical trial to evaluate the safety, tolerability, immunogenicity, and pharmacokinetics (the study of absorption, metabolism and action of drugs) of a single dose of Valortim® administered intravenously or intramuscularly in healthy volunteers. No drug-related serious adverse effects were reported. Minor adverse events reported included pain at the intramuscular injection site, headache, muscle aches, and occasionally bruising at the site of the intravenous catheter inserted for drug dosing and blood draws. Pharmacokinetic data indicate that Valortim® has good bioavailability following intramuscular injection; additionally, both intravenous and intramuscular injection result in a half-life of 22 to 33 days. Final results from the Phase I study were presented at the Infectious Disease Society of America meeting in October 2006.

Preclinical Studies: Post-exposure Prophylaxis Indication

We have conducted studies in two animal models to evaluate the use of Valortim® as a post-exposure prophylaxis, or, in other words, to protect exposed animals from developing the signs and from dying of inhalation anthrax. Treatment in both animal models was initiated within one hour following exposure to the anthrax spores. Eighty-five percent (85%) of rabbits treated intravenously with doses of Valortim® survived following inhalation exposure to anthrax spores. One hundred percent (100%) of cynomolgus monkeys treated intramuscularly with doses of Valortim® were protected from death following exposure to inhalation anthrax spores.

Preclinical Studies: Post-exposure Therapeutic Indication

We have conducted a study in rabbits to evaluate the use of Valortim® as a therapeutic intervention for inhalation anthrax. This indication for Valortim® would be intended to treat patients who have already developed signs and/or symptoms of inhalation anthrax. In this study, 89% of the animals treated with Valortim® intravenously 24 hours following inhalation exposure to anthrax spores survived. A second group of animals were not treated with Valortim® until 48 hours following exposure; 42% of the animals treated at this timepoint survived. In another study, 100% of the Valortim®-treated rabbits at an intravenous drug dose of 20mg/kg survived compared to 83% of the rabbits at a lower dose (10mg/kg) and 8% percent in the control group. These animals were treated when they had evidence of inhalation anthrax as defined by evidence of PA in their blood or a significant increase in body temperature, whichever came first.

We have conducted an initial study in African green monkeys treated with Valortim® at the time they test positive for PA in the blood. The result of a test for PA in the blood is available within 1-2 hours which allows the animals to be treated earlier in the course of their illness than is possible using blood culture results that are not available for 24 or more hours. All control animals in the study died; 56% of treated animals survived following administration with Valortim® alone. Additional studies to

further test Valortim® in rabbits and monkeys are planned in 2009 as well as clinical studies to evaluate the safety of Valortim® in human volunteers when given in conjunction with antibiotics.

In addition to the animal efficacy and human safety studies to advance Valortim® toward licensure under the Animal Rule, work is also ongoing to further explore and define its mechanism of

Table of Contents

action. Preliminary data generated in collaboration with the University of Maryland suggests that Valortim® has the ability to enhance macrophage killing of *B. anthracis* spores within macrophages; this is in addition to its previously described toxin neutralizing activity. Further work is ongoing to fully elucidate these and other possible effects and functional properties of Valortim®.

Funding

On September 28, 2007, NIAID and 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. We have recognized revenue of $1.4 million through December 31, 2008 under this contract, which we expect will continue to be funded in installments through fiscal year 2011. BARDA has indicated that it plans to provide an additional $2 million to us under the existing NIAID contract, bringing the total amount to $15.9 million. In addition, in March 2009 BARDA issued a Broad Agency Announcement (BAA) for the Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures, which included an advanced development solicitation for proposals covering anthrax anti-toxins. The BAA states that research and technical objectives proposed by offerors may include non-clinical research and development, process development, formulation, manufacturing development, and clinical evaluation efforts. In response we submitted an initial proposal providing for further development of Valortim® and are awaiting a response. The BAA further states that offerors receiving a favorable evaluation from BARDA will be asked to prepare a full proposal for submission, and the government has stated that it intends to make final award decisions with respect to proposals for anthrax anti-toxins by September 30, 2009.

Protexia®: Pegylated Recombinant Human Butyrylcholinesterase

Protexia®, our nerve agent countermeasure, is a pegylated recombinant transgenic form of human butyrylcholinesterase (“BChE”). Preclinical studies in animal models suggest that Protexia® may be effective prophylactically and therapeutically for chemical nerve agent poisoning. BChE is a naturally occurring protein found in minute quantities in blood. In its native form, BChE functions as a natural bioscavenger, like a sponge, to absorb organophospate poisons (e.g. nerve agents) and eliminate them from the circulation before they cause neurological damage. Recombinant BChE is first purified as the unpegylated protein and then modified to arrive at its pegylated form, which confers desirable attributes such as enhanced half life for a longer period of protection and decreased potential for immunogenicity.

We, in collaboration with the Institute for Chemical Defense (ICD), a U.S. military organization where the testing of promising compounds intended for use against traditional and non-traditional nerve agents is performed, have screened recombinant BChE (“rBChE”) and pegylated rBChE (“PEG-rBChE”) for activity against a number of both traditional and non-traditional nerve agents. Protexia® will also be assessed against traditional agents as part of the work under the DoD contract described below. The DoD has also indicated that additional testing of Protexia® against non-traditional agents may be performed; the results of this testing, however, will be treated as classified national security information and will not be available to us or to the public. In addition, newer more potent forms of rBChE will be screened as second-generation rBChE molecules (having higher affinity binding characteristics and enhanced catalytic activity) become available.

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, we were awarded a multi-year contract by the DoD. The contract provides an initial $41 million for the advanced development of Protexia® through

Table of Contents

March 2009, and thereafter the U.S. government, at its sole discretion, may elect to continue development assistance with further funding of $65 million. We believe the DoD will make a decision in this regard by the end of the fourth quarter of 2009, following completion of the on-going Phase I human clinical trial for Protexia® and its review of the data from that trial and our manufacturing scale-up efforts. 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). We have recognized revenue of $35.5 million through December 31, 2008 under this contract.

Proof of Concept Studies Using rBChE or PEG-rBChE

Pre-exposure Prophylaxis Indication

Pre-treatment with PEG-rBChE provided 100% survival against multiple lethal doses of the nerve agents VX and soman in animal models and the surviving animals displayed no nerve agent side effects. In these experiments, two groups of animals were pre-treated with either PEG-rBChE or a negative control. Eighteen hours later, they were exposed to multiple lethal doses of nerve agent (VX or soman). Another group of animals was exposed to approximately 75% less nerve agent and then treated immediately with the current standard therapy, a three-drug cocktail of atropine, 2-PAM and diazepam. Animals were videotaped post-exposure and evaluated for toxic signs by observers blinded to the treatment groups. In addition, a battery of functional observations and neurological function tests (ability to balance and memory tests) were performed six hours after exposure. None of the control animals exposed to nerve agents alone survived while 100% of animals pretreated with PEG-rBChE survived with no visible nerve agent side effects and no loss of balance or memory relative to negative control animals. In contrast, the animals exposed to much lower levels of nerve agents and subsequently treated with the current standard therapy did not respond as well. Survival in these animals was mixed with 100% survival in animals exposed to VX but only 50% survival in animals exposed to soman, although all survivors had significant side effects including a pronounced loss of balance and loss of memory.

Post-Exposure Therapeutic Indication

Based on the demonstration of protection when PEG-rBChE was administered before nerve agent exposure, a series of experiments were conducted to determine whether rBChE was effective as a therapy when administered after exposure to nerve agent. The therapeutic efficacy of rBChE was first evaluated in a domestic pig model with rapid (intravenous) exposure to nerve agent (“VX”) followed by treatment with rBChE 15 minutes later. All of the control animals receiving nerve agent alone died with an average time to death of 1.5 hours while 50% of animals receiving rBChE survived with a prolonged time to death (average of 5.4 hours) in the animals that died. A second study was conducted to evaluate the therapeutic efficacy of rBChE in a different animal model and to increase the time before treatment with rBChE to one hour. Ninety percent (90%) of the animals exposed to VX on the skin and then treated with rBChE survived as compared to no survivors among the group that was not treated.

Additional work for a post-exposure indication is being conducted under grant funding from the NIH. One study has been completed to date. The study was designed to build upon the experience in the domestic pig model. Untreated animals exposed to VX applied topically to the ear showed signs of organophosphate (OP) poisoning and died within 2-3 hours. In contrast, animals receiving rBChE administered in 5 equal doses post-VX exposure survived with little or no signs of poisoning. Control animals received rBChE but no nerve agent or were exposed to topical VX and given the standard of care (2PAM and atropine). VX-exposed and treated animals showed mild signs of OP poisoning which cleared within 24 hours. The animals that were exposed to VX and treated with either rBChE or 2PAM-atropine

Table of Contents

gained weight at a comparable rate to that of the rBChE only animals. None of the surviving animals displayed any signs of cognitive impairment. The data suggest that rBChE is comparable to the current standard of care; future work will further refine this comparison.

Development Timeline and Phase I Clinical study

The potential of rBChE and PEG-rBChE as medical countermeasures have been demonstrated by their ability to protect animals from multiple lethal doses of nerve agents and binding to a broad spectrum of agents, including sarin, soman, tabun and VX. Following proof-of-concept studies and award of the DoD contract, we have developed the final product manufacturing process including selection of the PEG reagent. The final product is designated Protexia® to distinguish it from earlier versions of the recombinant protein. Two studies were completed to establish the pharmacokinetic profile of Protexia® in rats and cynomolgus monkeys that helped to guide the dosing strategy for the IND-enabling toxicology studies. The pharmacokinetic profile in rats and monkeys met expectations and compared favorably with that of human plasma-derived BChE.

We completed the manufacture of the first cGMP clinical lot of Protexia®. We filed an Investigational New Drug Application ("IND") with the FDA in the third quarter of 2008 and began a Phase I clinical trial in humans in October 2008. The primary and secondary endpoints of the study are an evaluation of the safety, tolerability, pharmacokinetics and immunogenicity of (i) escalating single doses of Protexia® given intramuscularly in healthy human volunteers and (ii) a second dose of Protexia® administered to a subset cohort approximately 2.5 months after the first dose, respectively. Approximately 32 subjects will participate in the study, comprised of healthy male and female volunteers between the ages of 18 and 55 years who are willing to give informed consent and are in general good health. Under the study protocol, either Protexia® or a saline control will be administered in escalating doses to five groups of volunteers. Safety data through 14 days post-dosing will be evaluated prior to escalation to a higher dose. Subjects in four of the groups (comprised of six subjects each) will receive a single dose of Protexia® and participate in the trial for two and a half months. One group of eight subjects will receive a second dose of Protexia® approximately 72 days following the first dose and will participate in the study for approximately five months. We expect this trial to be completed during the second half of 2009.

RypVax™: Recombinant F1 (rF1) and V (rV) antigen-based Plague Vaccine

RypVax™ is a recombinant plague vaccine comprising separate recombinant F1 (rF1) and V (rV) antigens produced in *Escherichia coli*. The purified antigens are adsorbed onto an Alhydrogel adjuvant and filled into single-use glass vials. Antibodies to rF1 have been shown to be protective against bubonic plague while antibodies to rV have been shown to enhance protection against pneumonic plague. As this vaccine combines both antigens, it is expected that it will protect against both forms of the disease. The vaccine is intended to be used to protect individuals before exposure to the *Yersinia pestis*. We believe that two or three doses, given several weeks apart, will be sufficient to induce protective immunity; this would potentially then be followed by an annual booster shot.

RypVax™ has successfully completed three Phase I human clinical trials. The vaccine has been demonstrated to be immunogenic, safe and well-tolerated. In preclinical animal models of vaccination with RypVax™ has induced antibodies which provide protection against a lethal aerosol challenge. The manufacturing process for this product is currently at full commercial scale.

Table of Contents

Non-clinical Studies

Three acute dose toxicity studies have been conducted in the CD strain of rat, and one study in the ICR-CD-1 mouse strain. A series of repeat dose studies have been carried out in rats (4 doses), rabbits (3 doses) and cynomolgus macaques (2 and 4 doses). A single reproductive toxicology study has been conducted in CD rats. All data generated in these studies to date demonstrated the safety of the vaccine for use in human clinical trials.

Non-clinical efficacy studies completed in aerosol challenge models of *Y. pestis* in mice and cynomologus macaques have shown the vaccine to be immunogenic and protective.

Clinical Studies

Three Phase I clinical trials have been conducted to evaluate the safety, tolerability, and immunogenicity of RypVax™. In total, 161 subjects have received RypVax™ with no vaccine-associated serious adverse events reported. RypVax™ has been shown to be safe, well-tolerated, and immunogenic in all trials conducted to date. A Phase II clinical trial is planned to commence in 2010.

Funding

In 2004, Avecia was awarded a multi-year contract, under which it could receive up to approximately $50.7 million from NIAID to support the advanced development of the plague vaccine candidate for military use. PharmAthene acquired this contract as part of the Avecia Acquisition. As of December 31, 2008, PharmAthene recognized revenue of $2.7 million 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.

Third Generation rPA-based Anthrax Vaccine

In addition to SparVax™, we are also developing a third generation rPA-based anthrax vaccine in response to the U.S. government's desire to have a stable product that does not require refrigeration and which can induce protective immunity in fewer doses than the currently licensed vaccine (AVA) and the existing second generation vaccine candidates. This vaccine candidate utilizes the rPA already being manufactured for the second generation product candidate (SparVax™), but it will be freeze-dried and will contain an additional immune stimulant not present in SparVax™, which we believe will allow for enhanced immunogenicity.

Manufacturing

Work in 2009 under the existing NIH funding (described below) will focus on advancing the manufacture of the third generation candidate vaccine, including the additional immune stimulant, toward intermediate scale cGMP manufacture.

Early data generated on the stability of the freeze-dried rPA component of the candidate vaccine suggest significantly improved stability properties, which we believe supports the likelihood that the vaccine candidate will be stable for 3 years at 35ºC. Additional data are needed to confirm this potential, and studies are planned as part of the work to be performed under the NIAID contract.

Pre-clinical Studies

The data generated to date have focused on proof-of-concept studies in animal models to evaluate the immunogenicity of the candidate vaccine. These studies have shown that the vaccine induces a rapid

Table of Contents

and enhanced immune response that is protective against infection with *Bacillus anthracis* in these animal models.

There have been no pre-clinical toxicology studies completed to date. We plan to initiate acute single dose toxicology studies in rodents in late 2009.

Clinical Studies

This vaccine candidate is in the early research and development stage. We do not anticipate filing an IND with the FDA before 2011, and we will not commence any human clinical trials before an IND has been filed and accepted by the FDA.

Funding

Two NIH grants made in 2005 and 2007 in the aggregate amount of $6.9 million have funded research activities to support the initial development of this vaccine candidate. On September 25, 2008, we were awarded a contract by NIAID for up to approximately $13.2 million for additional development work. We expect to receive this funding 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, we could receive up to approximately $83.9 million over a nine year period (including the base period and the $13.2 million disclosed above) under this contract, which includes a cost reimbursement component and a fixed fee component payable upon achievement of certain milestone events.

U.S. Government Regulatory Pathway

General

Regulation by governmental authorities in the United States and other countries will have a significant impact on our research, product development, manufacturing and marketing of any biopharmaceutical products. The nature and the extent to which regulations apply to us will vary depending on the nature of any such products. Our potential biopharmaceutical products will require regulatory approval by governmental agencies prior to commercialization. The products we are developing are subject to federal regulation in the United States, principally by the FDA under the Public Health Service Act and Federal Food, Drug, and Cosmetic Act (“FFDCA”) and by state and local governments, as well as regulatory and other authorities in foreign governments that include rigorous preclinical and clinical testing and other approval procedures. Such regulations govern or influence, among other things, the research, development, testing, manufacture, safety and efficacy requirements, labeling, storage, recordkeeping, licensing, advertising, promotion, distribution and export of products, manufacturing and the manufacturing process. In many foreign countries, such regulations also govern the prices charged for products under their respective national social security systems and availability to consumers.

The Public Health Service Act classifies our current drug candidates which are produced using biological systems, as biological drug products, or biologics (“Biologics”). All drugs intended for human

Table of Contents

use, including Biologics, are subject to rigorous regulation by the FDA in the United States and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before a biological drug product may be marketed in the United States are similar to steps required in most other countries and include, but are not limited to:

- completion of preclinical laboratory tests, preclinical animal testing and formulation studies;
- submission to the FDA of an IND, which must be in effect before clinical trials may commence;
- performance of adequate and well-controlled clinical trials to establish the safety, purity and potency (including efficacy) of the Biologic and to characterize how it behaves in the human body;
- completion of comparability studies, if necessary;
- submission to the FDA of a BLA that includes preclinical data, clinical trial data and manufacturing information;
- FDA review of the BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities; and
- FDA approval of the BLA, including approval of all product labeling.

Preclinical testing includes laboratory evaluations to characterize the product’s composition, impurities, stability, and mechanism of its biologic effect, as well as animal studies to assess the potential safety, purity and potency of each product. Preclinical safety tests must be conducted by laboratories that comply with FDA regulations regarding Good Laboratory Practices (“GLP”) and the U.S. Department of Agriculture’s Animal Welfare Act. Violations of these laws and regulations can, in some cases, lead to invalidation of the tests, requiring such tests to be repeated. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical trials. Unless the FDA objects to an IND by placing the study on clinical hold, the IND will go into effect 30 days following its receipt by the FDA. The FDA may authorize trials only on specified terms and may suspend clinical trials at any time on various grounds, including a finding that patients are being exposed to unacceptable health risks. If the FDA places a study on clinical hold, the sponsor must resolve all of the FDA’s concerns before the study may proceed. The IND application process may become extremely costly and substantially delay development of products. Similar restrictive requirements also apply in other countries. Additionally, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Clinical trials involve the administration of the investigational product to humans under the supervision of qualified principal investigators. Our clinical trials must be conducted in accordance with Good Clinical Practice ("GCP") under protocols submitted to the FDA as part of an IND. In addition, each clinical trial is approved and conducted under the auspices of an institutional review board ("IRB") and with the patients' informed consent. The IRB considers, among other things, ethical factors, the safety of human subjects, and the possibility of liability of the institutions conducting the trial. The IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for a variety of reasons, including a belief that the test subjects are being exposed to an unacceptable health risk. Since our products are being developed using funding from the U.S. government, additional review

Table of Contents

by either the NIH's IRB or the DoD's IRB-equivalent will also be required. These reviews take place following approval by the independent IRB. As the sponsor, we can also suspend or terminate a clinical trial at any time.

Clinical trials are typically conducted in three sequential phases, Phases I, II, and III, involving an increasing number of human subjects. Phase I trials are safety studies performed in a small number of subjects. Phase II studies, which may involve hundreds of subjects, take an in-depth look at the effectiveness of the drug and may include analysis of dose ranges and dose regimens. Finally, Phase III trials typically involve thousands of individuals and provide the documentation of effectiveness and important additional safety data required for licensing.

In 2002, however, the FDA amended its requirements applicable to BLAs to permit the approval of certain Biologics that are intended to reduce or prevent serious or life-threatening conditions based on evidence of safety from trial in healthy subjects and effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. These regulations, also known as the "Animal Rule", and published in the Code of Federal Regulations (21 CFR 601 Subpart H) authorize the FDA to rely on evidence from animal studies to provide substantial proof of a product's effectiveness under circumstances where there is a reasonably well-understood mechanism for the toxicity of the agent. Under these requirements, Biologics used to reduce or prevent the toxicity of chemical, biological, radiological or nuclear substances may be approved for use in humans based on evidence of effectiveness derived from appropriate animal studies and any additional supporting data. Products evaluated for effectiveness under this rule are evaluated for safety under preexisting requirements for establishing the safety of new drug and biological products, including Phase I through Phase II clinical trials. Under certain circumstances 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 must allow for selection of an effective dose in humans. We intend to rely on the Animal Rule in seeking marketing approval for our product candidates because we cannot ethically expose humans to anthrax, nerve agents or plague. 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.

Success in early-stage animal studies and clinical trials does not necessarily assure success in later-stage clinical trials. Data obtained from animal studies and clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or even prevent regulatory approval.

All data obtained from the preclinical studies and clinical trials, in addition to detailed information on the manufacture and composition of the product, would be submitted in a BLA to the FDA for review and approval for the manufacture, marketing and commercial shipments of any of our products. FDA approval of the BLA is required before commercial marketing or non-investigational interstate shipment may begin in the United States. However, Project Bioshield gave authority to the FDA to grant EUA for use of unlicensed/unapproved products should there be an emergency declared by the appropriate authority within the DHHS. This legislation will also allow unlicensed products to be procured for the SNS so that they are available at the time an emergency is declared. Our products will be eligible both for consideration for procurement into the SNS and for use in the event of an emergency, although there is no guarantee that our products will meet the criteria set forth by DHHS or the FDA for procurement and EUA, respectively.

With regard to a BLA, the FDA may deny or delay approval of an application that does not meet applicable regulatory criteria, e.g. if the FDA determines that the preclinical or clinical data or the

Table of Contents

manufacturing information does not adequately establish the safety, purity and potency (including efficacy) of the Biologic. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its BLA. The FDA can request additional information, seek clarification regarding information already provided in the submission or ask that clinical trials be conducted, all of which can delay approval. The FDA also may, at any time, require the submission of product samples and testing protocols for lot-by-lot confirmatory review or testing, known as lot release, by the FDA prior to commercial distribution. This means a specific lot of Biologic cannot be released for commercial distribution until the FDA has authorized such release. Similar types of regulatory processes will be encountered as efforts are made to market any Biologic internationally. We will be required to assure product performance and manufacturing processes from one country to another.

Once it approves a BLA, the FDA may revoke or suspend the product approval if compliance with post-market regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies to monitor the effect of approved products, and may limit further marketing of the product based on the results of these post-market studies. The Animal Rule is clear that post-marketing studies are required should the products be used in humans; the nature of these studies will be discussed with FDA as part of the BLA process. The FDA has broad post-market regulatory and enforcement powers, including the ability to levy civil and criminal penalties, suspend or delay issuance of approvals, seize or recall products and revoke approvals.

Facilities used to manufacture Biologics are subject to periodic inspection by the FDA and other authorities, where applicable, and must comply with the FDA's current Good Manufacturing Practices ("cGMP") regulations, the FDA's general biological product standards, and the product establishment standards set forth in the approved BLA. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or recall of a product. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be revoked if compliance with regulatory requirements is not maintained or if problems concerning safety or effectiveness of the product occur following approval. With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote Biologics, including, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in administrative and judicial enforcement actions, including the issuance of a Warning Letter directing correction of deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions. Foreign regulatory bodies also strictly enforce these and other regulatory requirements.

Orphan Drug Act

The Orphan Drug Act is intended to provide incentives to pharmaceutical companies to develop and market drugs and Biologics for rare diseases or conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. Orphan drug designation does not convey any advantage in,

or shorten the duration of, the regulatory review and approval process. Clinical testing requirements for orphan drugs are the same as those for products that have not received orphan drug designation but pharmaceutical companies may receive grants or tax credits for research, as well as protocol assistance. Further, if a drug or Biologic that receives orphan drug designation and is the first product to receive FDA marketing approval for the orphan designated indication, the product receives a seven-year period of marketing exclusivity during which the FDA cannot approve any application by another party to market the same drug for treatment of an identical indication. There are

Table of Contents

exceptions to this exclusivity, however. For example, the FDA is allowed to approve a second product with the same active ingredient for the same indication if the sponsor of the approved orphan product consents, grants a license to the second applicant or is unable to assure an adequate supply of the drug, or if the second product has been shown to be clinically superior to the approved orphan drug. Further, orphan drug exclusivity does not block approval of a drug that, although proposed for the same indication, is considered by the FDA (applying a regulatory standard) to be a different drug than the previously approved orphan drug. In addition, the holder of orphan drug status must notify the FDA of any decision to discontinue active pursuit of drug approval or, if such approval or license is in effect, notify the FDA at least one year prior to any discontinuance of product production. If the holder of an orphan designation cannot assure the availability of sufficient quantities of the product to meet the needs of affected patients, the FDA may withdraw orphan drug status.

Fraud and Abuse

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, false claims laws and physician self-referral laws. Violations of these laws are punishable by criminal, civil and/or administrative sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and veterans' health programs. Because of the far-reaching nature of these laws, we cannot assure you that the occurrence of one or more violations of these laws would not result in a material adverse effect on our business, financial condition and results of operations.

Anti-Kickback Laws

Our operations are subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act prohibit entities such as us from knowingly and willingly offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribes or rebates) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the DHHS may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payors.

Other Regulatory Schemes

In addition to the substantial regulations enforced by the FDA, we are also subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our various activities. We cannot accurately predict the extent of government regulation that might result from any future legislation or administrative action.

Table of Contents

Manufacturing

While we have no drug substance or drug product manufacturing or production facilities of our own and limited manufacturing capabilities for the supply of transgenic milk (as described below), we believe that acceptable alternatives are available through third-party contract manufacturing organizations, or "CMOs", that have experience in operating under cGMPs established by the Code of Federal Regulations and the Food, Drug and Cosmetic Act (Biologics) regulated by the FDA, and we rely on them for clinical and future commercial production of our product candidates.

For SparVax™ and our third-generation anthrax vaccine, to date the rPA has been produced in *Escherichia coli* at the Avecia bacterial fermentation facilities. Avecia currently serves as our commercial manufacturing organization (CMO) for the bulk drug substance rPA antigen used to make the 2nd and 3rd generation anthrax vaccines. The bulk drug substance manufacturing process is performed at final commercial scale using standard purification unit operations yielding high purity rPA. If we are awarded a contract under RFP-BARDA-08-15 for the advanced development and procurement of 25 million doses of SparVax™, we anticipate engaging a new contract manufacturer for the bulk drug substance for SparVax™ and commencing a technology transfer process from Avecia to this new CMO. Formulation and filling of the final drug product, adjuvanted rPA, is performed at Baxter Pharmaceutical Solutions LLC, located in the United States. The final dosage presentation is in unit dose syringes.

For Protexia®, the starting material used to produce the purified rBChE comes from the milk of transgenic goats raised on a farm we own and operate. We are producing rBChE at commercially feasible quantities. For commercial manufacturing, the bulk rBChE starting material is produced on our farm and the final purification of the bulk drug substance will be performed at a CMO. Final formulation processes and product presentation are still being developed.

For Valortim®, the cell culture process was developed by Medarex, and results in a commercially feasible and high purity product that would be manufactured commercially by a CMO. We have successfully manufactured bulk drug substance at large scale following technology transfer to a CMO. The final drug product has been formulated and filled , tested and released for labeling.

For RypVax™ , the recombinant F1 (rF1) and V (rV) antigens are independently produced in *Escherichia coli* at large scale in the Avecia facilities. The bulk drug substance components are purified by precipitation, chromatographic and filtration processes yielding the high purity recombinant antigens.

Table of Contents

The purified antigens are combined, formulated/adjuvanted and filled as a liquid divalent recombinant plague vaccine.

Certain raw materials used in producing our product candidates are available from only one source or a limited number of sources. We attempt to mitigate the risk associated with such sole source raw materials by actively managing our inventories. We have not experienced any shortages in supplies of such raw materials. Unavailability of certain materials or the loss of current sources of production could cause an interruption in production on a temporary basis pending establishment of new sources or, in some cases, implementation of alternative processes.

Intellectual Property

Our success depends in part on our ability to obtain patents, to protect trade secrets, and to operate without infringing upon the proprietary rights of others. We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to the proprietary technology, inventions and improvements that are important to our business. We currently hold two issued U.S. patents relating to Protexia® and four corresponding foreign patents. These patents are directed to direct gene transfer into the ruminant mammary gland and the method for development of transgenic goats. The issued patents have expiration dates in 2015. In accordance with ongoing research and development efforts, we have six pending U.S. patent applications and 14 corresponding foreign applications covering relevant and newly-developed portions of our transgenic technology.

The following table identifies each of our issued and non-abandoned patents and published pending applications:

Patent/Patent Application	Patent Number/ Application Number	Country of Issue/Filing	Issue Date/File Date	Expiration Date
Direct Gene Transfer Into the Ruminant Mammary Gland	5,780,009	U.S.	Issued July 14, 1998	July 15, 2015
Method for Development of Transgenic Goats	5,907,080	U.S.	Issued May 25, 1999	December 1, 2015
Method for Development of Transgenic Goats	0871357	Netherlands Great Britain France Germany Belgium Switzerland Liechtenstein	May 2, 2003	November 27, 2016
Method for Development of Transgenic Goats	721,132	Australia	Issued October 5, 2000	November 27, 2016
Production of Butyrylcholinesterase in Transgenic Mammals	10/326,892	U.S.	Filed December 20, 2002	December 21, 2022
Production of Butyrylcholinesterase in Transgenic Mammals	051024531	Hong Kong	March 22, 2005	December 19, 2022

Table of Contents

Patent/Patent Application	Patent Number/ Application Number	Country of Issue/Filing	Issue Date/File Date	Expiration Date
Production of Butyrylcholinesterase in Transgenic Mammals	1458860	Europe	December 19, 2002	December 19, 2022
Long Half-Life Recombinant Butyrylcholinesterase	US07/017279 60/835,827 12/309909 US07/017279 07811030.1 US07/017279 US07/017279 196,871	WO U.S. U.S. Japan Spain Canada Australia Israel	Filed August 2, 2007 August 4, 2006 February 2, 2009 February 4, 2009 August 27, 2007 February 3, 2009 February 10, 2009 February 4, 2009	August 3, 2027 August 3, 2027 August 3, 2027 August 3, 2027 August 3, 2027 August 3, 2027 August 3, 2027 August 3, 2027
Production of HSA-linked Butyrylcholinesterases	11/401,390 10/326,892	U.S. U.S.	Filed April 10, 2006 December 20, 2002	December 21, 2022 December 21, 2022
Method for Assaying Antigens	GB07/001353 GB 0607462.9 12/226101 2009-504819 2010914 2,648,850 2007242647 194459	WO Great Britian U.S. Japan Spain Canada Australia Israel	April 12, 2007 April 13, 2006 October 7, 2008 October 10, 2008 November 10, 2008 October 9, 2008 October 24, 2008 October 2, 2008	April 13, 2027 April 13, 2027 April 13, 2027 April 13, 2027 April 13, 2027 April 13, 2027 April 13, 2027 April 13, 2027
Vaccine Composition	GB 0801122.3 GB2009/050050	Great Britian WO	January 22, 2008 January 22, 2009	January 22, 2029 January 22, 2029
Anthrax Vaccine Formulation and Uses Thereof	61/194967	U.S.	October 2, 2008	October 2, 2009
Stable vaccine compositions and methods of use	12/321564 GB2009/050051	U.S. WO	January 22, 2009 January 22, 2009	January 23, 2029 January 23, 2029

In addition, we are a party to various exclusive and non-exclusive licenses, which provide access to intellectual property and know-how useful for our products. For the Protexia® program, we are party to licenses with Exeter Life Sciences for intellectual property related to creating animal clones, GTC Biotherapeutics, Inc. for

intellectual property related to the purification of proteins from milk and know-how related to the development of protein drugs in the milk of transgenic animals, Nektar Therapeutics AL, Corporation for intellectual property and know-how related to the pegylation of proteins, Yissum Research Development Company for intellectual property related to the production of proteins in the milk of transgenic animals.

Furthermore, in connection with the Avecia Acquisition, we acquired license agreements with The Defence Science and Technology Laboratory of the United Kingdom Ministry of Defence ("DSTL") originally executed May and December 2006, and recently amended in February 2009. These agreements allow for the licensing of certain patents and technology useful in our rPA and plague vaccine programs under our government contracts with the NIAID. Upon commercialization of a product covered by a license, the license agreements require that we make royalty payments equal to a specified percentage of future sales of products for both government procurement and commercial markets. No royalty payments on these licenses have been incurred. Some of our licenses, which generally extend for the life of any

Table of Contents

applicable patent, require us to pay royalties on sales of products that may be derived from or produced using the licensed technology. We derive rights to the patents, patent applications and know-how relating to Valortim® through our collaboration arrangement with Medarex, which owns such rights. For additional information on our license agreements, please refer to Note 10–Commitments and Contingencies–License Agreements in the Notes to our Consolidated Financial Statements.

The expiration dates for the licenses described above are as follows:

License	Expiration Date
Exeter Life Sciences	When sale of licensed product in a specific country or jurisdiction is no longer covered by a valid patent claim
GTC Biotherapeutics, Inc.	December 31, 2026
Nektar Therapeutics AL	On a country-by-country basis upon the expiration of all royalty obligations in the applicable country
Yissum Research Development Company	When the last registered patent expires
DSTL Anthrax	No expiration specified
DSTL Plague	No expiration specified
Medarex	Two years after the earlier of the date that (a) the collaboration product is no longer exploited under the agreement or (b) Unilateral Product (as defined in our collaboration agreement with Medarex) is no longer exploited under a unilateral development and commercialization agreement.

We rely upon certain proprietary trade secrets, know-how and continuing technological advances to develop a competitive position. In efforts to maintain confidentiality and ownership of trade secrets, proprietary information and developments, all of our employees are required to execute agreements regarding confidentiality and assigning to us all rights to any inventions and processes they develop while they are employed by us.

We intend to use license agreements to access external products and technologies, as well as to convey our own intellectual property to others. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Research and Development Costs

During the years ended December 31, 2008 and 2007, we incurred $31.8 million and $16.6 million, respectively, of development expenses related to our research and development programs.

Competition

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. A large number of companies of all sizes engage in activities similar to our activities and many of our competitors have substantially greater financial and other resources available to them.

Table of Contents

Anthrax Product Competition

With respect to the development of a PA-based vaccine, we are aware of two other companies developing competing vaccines: Emergent BioSolutions, Inc., which is the sole supplier to the U.S. government of the only currently available anthrax vaccine - BioThrax® Anthrax Vaccine Adsorbed, and Panacea Biotec Ltd.

Monoclonal antibodies ("MAbs") directed against PA are being developed for post-exposure prophylaxis and as symptomatic therapy for anthrax infection. There are a limited number of companies we are aware of with anti-anthrax MAbs and/or polyclonal antibodies in development, including: Cangene Corporation, Human Genome Sciences, Inc., Elusys Therapeutics, Inc., Emergent BioSolutions, Inc., and IQ Corporation BV.

There are a number of orally available small molecule and other drugs approved and/or under development for the treatment of anthrax. These include broad spectrum antibiotics as well as anthrax specific products. Bayer AG produces Ciprofloxacin, or "Cipro," which has been approved for the post-exposure prophylaxis of inhalation anthrax. In late 2004, generic versions of Cipro were also approved by the FDA. In addition, levofloxacin, an antibiotic marketed in the United States by Ortho-McNeil Pharmaceuticals, and the generic antibiotic, doxycycline, are both approved for post-exposure prophylaxis of inhalation anthrax.

We also believe that third generation anthrax vaccines, consisting of improved formulations of the anthrax Protective Antigen are being developed by Bavarian Nordic, Emergent BioSolutions, Inc., LigoCyte Pharmaceuticals, Inc., and Intercell AG.

Nerve Agent Product Competition

Nerve agents are among the most lethal chemical warfare agents and there are few antidotes available. Symptoms of intoxication develop within seconds and death can result within minutes after exposure by inhalation, absorption through the skin, or by oral consumption.

We are aware of antidotes to nerve agents being developed by pharmaceutical companies, including Countervaile Corporation, Meridian Medical Technologies, a subsidiary of King Pharmaceuticals Inc., and Dynport Vaccine Company, LLC, in collaboration with Baxter Healthcare Corporation.

Plague Product Competition

RypVax™, our recombinant plague vaccine candidate for immunisation against pneumonic or bubonic plague caused by *Y. pestis* infection consists of two recombinant antigens (rF1 and rV), produced in *Escherichia coli*. Dynport Vaccines Corporation has an rF1V fusion vaccine candidate under development in collaboration with the DoD.

Employees

As of December 31, 2008, we employed 151 persons on a full-time basis and 4 on a part-time basis, including 100 individuals engaged in research and development activities and 55 individuals engaged in general and administrative functions such as human resources, finance, accounting, legal and investor relations. Our staff includes 28 employees with Ph.D. or M.D. degrees. None of our employees are party to any collective bargaining agreement, and we believe that our relationship with our employees is good.

Table of Contents

Information concerning our directors and executive officers can be found in Part III, Item 10 under the caption “Directors, Executive Officers and Corporate Governance.”

Item 1A. Risk Factors

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

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

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

On February 29, 2008, the DHHS issued a formal Request for Proposal (RFP-BARDA-08-15) for an ‘‘Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile,’’ which includes a requisition for 25 million doses of an rPA anthrax vaccine. We submitted a response to this solicitation on July 31, 2008. While the original solicitation indicated that an award would be made by September 26, 2008, which was later extended to December 31, 2008, DHHS subsequently delayed the award date further because, among other things, of a protest filed by a bidder that had been eliminated from further consideration under the solicitation. The U.S. General Accounting Office (the ‘‘GAO’’) subsequently denied that protest, and, based on communication we have had with DHHS, we believe that an award may be made in the first half of April 2009. Nevertheless, there can be no assurance that DHHS will not again extend the timeline for issuing an award.

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

Table of Contents

Risks Related to Our Financial Condition

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

We have incurred significant losses since we commenced operations. For the year ended December 31, 2008, we incurred an operating loss of approximately $35.2 million and had an accumulated deficit of approximately $123.8 million at December 31, 2008. Our losses to date have resulted principally from research and development costs related to the development of our product candidates, general and administrative costs related to operations, and costs related to the Avecia Acquisition.

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

- developing our existing products and developing and testing new product candidates;
- carrying out our intellectual property strategy;
- establishing our 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 more slowly than we anticipate, or if operating expenses exceed our expectations or cannot be adjusted accordingly, then our business, results of operations, financial condition and cash flows will be materially and adversely affected. Because our strategy might include acquisitions of other businesses, acquisition expenses and any cash used to make these acquisitions will reduce our available cash. As a result of our continuing losses and our continuing obligations, including those under the agreements relating to the Avecia Acquisition, without additional funding through contracts and grants with the U.S. or foreign governments, we would need to identify additional financing within the next 12 months. At December 31, 2008, our available cash and cash equivalents was approximately $19.8 million, we had $6.3 million of cash that was restricted under our credit facility with Silicon Valley Bank and Oxford Finance Corporation, $7 million of cash that was restricted under our agreements with Avecia, and our short-term investments were $3.2 million. However, at December 31, 2008, we had outstanding debt to the holders of our 8% unsecured convertible notes of approximately $13.4 million, approximately $5.0 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 October 2, 2009. In addition, if we receive the award from DHHS for procurement of SparVax™, we would be obligated to make $10 million in milestone payments to Avecia within 90 days of the receipt of such award. Even

Table of Contents

taking into consideration our recent registered offering of securities, we may be required to seek additional financing in the future.

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. Our requirements for additional capital may be substantial and will be dependent on many factors, including the success of our research and development efforts, our ability to commercialize and market products, our ability to successfully pursue our licensing and collaboration strategy, the receipt of continued government funding, competing technological and marketing developments, costs associated with the protection of our intellectual property and any future change in our business strategy.

To the extent that we raise additional capital through the sale of securities, the issuance of those securities could result in dilution which may be substantial to our stockholders. In addition, if we incur 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 our business activities.

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

Risks Related to Product Development and Commercialization

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

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

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

Table of Contents

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

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

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

As described in “*Business—U.S. Government Regulatory Pathway—General*”, to obtain FDA approval for our biological warfare defense products under current FDA regulations, we are required to utilize animal model studies for efficacy and provide animal and human safety data under the “Animal Rule.” For many of the biological and chemical threats, animal models are not yet available, and as such we are developing, or will have to develop, appropriate animal models, which is a time-consuming and expensive research effort. Further, we may not be able to sufficiently demonstrate the animal correlation to the satisfaction of the FDA, as these corollaries are difficult to establish and are often unclear. The FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Further, other countries do not, at this time, have established criteria for review and approval of these types of products outside their normal review process; i.e., there is no “Animal Rule” equivalent, and consequently there can be no assurance that we will be able to make a submission for marketing approval in foreign countries based on such animal data.

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

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

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

We and our contract manufacturers (CMOs) will also be required to comply with the applicable FDA current Good Manufacturing Practice ("cGMP") regulations. These regulations include

Table of Contents

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

In particular, if we are awarded a contract under RFP-BARDA-08-15 for the advanced development and procurement of 25 million doses of SparVax™, we anticipate engaging a new contract manufacturer to manufacture bulk drug substance for SparVax™. This contract manufacturer has not manufactured that bulk drug substance before, and we would need to commence a process of technology transfer from Avecia, the prior manufacturer of the bulk drug substance, to this new contract manufacturer. There can be no assurance that we would be successful in our technology transfer efforts or that this new contract manufacturer would ever be able to manufacture sufficient amounts of cGMP quality bulk drug substance necessary for us to meet our obligations under any such contract.

We 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 effect upon our business.

We have completed one Phase I clinical trial for Valortim® with our development partner, Medarex, without any reported drug-related significant adverse events. However, before we may begin selling any doses of Valortim®, we will need to conduct more comprehensive safety trials in a significantly larger group of human subjects. We will be required to expend a significant amount to finalize manufacturing capability through a contract manufacturer to provide material to conduct the pivotal safety and efficacy trials. If our contract manufacturer is unable to produce sufficient quantities at a reasonable cost, or has any other obstacles to production, such as volatile manufacturing, then we will be unable to commence these required clinical trials and studies. Even after we expend sufficient funds to complete the development of Valortim® and when and if we enter into an agreement to supply Valortim® to the U.S. government, we will be required to share any and all profits from the sale of products with our partner in accordance with a pre-determined formula.

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

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

For example, we have an agreement with Medarex to develop Valortim®, a fully human monoclonal antibody product designed to protect against and treat inhalation anthrax. Under the agreement with Medarex, we will be entitled to a variable percentage of profits derived from sales of Valortim®, if any, depending, in part, on the amount of our investment. In addition, we have entered into licensing and research and development agreements with a number of other parties and collaborators. There can be no assurances that the research and development conducted pursuant to these agreements will result in revenue generating product candidates. If our suppliers or other collaboration partners experience financial difficulties as a result of the current credit crisis and weakening of the global economy, they might be forced to shift resources away from the research, development and/or manufacturing efforts intended to benefit our products, which could lead to significant delays in our development programs and potential future sales. In addition, our current licensing, research and development, and supply agreements may expire and may not be renewable or could be terminated if we do not meet our obligations.

Table of Contents

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

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

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

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

In addition, if a product liability claim is brought against us, the cost of defending the claim could be significant and any adverse determination may result in liabilities in excess of our insurance coverage. Although our anthrax countermeasurers are covered under the general immunity provisions of the U.S. Public Readiness and Emergency Preparedness Act (the "Public Readiness Act"), there can be no assurance that the U.S. Secretary of Health and Human Services will make other declarations in the future that cover any of our other product candidates or that the U.S. Congress will not act in the future to reduce coverage under the Public Readiness Act or to repeal it altogether. For further discussion of that act, see "Risk Factors - *Legislation limiting or restricting liability for medical products used to fight bioterrorism is new, and we cannot be certain that any such protection will apply to our products or if applied what the scope of any such coverage will be"* below. Additionally, we are considering applying for indemnification under the U.S. Support Anti-terrorism by Fostering Effective Technologies (SAFETY)

Table of Contents

Act of 2002 which preempts and modifies tort laws so as to limit the claims and damages potentially faced by companies who provide certain "qualified" anti-terrorism products. However, we cannot be certain that we will be able to obtain or maintain coverage under the SAFETY Act or adequate insurance coverage on acceptable terms, if at all.

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

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

For the foreseeable future, we believe our main customer will be national governments, primarily the U.S. government. Substantially all of our revenues to date have been derived from grants and U.S. government contracts. There can be no assurances that existing government contracts will be renewed or that we can enter into new contracts or receive new grants. The process of obtaining government contracts is lengthy and uncertain and we will have to compete with other companies for each contract. For example, while RFP-BARDA-08-15 for an rPA vaccine for the SNS initially indicated that the government would make an award by September 26, 2008 (later extended to December 31, 2008), as of the date this annual report on Form 10-K is filed, the government has still not issued an award under that solicitation. There can be no assurances that we will be awarded any contracts to supply the U.S. or other governments with our products as such awards may be made, in whole or in part, to our competitors. If the U.S. government makes significant future contract awards for the supply to the U.S. emergency stockpile of a competing product, our business will be harmed and it is unlikely that we will ultimately be able to supply that particular treatment or product to foreign governments or other third parties. Further, changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on procuring the biodefense products we are developing. For example, our existing contracts for the advanced development of plague vaccine, RypVax™, expire in the first half of 2010, and future government funding for this development program remains uncertain at this time. Furthermore, under the terms of our 2006 contract with the U.S. Department of Defense regarding Protexia®, the Department of Defense may elect not to continue development assistance of this nerve agent countermeasure after initial funding of $41 million has been received (which decision we anticipate may occur by the end of the fourth quarter of 2009), or, if the Department of Defense does so elect to continue funding and we meet all development milestones, it may nevertheless choose not to procure any doses of Protexia®.

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

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

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

- suspend or prevent us for a set period of time from receiving new contracts or extending existing contracts based on violations or suspected violations of laws or regulations;
- terminate our contracts, including if funds become unavailable to the applicable governmental agency;

Table of Contents

- reduce the scope and value of our contracts;
- audit and object to our contract-related costs and fees, including allocated indirect costs;
- control and potentially prohibit the export of our products; and
- change certain terms and conditions in our contracts.

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

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

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

The laws and regulations governing the procurement of goods and services by the U.S. government provide procedures by which other bidders and other interested parties may challenge the award of a government contract. If we are awarded a government contract, such challenges or protests could be filed even if there are not any valid

legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of goods and services and payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate our contract and reselect bids. The government could even be directed to award a potential contract to one of the other bidders. A recent example is the protest filed by a third-party bidder with the GAO challenging the decision of the DHHS to eliminate that bidder from further consideration under the solicitation for an rPA vaccine for the Strategic National Stockpile (RFP-BARDA-08-15), a result of which was a delay to the contract award date under this solicitation.

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

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

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

Table of Contents

or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

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

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

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

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

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

Foreign governments typically also have laws and regulations governing contracts with their respective agencies. These foreign laws and regulations affect how we and our customers conduct business and, in some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

Table of Contents

Risks Related to Dependence on or Competition From Third Parties

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

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

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

We do not have any of our own manufacturing facilities. We have therefore utilized, and intend to continue utilizing, third parties to manufacture, package and distribute our product candidates and key components of our product candidates. Any material disruption in manufacturing could cause a delay in our development programs

and potential future sales. Furthermore, certain compounds, media, or other raw materials used to manufacture our drug candidates are available from any one or a limited number of sources. Any delays or difficulties in obtaining key components for our product candidates or in manufacturing, packaging or distributing our product candidates could delay clinical trials and further development of these potential products. Additionally, the third parties we rely on for manufacturing and packaging are subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities.

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

Finally, third-party manufacturers, suppliers and distributors, like most companies, have been adversely affected by the current credit crisis and weakening of the global economy. It has, for example, become increasingly challenging for companies to secure debt capital to fund their operations as financial institutions have significantly curtailed their lending activities. If our third-party suppliers continue to experience financial difficulties as a result of weakening demand for their products or for other reasons and are unable to obtain the capital necessary to continue their present level of operations, they may have to reduce their activities. A material deterioration in their ability to meet their obligations to us could cause a delay in our development programs and potential future sales and jeopardize our ability to meet our obligations under our contracts with the government or other third parties.

Table of Contents

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

The biopharmaceutical industry is characterized by rapid and significant technological change. Our success will depend on our ability to develop and apply our technologies in the design and development of our product candidates and to establish and maintain a market for our product candidates. There are many organizations, both public and private, including major pharmaceutical and chemical companies, specialized biotechnology firms, universities and other research institutions engaged in developing pharmaceutical and biotechnology products. Many of these organizations have substantially greater financial, technical, intellectual property, research and development, and human resources than we have. Competitors may develop products or other technologies that are more effective than any that we are developing or may obtain FDA approval for products more rapidly.

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

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

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

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

Table of Contents

Risks Related to Political and Social Factors

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

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

Risks Related to Intellectual Property

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

The patent position of biotechnology firms generally is highly uncertain and involves complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty. To date, no consistent policy has emerged regarding the breadth of claims allowed in biotechnology patents. We currently hold two U.S. patents, have three pending U.S. patent applications, and have 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 us will result in patents being issued or that the patents, whether existing or issued in the future, will afford protection against competitors with similar technology. Any conflicts resulting from third-party patent applications and patents could significantly reduce the coverage of the patents owned, optioned by or licensed to us or our collaborators and limit our ability or that of our collaborators to obtain meaningful patent protection.

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

We are also aware of pending applications directed to pegylated butyrylcholinesterase. Protexia® incorporates butyrylcholinesterase. If patents are issued to third parties that cover Protexia® or other products, we and/or our licensors and/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. We and/or 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 ultimate outcome is favorable. An outcome of any patent prosecution or litigation

Table of Contents

that is unfavorable to us or one of our licensors or collaborators may have a material adverse effect on us. The expense of a protracted infringement suit, even if ultimately favorable, would also have a material adverse effect on us.

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

Risks Related to Regulatory Approvals and Legislation

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

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

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

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

Upon a declaration by the Secretary of Health and Human Services, a compensation fund would be created to provide “timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure.” The “covered injuries” to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. A willful misconduct action could be brought against us if an individual(s) has exhausted their remedies under the compensation program which thereby could expose us to liability. Furthermore, there is no assurance that the Secretary of Health and Human Services will issue under this act a declaration to establish a compensation fund. We may also become subject to

Table of Contents

standard product liability suits and other third party claims if products we develop which fall outside of the Public Readiness Act cause injury or if treated individuals subsequently become infected or otherwise suffer adverse effects from such products.

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

Our product candidates are subject to the Export Administration Regulations (“EAR”) administered by the U.S. Department of Commerce and are, in certain instances (such as regarding aspects of our Protexia® product candidate) subject to the International Traffic in Arms Regulations (“ITAR”) administered by the U.S. Department of State. EAR restricts the export of dual-use products and technical data to certain countries, while ITAR restricts the export of defense products, technical data and defense services. The U.S. government agencies responsible for administering EAR and ITAR have significant discretion in the interpretation and enforcement of these regulations. Failure to comply with these regulations can result in criminal and civil penalties and may harm our ability to enter into contracts with the U.S. government. It is also possible that these regulations could adversely affect our ability to sell our products to non-U.S. customers.

Risks Related to Personnel

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

We rely, and will continue to rely, on our key management and scientific staff, all of whom are employed at-will. The loss of key personnel or the failure to recruit necessary additional qualified personnel could have a material adverse effect on our business and results of operations. There is intense competition from other companies,

research and academic institutions and other organizations for qualified personnel. We may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. If we do not succeed in retaining and recruiting necessary personnel or developing this expertise, our business could suffer significantly.

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

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

Risks Related to our Common Stock

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

We will likely seek to raise additional capital and may do so at any time through various financing alternatives, including potentially selling shares of common or preferred stock, notes and/or

Table of Contents

warrants convertible into, or exercisable for, shares of common or preferred stock. Even following the registered offering of securities completed on March 27, 2009, we could again rely upon the shelf registration statement on Form S-3, which was declared effective on February 12, 2009, in connection with a sale from time to time of common stock, preferred stock or warrants or any combination of those securities, either individually or in units, in one or more offerings for up to $50,000,000 (inclusive of the gross proceeds from our recent offering of $5.5 million). Raising capital in this manner or any other manner may depress the market price of our stock, and any such financing(s) will dilute our existing shareholders.

In addition, as of December 31, 2008, we had outstanding options to purchase approximately 4.0 million shares of common stock. Additional shares are reserved for issuance under our 2007 Long-Term Incentive Compensation Plan. Our stock options are generally exercisable for ten years, with a significant portion exercisable either immediately or beginning one year after the date of the grant. As of December 31, 2008, we had outstanding debt including accrued and unpaid interest to noteholders of approximately $13.4 million in the form of convertible notes, which are convertible at $10 per share. As of December 31, 2008, we had outstanding warrants exercisable for approximately 12.5 million shares of common stock of which 9.4 million of these warrants are exercisable at $6.00 per share and expire in July 2009. The issuance or even the expected issuance of a large number of shares of our common stock upon conversion or exercise of the securities described above could depress the market price of our stock and the issuance of such shares will dilute the stock ownership of our existing shareholders.

NYSE Amex may delist our securities from trading which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

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

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

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

We have not paid any dividends on our common stock in 2007 and 2008 and do not intend to declare any dividends in the foreseeable future. While subject to periodic review, our current policy is to retain all earnings, if any, primarily to finance our future growth. We make no assurances that we will

Table of Contents

ever pay dividends, cash or otherwise. Whether we pay any dividends in the future will depend on our financial condition, results of operations, and other factors that we will consider.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties

Our principal executive offices are located at One Park Place, Suite 450, Annapolis, MD 21401 and are comprised of approximately 12,600 square feet. Effective the first quarter of 2009, we leased approximately 9,300 additional square feet of office space at this location. The lease terms expire in 2017. We sublease from Avecia approximately 12,700 square feet of office space in Haverton Hills, England which expires in October 2010. We also sublease from Avecia in Medford, Massachusetts 8 offices until April 2009. A replacement facility is in the process of being finalized.

We own a farm in Canada consisting of 180 acres of land where we raise transgenic goats. We also leased office space in Canada, but with the closing of our Canadian research facility located in Ville St. Laurent, Montreal this lease was terminated effective May 31, 2008.

Management believes that these facilities are suitable and adequate to meet the Company's anticipated needs.

Item 3. Legal Proceedings.

The Company is not a defendant in any legal proceedings, other than ordinary routine litigation incidental to our business which we believe will not have a material effect on our financial position or results of operations.

On December 20, 2006, we filed a complaint against Siga Technologies, Inc. ("SIGA") in the Delaware Chancery Court. Our complaint alleges, among other things, that we have the right to license exclusively development and marketing rights for SIGA's drug candidate, SIGA-246, pursuant to a merger agreement between the parties that was terminated in October 2006. The complaint also alleges that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement. We are seeking alternatively a judgment requiring SIGA to enter into an exclusive license agreement with us for SIGA-246 in accordance with the terms of the term sheet attached to the merger agreement or monetary damages. On January 16, 2008, the Delaware Chancery Court issued a ruling denying a motion by SIGA to dismiss the complaint. The parties are now engaged in discovery.

Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted to a vote of the Company's security holders during the quarter ended December 31, 2008.

Table of Contents

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

Market

Our common stock trades on the NYSE Amex (formerly the NYSE Alternext US or American Stock Exchange) under the symbol PIP. The following table sets forth the range of high and low trading prices of our common stock on the NYSE Amex for the past two years during the fiscal periods shown.

Fiscal Year 2008	High	Low
4th Quarter Ended December 31	$ 2.46	$ 0.05
3rd Quarter Ended September 30	$ 2.70	$ 1.74
2nd Quarter Ended June 30	$ 3.17	$ 2.27
1st Quarter Ended March 31	$ 3.99	$ 2.37

Fiscal Year 2007	High	Low
4th Quarter Ended December 31	$ 5.36	$ 3.35
3rd Quarter Ended September 30	$ 7.68	$ 3.95
2nd Quarter Ended June 30	$ 7.63	$ 7.23
1st Quarter Ended March 31	$ 8.00	$ 7.28

Holders

As of March 23, 2009, in accordance with our transfer agent records, we had 48 record holders of our common stock.

Dividends

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

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

On September 30, 2008, we 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 our 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 our 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 and net proceeds of approximately $12.7 million.

Upon the closing of the transaction, Panacea Biotec, through its subsidiary Kelisia, owns approximately 14.5% of our 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,

Table of Contents

following any warrant exercise, of 19.99% of our issued and outstanding common stock as of such exercise date.

The issuance of the shares and warrant to Kelisia was not registered under the Securities Act of 1933, as amended (the "Securities Act"). The issuance was exempt from registration pursuant to Section 4(2) of the Securities Act and Regulation D thereunder, as it was a transaction by the issuer that did not involve a public offering of securities and involved an issuance to an accredited investor.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with (i) our consolidated financial statements, which present our results of operations for the years ended December 31, 2008 and 2007 as well as our financial positions at December 31, 2008 and 2007, contained elsewhere in this Annual Report on Form 10-K and (ii) our

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. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward Looking Statements" and "Risk Factors" sections of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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

- SparVax™ - a second generation rPA anthrax vaccine,
- Valortim® - a fully human monoclonal antibody 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 , and
- a third generation rPA anthrax vaccine.

Recent Events

In March 2009, BARDA issued a Broad Agency Announcement (BAA) for the Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures, which included an advanced development solicitation for proposals covering anthrax anti-toxins. The BAA states that research and technical objectives proposed by offerors may include non-clinical research and development, process development, formulation, manufacturing development, and

Table of Contents

clinical evaluation efforts. In response we submitted an initial proposal providing for further development of Valortim® and are awaiting a response.

On March 27, 2009, we closed on the public sale of an aggregate of 2,116,055 newly issued shares of our common stock at $2.60 per share and warrants to purchase an aggregate of 705,354 shares of our common stock at an exercise price of $3.00 per share, resulting in aggregate gross proceeds of $5,501,743. The warrants will be exercisable beginning on September 27, 2009 and will expire on September 27, 2014, five years from the date they become exercisable. We intend to use the net proceeds for general corporate purposes, including the satisfaction of existing obligations.

Critical Accounting Policies

Estimates

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

We generate our revenue from two different types of contractual arrangements: cost-plus-fee contracts and cost reimbursable grants. Revenues on cost-plus-fee contracts are recognized to the extent of costs incurred plus an estimate of the applicable fees earned. We consider fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. We analyze each cost reimbursable grant to 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.

Our contracts may include the provisions of more than one of our 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, we recognize 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.

Table of Contents

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, we recognize 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, we 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 we acquire development products, we allocate the purchase price, including acquisition expenses and assumed liabilities, to tangible and intangible assets, including goodwill. The portion allocated to intangible assets may be allocated to trademarks, patents and other intangibles. We estimate 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 we work 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, we assess 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.

Results of Operations

Revenue

We recognized revenues of $32.9 million and $14.6 million during the years ended December 31, 2008 and 2007, respectively. These revenues consisted primarily of contract funding from the U.S. government for the development of Protexia®, SparVax™ and RypVax™. Of the $32.9 million in 2008 revenues, $11.9 million were due to 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.

During the years ended December 31, 2008 and 2007, we recognized revenues related to U.S. government awarded contracts and grants as follows:

- Under the September 2006 contract for the advanced development of Protexia®, we recognized $19.5 million and $14.5 million of revenue for the years ended December 31, 2008 and 2007, respectively.
- Under the September 2007 contract for the advanced development of Valortim®, we recognized $1.4 million and $0.1 million of revenue for the years ended December 31, 2008 and 2007, respectively.
- Under our contract for the development of SparVax™, acquired as part of the Avecia Acquisition in the second quarter of 2008, we recognized approximately $9.2 million of revenue for the year ended December 31, 2008.
- Under our contract for the advanced development of a plague vaccine, RypVax™, acquired as part of the Avecia Acquisition in the second quarter of 2008, we recognized approximately $2.7 million of revenue for the year ended December 31, 2008.
- Under our September 2008 contract award for the additional development work on our third generation rPA anthrax vaccine, we recognized approximately $0.1 million in revenue for the year ended December 31, 2008.

Research and Development Expenses

Our research and development expenses were $31.8 million and $16.6 million for the years ended December 31, 2008 and 2007, respectively. These expenses resulted from research and development activities related to programs for Valortim® and Protexia®, as well as from activities related to the SparVax™ and RypVax™ programs which we acquired in the second quarter of 2008. These research and development expenses are primarily funded through U.S. government contracts and grant awards. We incurred both direct expenses, which included salaries and other costs of personnel, raw materials and supplies, and 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 years ended December 31, 2008 and 2007, respectively, were attributable to research programs as follows:

(amounts in millions)	Year ended December 31, 2008	2007
Anthrax therapeutic and vaccines	$ 14.9	$ 4.5
Chemical nerve agent protectants	11.8	10.9
Recombinant dual antigen plague vaccine	4.1	—
Internal research and development	1.0	1.2
Total research and development expenses	$ 31.8	$ 16.6

For the year ended December 31, 2008 as compared to the year ended December 31, 2007, research and development expenses increased $15.2 million primarily attributable to $12.3 million of costs incurred from the programs acquired as a result of the Avecia Acquisition. The anthrax therapeutic and

vaccines program increased $10.4 million primarily as a result of increased process development and manufacturing activity of $5.9 million and increased preclinical and clinical activities of $2.8 million. Costs related to the anthrax therapeutic and vaccines program further increased due to additional internal resource costs. The clinical nerve

agent protectant program expenses increased by a net amount of $0.9 million as a result of $1.4 million in additional process development, manufacturing and increased clinical activities during the year, partially offset by reduced internal resource costs. Expense related to the recombinant dual antigen plague vaccine consist of development and preclinical activities.

The research and development expense amounts disclosed above for the years ended December 31, 2008 and 2007 are net of the following cost reimbursements under our 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 us a $1.7 million grant to support continued development of Protexia®. We recognize cost reimbursements under this grant as a reduction to offset research expenses. Through the year ended December 31, 2008, $0.1 million of funding on this grant has been recognized as an offset to research and development costs.

- We were awarded approximately $2.7 million in congressional appropriations from the United Stated Army Medical Research and Material Command (USAMRMC) for the development to advance Valortim®. We recognized cost reimbursements of approximately $1.0 million and $0.1 million under this funding as a reduction to offset research expenses for the years ended December 31, 2008 and 2007, respectively.

- We recognized cost reimbursements of approximately $1.0 million under the NIH grant funding for development of our third generation anthrax vaccine candidate, which we acquired from Avecia Vaccines in the second quarter of 2008, as a reduction to offset research expenses for the year ended December 31, 2008.

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 of $0.6 million and $0.4 million for the years ended December 31, 2008 and 2007, respectively.

General and Administrative Expenses

General and administrative functions include executive management, finance and administration, government affairs and regulations, corporate development, human resources, legal, and compliance. For each function, we may incur direct expenses such as salaries, supplies and third-party consulting and other external costs and non-cash expenditures such as expense related to stock option and restricted share awards. 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 were $19.4 million and $13.9 million for the years ended December 31, 2008 and 2007, respectively. These amounts include non-cash stock compensation expense of $2.5 million and $1.4 million for the years ended December 31, 2008 and 2007, respectively.

General and administrative expenses increased $5.5 million for the year ended December 31, 2008 as compared to the year ended December 31, 2007 primarily due to increased stock compensation expense (non-cash expenditure) of $1.1 million (partially as a result of increased headcount acquired

Table of Contents

through the Avecia Acquisition), and increased 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 of $2.8 million. Additionally, employee costs, including related travel expenses, increased $1.1 million resulting primarily from the additional headcount acquired through the Avecia Acquisition.

Acquired In-process Research and Development

For the year ended December 31, 2008, we recorded acquired in-process research and development of $16.1 million associated with the Avecia Acquisition. We 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 $0.8 million and $0.7 million for the years ended December 31, 2008 and 2007, respectively. For the years ended December 31, 2008 and 2007, depreciation was $0.6 million and $0.5 million respectively. Depreciation expenses relate primarily to farm building improvements, leasehold improvements related to newly leased office space and laboratory equipment. For the years ended December 31, 2008 and 2007, we recorded amortization expense of $0.2 million and $0.2 million, respectively, related to patents acquired as part of the acquisition of Nexia Biotechnologies.

Other Income and Expenses

Other income and expenses primarily consists of income on our investments, interest expense on our debt and other financial obligations, changes in market value of our derivative financial instruments and foreign currency translation gains or losses. For the years ended December 31, 2008 and 2007, we recognized interest income of $1.2 million and $1.1 million, respectively.

We incurred interest expense of $2.6 million and $2.1 million for the years ended December 31, 2008 and 2007, respectively. Interest expense relates primarily to our outstanding 8% Convertible Notes (as defined below) and our $10.0 million credit facility.

During the year ended December 31, 2006, we 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. We recognized interest expense related to the Notes of $1.7 million and $1.2 million for the years ended December 31, 2008 and 2007, respectively. For the years ended December 31, 2008 and 2007, the Company recorded $0.1 million and $0.6 million, respectively, as a mark-to-market gain relating to the conversion feature of the Notes. Additionally, the Company recognized a $0.9 million gain on the extinguishment of debt as a result of the conversion of notes during fiscal year 2007.

We entered into a $10.0 million credit facility on March 30, 2007 with Silicon Valley Bank and Oxford Financial Corporation. We recognized interest expense of $0.9 million and $0.9 million related to this facility for the years ended December 31, 2008 and 2007, respectively.

Table of Contents

Liquidity and Capital Resources

Overview

Our primary cash requirements are to fund our 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 we will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have incurred cumulative net losses and expect to incur additional losses in conducting further research and development activities. We do not have commercial products and, given the substantial costs relating to the development of pharmaceutical products, have 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 our research and development programs and our ability to obtain adequate financing. Our consolidated financial statements do not include any adjustments relating to recoverability of the carrying amount of recorded assets and liabilities that might result from the outcome of these uncertainties.

On March 27, 2009, we closed on the public sale of an aggregate of 2,116,055 newly issued shares of our common stock at $2.60 per share and warrants to purchase an aggregate of 705,354 shares of our common stock at an exercise price of $3.00 per share, resulting in aggregate gross proceeds of $5,501,743. The warrants will be exercisable beginning on September 27, 2009 and will expire on September 27, 2014, five years from the date they become exercisable. We intend to use the net proceeds for general corporate purposes, including the satisfaction of existing obligations.

Sources and Uses of Cash

Our cash and cash equivalents were $19.8 million and $40.6 million at December 31, 2008 and 2007, respectively. The $20.8 million decrease in cash and cash equivalents as of December 31, 2008

Table of Contents

from December 31, 2007 primarily was attributable to the following: (i) a decrease of $17.0 million, reflecting the $10.0 million initial consideration paid in the Avecia Acquisition and the related funding of the $7.0 million letter of credit, (ii) a decrease of $13.2 million for the funding of operations; (iii) a decrease of $6.3 million reflecting the funding of restricted cash obligations per our amended loan agreement with Silicon Valley Bank and Oxford Finance Corporation, (iv) a decrease of $4.0 million relating to the repayment of debt, and (v) an increase of $12.7 million in connection with the issuance of common stock and warrants as described below. Our short-term investments were $3.2 million and $12.2 million at December 31, 2008 and 2007, respectively.

On October 10, 2008, in exchange for gross proceeds of $13.1 million, we sold and issued to a subsidiary of Panacea Biotec 3,733,334 shares of our common stock and a 12-month warrant to purchase up to 2,745,098 additional shares of our 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 our issued and outstanding common stock as of such exercise date).

Operating Activities

Net cash used in operating activities was $13.2 million and $13.6 million for the years ended December 31, 2008 and 2007, respectively. Cash used in operations during the year ended December 31, 2008 reflects a net loss after the effect of non-cash adjustments of $14.8 million, an increase in accounts receivable of $2.2 million, and an increase in accrued expenses and accounts payable of $4.1 million. Non-cash adjustments for the year ended December 31, 2008 included a charge to expense of acquired in-process research and development of $16.1 million as a result of the Avecia Acquisition, non-cash stock compensation expense of $3.0 million and non-cash interest expense of $1.8 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™ and compliance-related, bid and proposal and litigation expenses.

Cash used in operations in 2007 reflects a net loss after the effect of non-cash adjustments of $13.8 million and an increase in accounts receivable of $3.6 million partially offset by an increase in accrued expenses and accounts payable of $3.4 million. Non-cash adjustments for the year ended December 31, 2007 included a $2.4 million credit that resulted from the cancellation of Former PharmAthene's preferred stock warrants, a $0.9 million gain on the extinguishment of debt, a $0.6 million mark to market gain on derivative instruments and stock compensation expense of $1.7 million. Accounts receivable increased due to contract award receivables due from the DoD related to increased activities related to the advanced development of Protexia®. Accounts payable and accrued expenses increased due to approximately $1.1 million in increased development activities, approximately $0.5 million for performance-based employee bonuses, approximately $0.4 million of deferred rent expenses related to the Company's newly leased office space and approximately $0.8 million in increased legal and other administrative activities.

Investing Activities

Net cash used in investing activities was $10.1 million for the year ended December 31, 2008 as compared to $12.9 million for the year ended December 31, 2007. During the year of 2008, we paid $10 million to Avecia and funded a $7 million letter of credit in connection with the Avecia Acquisition. Additionally, we 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

Table of Contents

obligations pursuant to the Loan Modification Agreement, approximately a net $9.0 million of available-for-sale securities were sold.

Net cash used in investing activities of $12.9 million for the year ended December 31, 2007 resulted primarily from the fourth quarter 2007 purchase of approximately $12.1 million of available-for-sale securities. The remaining $0.8 million of investing activities for the period ended December 31, 2007 related to the

purchase of property and equipment.

Financing Activities

Net cash provided by financing activities was $2.4 million for the year ended December 31, 2008 as compared to $61.9 million for the year ended December 31, 2007. As noted above, we issued 3,733,334 of common stock for net proceeds of $12.7 million in the fourth quarter of 2008. Additionally, we made principal repayments of $4.0 million under outstanding credit facilities for the year ended December 31, 2008.

We are 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, we borrowed $10 million, which bears interest at an annual rate of 11.5%. The Loan Agreement contains customary affirmative and negative covenants which, among other things, restrict our ability to undertake certain acquisitions, incur certain indebtedness or make certain investments. As a consequence, we 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. We have made cumulative principal repayments of $5.0 million through December 31, 2008.

Net cash provided by financing was $61.9 million for the year ended December 31, 2007. Financing resulted from the $57.9 million of proceeds from the reverse merger with HAQ, and the $10 million credit facility, partially offset by $4.7 million in merger related costs and debt repayment of $1.2 million.

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 above, we received net proceeds of approximately $12.7 million from the investment by Panacea Biotec's subsidiary in October 2008, and 5.5 million from our registered offering of securities in March 2009. However, as a result of our continuing losses and our continuing obligations, including those under the agreements relating to the Avecia Acquisition, without additional funding through contracts and grants with the U.S. or foreign governments, we would need to identify additional financing within the next 12 months. 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

Table of Contents

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

Our requirements for additional capital may be substantial and will be dependent on many factors, including the success of our research and development efforts, our ability to commercialize and market products, our ability to successfully pursue our licensing and collaboration strategy, the receipt of continued government funding, competing technological and marketing developments, costs associated with the protection of our intellectual property, and any future change in our business strategy.

Off-Balance Sheet Arrangements

We have entered into facility and equipment operating lease agreements. Our obligations under these agreements are presented in this section under "Contractual Obligations."

Contractual Obligations

The following are contractual commitments at December 31, 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	$ 4,134,400	$ 661,400	$ 1,060,400	$ 845,300	$ 1,567,300
Research and development agreements	18,189,800	11,945,200	6,244,600	—	—
Notes payable, including interest	19,471,400	18,795,100	676,300	—	—
Total contractual obligations	$ 41,795,600	$ 31,401,700	$ 7,981,300	$ 845,300	$ 1,567,300

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Our exposure to market risk is currently confined to our cash and cash equivalents, restricted cash and short-term investments. We believe that any interest rate change related to our investment securities held as of December 31, 2008 is not material to our consolidated financial statements. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. Our debt is at rates fixed by the lenders. Due to the short-term nature of our debt, we do not believe an increase in the market rates would have a significant impact to our consolidated financial statements.

Item 8. Financial Statements and Supplementary Data.

Our financial statements and supplementary data required to be filed pursuant to this Item 8 appear in a separate section of this report beginning on page F-1.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Table of Contents

Item 9A. 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) and Rule 15d-15 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 Annual Report on Internal Control Over Financial Reporting

Our 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. Our 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. Our 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 our 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 our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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 our internal control over financial reporting as of December 31, 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*.

Based on this assessment, management determined that we maintained effective internal control over financial reporting as of December 31, 2008.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm, Ernst & Young LLP, regarding internal control over financial

Table of Contents

reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this annual report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Internal Control

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.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be incorporated by reference from our definitive proxy statement or will be filed as an amendment to our Annual Report on Form 10-K within 120 days of our fiscal year end.

Item 11. Executive Compensation.

The information required by this Item 11 will be incorporated by reference from our definitive proxy statement or will be filed as an amendment to our Annual Report on Form 10-K within 120 days of our fiscal year end.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be incorporated by reference from our definitive proxy statement or will be filed as an amendment to our Annual Report on Form 10-K within 120 days of our fiscal year end.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be incorporated by reference from our definitive proxy statement or will be filed as an amendment to our Annual Report on Form 10-K within 120 days of our fiscal year end.

Table of Contents

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be incorporated by reference from our definitive proxy statement or will be filed as an amendment to our Annual Report on Form 10-K within 120 days of our fiscal year end.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)

(1) Financial Statements

Reference is made to the Index to the Consolidated Financial Statements beginning on page F-1 of this report.

(2) Financial Statement Schedules

None.

(b) Exhibit Index

Table of Contents

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated January 19, 2007, by and among Healthcare Acquisition Corp., PAI Acquisition Corp., and PharmAthene, Inc. (6)
2.2	Sale and Purchase Agreement, dated March 20, 2008, by and among the Registrant and Avecia Investments Limited, Avecia Biologics Limited and Avecia Biologics, Inc. (10)
2.3	Amendment Agreement, dated April 2, 2008, by and among, PharmAthene, Inc., PharmAthene UK Limited and PharmAthene US Corporation and Avecia Investments Limited, Avecia Biologics Limited and Avecia Biologics, Inc. (12)
3.1.1	Amended and Restated Certificate of Incorporation. (8)
3.1.2	Certification of Amendment to Amended and Restated Certificate of Incorporation. (14)
3.2	By-laws, as amended. (13)
4.1	Specimen Unit Certificate. (1)
4.2	Specimen Common Stock Certificate. (9)
4.3	Specimen Warrant Certificate. (1)
4.4	Form of Warrant Agreement between Continental Stock Transfer & Trust Company and the Registrant. (3)
4.5	Form of Note Exchange Agreement. (6)
4.6	Form of 8% Convertible Note of Healthcare Acquisition Corp. (6)
4.7	Amendment to Unit Purchase Option by and between the Registrant and Maxim Partners, LLC dated January 28, 2007. (7)
4.8	Warrant Clarification Agreement by and between the Registrant and Continental Stock Transfer & Trust Company, dated January 23, 2007. (7)
10.1.1	Letter Agreement among the Registrant, Maxim Group LLC and John Pappajohn dated May 6, 2005. (2)
10.1.2	Letter Agreement among the Registrant, Maxim Group LLC and Derace L. Schaffer, M.D. dated May 6, 2005. (2)
10.1.3	Letter Agreement among the Registrant, Maxim Group LLC and Matthew P. Kinley dated May 6, 2005. (2)
10.1.4	Restated Letter Agreement among the Registrant, Maxim Group LLC and Edward B. Berger dated June 8, 2005. (3)

Exhibit No.	Description
10.1.5	Letter Agreement among the Registrant, Maxim Group LLC and Wayne A. Schellhammer dated June 8, 2005. (3)
10.2	Form of Investment Management Trust Agreement between Continental Stock Transfer & Trust Company and the Registrant. (3)
10.2.1	Amendment No. 1 to of Investment Management Trust Agreement between Continental Stock Transfer & Trust Company and the Registrant. (5)
10.3	Form of Stock Escrow Agreement between the Registrant, Continental Stock Transfer & Trust Company and the Initial Stockholders. (3)
10.4	Form of Registration Rights Agreement among the Registrant and the Initial Stockholders. (1)
10.5.1	Office Services Agreement by and between the Registrant and Equity Dynamics, Inc. (1)
10.5.2	Office Services Agreement by and between the Registrant and The Lan Group. (1)
10.6.1	Promissory Note, dated April 28, 2005, issued to John Pappajohn, in the amount of $70,000. (1)
10.6.2	Promissory Note, dated April 28, 2005, issued to Derace L. Schaffer, M.D., in the amount of $70,000. (1)
10.6.3	Promissory Note, dated April 28, 2005, issued to Matthew P. Kinley, in the amount of $35,000. (1)
10.6.4	Promissory Note, dated July 26, 2005, issued to John Pappajohn, in the amount of $30,000. (4)
10.6.5	Promissory Note, dated July 26, 2005, issued to Derace L. Schaffer, M.D., in the amount of $30,000. (4)
10.6.6	Promissory Note, dated July 26, 2005, issued to Matthew P. Kinley, in the amount of $15,000. (4)
10.7	Form of Unit Option Purchase Agreement between the Registrant and Maxim Group LLC. (3)
10.8	Form of Warrant Purchase Agreement by and between the Registrant, Maxim Group LLC and the Initial Stockholders. (2)
10.9	Form of Registration Rights Agreement by and among Healthcare Acquisition Corp. and the former stockholders and note holders of PharmAthene, Inc. (6)

Exhibit No.	Description
10.10	Stock Escrow Agreement, dated August 3, 2007, by and among the Registrant, a representative of the former stockholders and option holders of the Registrant and Continental Stock Transfer and Trust Company. (11)
10.11	Advisory Agreement by and among Maxim Group LLC and the Registrant, dated January 8, 2007. (7)
10.12	Amended and Restated 2007 Long-Term Incentive Compensation Plan. (15)
10.13	Employment Agreement, dated August 3, 2007, between the Registrant and David P. Wright. (8)
10.14	Employment Agreement, dated December 22, 2006, between the Registrant and Christopher C. Camut. (9)
10.15	Employment Agreement, dated November 3, 2003, between the Registrant and Francesca Marie Cook. (9)
10.16	Employment Agreement, dated November 3, 2003, between the Registrant and Eric Ian Richman. (9)
10.17	Employment Agreement, dated November 3, 2003, between the Registrant and Valerie Dean Riddle. (9)
10.18	Employment Agreement, dated January 31, 2005, between the Registrant and Wayne Morges. (9)
10.19.1	Loan and Security Agreement, dated March 30, 2007, by and among the Registrant, Silicon Valley Bank, Oxford Finance Corporation, and other lenders listed on Schedule 1.1 thereof. (9)
10.19.2	Consent and First Loan Modification Agreement, dated March 20, 2008, by and among the Registrant, Silicon Valley Bank and Oxford Finance Corporation (10).
10.20	U.S. Army Space & Missile Defense Command—"Development and Licensure of Bioscavanger Increment II (Recombinant Drug Candidate)" Award/Contract No. W9113M-06-C-0189, dated September 22, 2006, by and between the Company and the U.S. Army Space & Missile Defense Command. (9)+
10.21	Cooperative Research and Development Agreement, dated September 12, 2006, by and between the Company and the U.S. Army Medical Research Institute of Infectious Diseases. (9)+
10.22	Center for Scientific Review, National Institute of Health, Research Project Cooperative Agreement, Notice of Grant Award No. 1 U01 NS058207-01, dated September 30, 2006, awarded to the Company. (9)+
10.23	Collaboration Agreement, dated November 29, 2004, by and between the Company and Medarex, Inc. (9)+

Exhibit No.	Description
10.24	Research and License Agreement, dated August 8, 2006, by and between the Company and Nektar Therapeutics AL, Corporation. (9)+
10.25	License Agreement, dated March 12, 2007, by and between the Company and GTC Biotherapeutics, Inc. (9)+
10.26.1	Office Lease, dated September 14, 2006, by and between the Company and Park Place Trust, as amended by First Amendment to Office Lease, dated January 22, 2007. (9)
10.26.2	Second Amendment to Office Lease, by and between the Company and Park Place Trust, dated September 16, 2008. (19)
10.27	Biopharmaceutical Development and Manufacturing Services Agreement, dated June 15, 2007, by and between the Company and Laureate Pharma, Inc. (9)+
10.28	Services Agreement, dated March 2, 2007, by and between the Company and GTC Biotherapeutics, Inc. (9)+
10.29	Transitional Services Agreement, dated April 2, 2008, between Avecia Biologics Limited and PharmAthene UK. (16)
10.30	Form of PharmAthene Inc. Executive Employment Agreement. (17)
10.31	Form of PharmAthene Inc. Confidentiality and Non-Solicitation Agreement. (17)
10.32	Master Services Agreement, dated April 2, 2008, between PharmAthene UK Limited and Avecia Biologics Limited. (17) +
10.33	Master Service Agreement, dated December 15, 2004, between Avecia Limited and the Secretary of State for Defence, acting through the Defence Science and Technology Laboratory (DSTL). (18)+
10.34	Master Service Agreement, dated August 18, 2005, between Avecia Limited and DSTL. (18) +
10.35	Manufacturing Licence Agreement, dated June 20, 2006, between Avecia Limited and DSTL. (18) +
10.36	Manufacturing and Marketing Licence Agreement, dated December 4, 2006, between Avecia Limited and DSTL. (18) +
10.37	Letter Agreement, dated March 20, 2008, between Avecia Biologics Limited and DSTL. (18)+
10.38	Contract Award by the National Institute of Allergy and Infectious Diseases (NIAID), dated September 25, 2008. (19)+

Exhibit No.	Description
10.39	Securities Purchase Agreement, dated September 30, 2008, between PharmAthene, Inc. and Kelisia Holdings Ltd. (19)
10.40	Letter Agreement, dated September 30, 2008, between PharmAthene, Inc. and Panacea Biotec, Ltd. (19)
10.41	Investor Rights Agreement, dated October 10, 2008, between PharmAthene Inc. and Kelisia Holdings Ltd. (19)
10.42	Common Stock Purchase Warrant, dated October 10, 2008 in favor of Kelisia Holdings Ltd. (19)
10.43	Deed of Confidentiality between PharmAthene UK Limited, and its employees. (19)
10.44	Contract with the National Institutes of Health for the Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine (#N01-AI-30052) (“NIH Prime Contract-Anthrax”), dated September 29, 2003 *, +
10.45	Amendments 1 through 13 to the NIH Prime Contract-Anthrax *, **, +
10.46	Contract with the National Institutes of Health for the Development, Testing and Evaluation of Candidate Vaccines Against Plague (#HSSN266200400034C) (“NIH Prime Contract-Plague”), dated September 30, 2004 *, +
10.47	Amendments 1 through 10 to the NIH Prime Contract-Plague *, **, +
14	Code of Ethics. (3)
21	Subsidiaries. *
23	Consent of Ernst & Young LLP Independent Registered Public Accounting Firm*
31.1	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a).
31.2	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a).
32.1	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.
32.2	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.
	*****

(1) Incorporated by reference to the Registration Statement on Form S-1 of the Registrant filed on May 6, 2005.

Table of Contents

(2) Incorporated by reference to the Registration Statement on Form S-1/A of the Registrant filed on June 10, 2005.

(3) Incorporated by reference to the Registration Statement on Form S-1/A of the Registrant filed on July 12, 2005.

(4) Incorporated by reference to the Registration Statement on Form S-1/A of the Registrant filed on July 27, 2005.

(5) Incorporated by reference to the Quarterly Report on Form 10-Q filed by the Registrant on November 14, 2005.

(6) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on January 22, 2007.

(7) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on January 25, 2007.

(8) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on August 9, 2007.

(9) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on September 24, 2007.

(10) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on March 26, 2008.

(11) Incorporated by reference to the Annual Report on Form 10-K filed by the Registrant on March 31, 2008.

(12) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on April 8, 2008.

(13) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on May 2, 2008.

(14) Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on June 19, 2008.

(15) Incorporated by reference to Appendix B to the Proxy Statement on Schedule 14A filed by the Registrant on May 15, 2008.

(16) Incorporated by reference to the Current Report on Form 8-K/A filed by the Registrant on June 18, 2008.

(17) Incorporated by reference to the Quarterly Report on Form 10-Q filed by the Registrant on August 14, 2008.

Table of Contents

(18) Incorporated by reference to the Amendment to the Quarterly Report on Form 10-Q/A filed by the Registrant on August 19, 2008.

(19) Incorporated by reference to the Quarterly Report on Form 10-Q filed by the Registrant on November 14, 2008.

* Filed herewith.

** Amendments No. 2 and 5 to the NIH Prime Contract-Anthrax have been superseded in full by subsequent amendments filed herewith and are therefore omitted. Amendment No. 12 to the NIH Prime Contract-Anthrax and Amendment No. 8 to the NIH Prime Contract-Plague were never executed and are therefore omitted.

\+ Certain confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

(c) Financial Statements and Schedules of Subsidiaries and Affiliates

None.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the city of Annapolis, State of Maryland, on the 31st day of March, 2009.

PHARMATHENE, INC.

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

POWER OF ATTORNEY

BY THESE PRESENTS, each person whose signature appears below constitutes and appoints David P. Wright, Christopher C. Camut, and Jordan P. Karp his true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and

Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David P. Wright David P. Wright	Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2009
/s/ Christopher C. Camut Christopher C. Camut	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2009
/s/ John Pappajohn John Pappajohn	Chairman of the Board	March 31, 2009
/s/ John Gill John Gill	Director	March 31, 2009
/s/ James H. Cavanaugh James H. Cavanaugh	Director	March 31, 2009

Table of Contents

/s/ Steven St. Peter Steven St. Peter	Director	March 31, 2009
/s/ Derace Schaffer, MD Derace Schaffer, MD	Director	March 31, 2009
/s/ Joel McCleary Joel McCleary	Director	March 31, 2009

Table of Contents

PHARMATHENE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders of PharmAthene, Inc.

We have audited the accompanying consolidated balance sheets of PharmAthene, Inc. and subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, convertible redeemable preferred stock and stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of PharmAthene, Inc. and subsidiaries at December 31, 2008 and 2007, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

McLean, Virginia
March 30, 2009

Table of Contents

PHARMATHENE, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,752,404	$ 40,582,643
Restricted Cash	12,000,000	—
Short-term investments	3,190,912	12,153,945
Accounts receivable	8,890,077	4,005,694
Other receivables	1,391,512	1,240,069
Prepaid expenses and other current assets	917,125	492,294
Total current assets	46,142,030	58,474,645
Long-term restricted cash	1,250,000	—
Property and equipment, net	5,313,219	6,571,024
Patents, net	925,489	1,312,991
Other long term assets	220,531	183,588
Deferred costs	37,092	68,884
Goodwill	2,502,909	—
Total assets	$ 56,391,270	$ 66,611,132
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 3,870,871	$ 1,393,664
Accrued expenses and other liabilities	14,624,757	3,602,886
Convertible notes	13,377,505	—
Current portion of long term debt	4,000,000	4,000,000
Total current liabilities	35,873,133	8,996,550
Other long term liabilities	626,581	374,040
Long-term debt	928,117	16,668,458
Total liabilities	37,427,831	26,039,048
Stockholders' equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized; 25,890,143 and 22,087,121 shares issued and outstanding at December 31, 2008 and 2007, respectively;	2,589	2,209
Additional paid-in capital	142,392,163	126,490,647
Accumulated other comprehensive income	386,351	1,481,779
Accumulated deficit	(123,817,664)	(87,402,551)
Total stockholders' equity	18,963,439	40,572,084
Total liabilities and stockholders' equity	$ 56,391,270	$ 66,611,132

See the accompanying notes to the consolidated financial statements.

Table of Contents

PHARMATHENE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31, 2008	Year ended December 31, 2007
Contract revenue	$ 32,821,526	$ 14,624,595
Other revenue	89,802	19,020
	32,911,328	14,643,615

Operating expenses:		
Research and development	31,812,431	16,559,670
General and administrative	19,397,532	13,882,023
Acquired in-process research and development	16,131,002	—
Depreciation and amortization	813,891	705,370
Total operating expenses	68,154,856	31,147,063
Loss from operations	(35,243,528)	(16,503,448)
Other income (expense):		
Interest income	1,225,471	1,122,565
Gain on extinguishment of debt	—	886,963
Other income	58,106	—
Interest expense	(2,573,406)	(2,122,624)
Change in market value of derivative instruments	118,244	3,029,241
Total other (expense) income	(1,171,585)	2,916,145
Net loss	(36,415,113)	(13,587,303)
Accretion of redeemable convertible preferred stock to redemptive value	—	(4,133,733)
Net loss attributable to common shareholders	$ (36,415,113)	$ (17,721,036)
Basic and diluted net loss per share	$ (1.59)	$ (1.88)
Weighted average shares used in calculation of basic and diluted net loss per share	22,944,066	9,442,885

See the accompanying notes to the consolidated financial statements.

Table of Contents

PHARMATHENE, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY

	Convertible Redeemable Preferred Stock								Stockholders' Equity			
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of 12/31/2006	16,442,000	$19,130,915	30,448,147	$31,780,064	14,946,479	$14,480,946	621,281	$ 63	$ —	$ 63,954	$(69,851,819)	(69,787,802)
Net loss	—	—	—	—	—	—	—	—	—	—	(13,587,303)	(13,587,303)
Mark to market of available for sale securities	—	—	—	—	—	—	—	—	—	(99,250)		(99,250)
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	1,517,075	—	1,517,075
Comprehensive loss	—	—	—	—	—	—	—	—	—	1,417,825	—	(12,169,478)
Exercise of common stock options	—	—	—	—	—	—	62	—	13	—	—	13
Accrual of Series A dividends	—	912,090	—	—		—	—	—	(181,477)	—	(730,613)	(912,090)
Accretion of Series A issuance costs	—	12,429	—	—	—	—	—	—	—	—	(12,429)	(12,429)
Accretion of Series A deemed dividend	—	65,434	—	—	—	—	—	—	—	—	(65,434)	(65,434)
Accrual of Series B dividends	—	—	—	1,555,577	—	—	—	—	—	—	(1,555,577)	(1,555,577)
Accretion of Series B issuance costs	—	—	—	24,420	—	—	—	—	—	—	(24,420)	(24,420)

Table of Contents

	Convertible Redeemable Preferred Stock				Stockholders' Equity			
	Series A	Series B	Series C	Common Stock	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Stockholders'

	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Equity
Accretion of common stock purchase warrants	—	—	—	241,305	—	—	—	—	—	—	(241,305)	(241,305)
Accrual of Series C dividends	—	—	—	—	—	738,983	—	—	—	—	(878,293)	(878,293)
Accretion of Series C issuance costs	—	—	—	—	—	56,875	—	—	—	—	(56,875)	(56,875)
Accretion of common stock purchase warrants	—	—	—	—	—	36,893	—	—	—	—	(43,404)	(43,404)
Accretion of preferred stock purchase warrants	—	—	—	—	—	301,818	—	—	—	—	(355,079)	(355,079)
Conversion of stock resulting from reverse merger	(16,442,000)	(20,120,868)	(30,448,147)	(33,601,366)	(14,946,479)	(15,615,515)	—	—	72,284,048	—	—	72,284,048
Issuance of common stock							21,465,778	2,146	57,884,045	—	—	57,886,191
Merger acquisition costs									(5,279,591)			(5,279,591)
Stock compensation	—	—	—	—	—	—	—	—	1,783,609	—	—	1,783,609
Balance as of 12/31/2007	—	$ —	—	$ —	—	$ —	22,087,121	$ 2,209	$126,490,647	$ 1,481,779	$(87,402,551)	40,572,084
Net loss	—	—	—	—	—	—	—	—	—	—	(36,415,113)	(36,415,113)
Mark to market of short term investments	—	—	—	—	—	—	—	—	—	82,567		82,567
Foreign currency translation adjustment	—	—	—	—	—	—	—	—	—	(1,177,995)		(1,177,995)
Comprehensive loss	—	—	—	—	—	—	—	—	—	(1,095,428)		(37,510,541)

Table of Contents

	Convertible Redeemable Preferred Stock								Stockholders' Equity			
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Employee vesting of restricted shares							69,688	7	(7)			
Issuance of common stock, net issuance costs of $406,070							3,733,334	373	12,660,069			12,660,442
Merger acquisition costs									200,308			200,308
Stock compensation									3,041,146			3,041,146
Balance as of 12/31/2008	—	$ —	—	$ —	—	$ —	25,890,143	$ 2,589	$142,392,163	$ 386,351	$(123,817,664)	$18,963,439

See the accompanying notes to the consolidated financial statements.

Table of Contents

PHARMATHENE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2008	2007
Operating activities		

Net loss	$ (36,415,113)	$ (13,587,303)
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	(118,244)	(3,029,241)
Extinguishment of debt	—	(886,963)
Depreciation and amortization	813,891	655,210
Compensation expense related to restricted shares and stock options	3,041,146	1,783,609
Non cash interest expense on debt	1,755,408	1,246,754
Changes in operating assets and liabilities:		
Accounts receivable	(2,195,580)	(3,631,770)
Prepaid expenses and other current assets	(266,403)	422,576
Other assets	(21,161)	24,924
Accounts payable	(60,704)	564,426
Accrued expenses	4,137,184	2,801,066
Net cash used in operating activities	(13,198,574)	(13,636,712)
Investing activities		
Purchases of property and equipment	(509,315)	(882,345)
Purchase of Avecia, net of cash acquired	(11,556,117)	—
Purchase of letter of credit	(7,000,000)	—
Purchases of short term investments	(17,169,388)	(12,054,695)
Proceeds from sales of short term investments	26,132,421	—
Net cash used in investing activities	(10,102,399)	(12,937,040)
Financing activities		
Net proceeds from reverse merger with Healthcare Acquisition Corp	—	57,907,248
Proceeds from stock options exercised	—	13
Proceeds from issuance of debt	—	9,904,622
Payments of debt obligations	(4,000,000)	(1,192,694)
Increase of restricted cash requirements	(6,250,000)	—
Net proceeds from issuance of common stock	12,660,442	—
Financing costs	—	(4,692,011)
Net cash provided by financing activities	2,410,442	61,927,178
Effects of exchange rates on cash	60,292	117,005
(Decrease) increase in cash and cash equivalents	(20,830,239)	35,470,431
Cash and cash equivalents, at beginning of year	40,582,643	5,112,212
Cash and cash equivalents, at end of year	$ 19,752,404	$ 40,582,643
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 800,481	$ 867,526

See the accompanying notes to the consolidated financial statements.

Table of Contents

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.” Through February 27, 2009, our operations were conducted by our wholly-owned subsidiary, PharmAthene US Corporation. Effective February 27, 2009, PharmAthene US Corporation was merged with and into PharmAthene, Inc., with PharmAthene, Inc. being the surviving 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 (the “Avecia 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 SparVaxTM, a recombinant dual antigen plague vaccine (“rYP”) which is now referred to as RypVaxTM, and a third generation rPA anthrax vaccine program. 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 audited consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States.

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.

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 Income

The Company reports comprehensive income 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, a separate component of stockholders' equity.

Additionally, all unrealized gains and losses on short term investments are included in comprehensive loss. Comprehensive loss for each of the twelve month periods ended December 31, 2008 and 2007 was approximately $37.5 million and $12.2 million, respectively.

Foreign currency translation

The functional currency of the Company's wholly owned foreign subsidiaries located in Canada and the United Kingdom are their local currency. Assets and liabilities of the foreign subsidiaries are translated to United States dollars based on exchange rates at the end of the reporting period. Income and expense items are translated at the weighted average exchange rates prevailing during the reporting period. Translation adjustments are accumulated in a separate component of stockholder's equity. Translation gains or losses are included in the determination of operating results.

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 $1.2 million and $1.1 million for the years ended December 31, 2008 and 2007, 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 fully disclosed in Note 9, 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 December 31, 2008, the Company recorded $5.0 million and $1.3 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 December 31, 2008, the letter of credit is shown on the balance sheet as short-term restricted cash and is included in accrued expenses and other current liabilities as it is due to Avecia in October 2009.

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 U.S. and global market conditions. We assess the risk of impairment related to securities held in our investment portfolio on

a regular basis and noted no impairment during the year ended December 31, 2008. Additionally, the Company's Audit Committee reviews the investment portfolio and strategy on an annual basis.

Table of Contents

Significant Customers and Accounts Receivable

The Company's primary customers are the U.S. Department of Defense (the "DoD"), the National Institute of Allergy and Infectious Diseases ("NIAID"), the Biomedical Advanced Research and Development Authority ("BARDA"), and the National Institute of Health ("NIH"). For the years ended December 31, 2008 and 2007, contract revenues from the DoD and NIAID related to ProtexiaÒ and ValortimÒ comprised 64% and 100%, of total revenues, respectively. Contract revenues related to SparVax™ and RypVax™, acquired during fiscal year 2008, represented 36% of total revenues for the year ended December 31, 2008. As of December 31, 2008 and 2007, the Company's receivable balances were comprised 100% of receivables from these customers. Unbilled accounts receivable, included in accounts receivable, totaling $5.0 million and $3.6 million as of December 31, 2008 and 2007, respectively, related to the contracts with these customers. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from the DoD, NIAID and NIH as well as amounts due under reimbursement contracts with other government entities.

While the Company has a policy to provide an allowance for any amount of accounts receivable which it determines to be uncollectible and the Company will write off any uncollectible account when the likelihood of that account's 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.

Other Receivables

Other receivables include Quebec provincial and Canadian Federal credits for internally and externally generated research and development expenditures and value added taxes due from the United Kingdom.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents, investments and accounts receivable. The Company maintains its cash, cash equivalent and 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 any or all of the U.S. government, the Canadian government or the United Kingdom government.

Property and Equipment

Property and equipment consist 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

Table of Contents

Intangible Assets

Patents are carried at cost less accumulated amortization which is calculated on a straight line basis over the estimated useful lives of the patents. The Company periodically reviews the carrying value of patents to determine whether the carrying amount of the patents is recoverable. For the years ended December 31, 2008, and 2007, there were no adjustments to the carrying values of the patents. The Company is amortizing the cost of the patents over an 11 year period.

Goodwill represents the excess of purchase price over the fair value of net identifiable assets associated with the Avecia Acquisition further described in Note 3. The Company reviews the carrying value of goodwill for impairment annually during the fourth quarter or more frequently if impairment indicators exist. Evaluating goodwill for impairment requires management judgment, including the estimation of future cash flows, future growth rates and profitability and the expected life over which cash flows will occur. Changes in the Company's business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of goodwill over its estimated fair value. For the year ended December 31, 2008, the Company determined that there was no impairment of goodwill.

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. For the year ended December 31, 2008, the Company determined that there was no impairment of long lived assets.

Accrued expenses

Management is required to estimate accrued expenses as part of the process of preparing financial statements. The estimation of accrued expenses involves identifying services that have been performed on the Company's behalf, and estimating the level of services performed and the associated cost incurred for such services as of each balance sheet date in the financial statements. Accrued expenses include professional service fees, such as fees paid to lawyers and accountants, contract service fees, such as those under contracts with clinical research organizations and investigators in conjunction with clinical trials, and fees to contract manufacturers in conjunction with the production of clinical materials. Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, the Company

recognizes these expenses as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management's judgment.

Table of Contents

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 years ended December 31, 2008 and 2007, respectively, the Company recorded approximately $2.2 million and $0.2 million of costs reimbursed from the government as a reduction to research and development expense as they are viewed as a 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 milestones 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.

In September 2006, the Company was awarded a multi-year cost reimbursement contract valued at up to $219 million from the Department of Defense Army Space and Missile Command for advanced development of the Company's broad spectrum chemical nerve agent prophylaxis, Protexia®. The Department of Defense has allocated $40.5 million for the initial stage of development, including manufacturing process development, preclinical and toxicity testing activities, of this contract. The Company recognized $19.5 million and $14.5 million of revenue on this contract for the years ended December 31, 2008 and 2007, respectively.

On September 28, 2007, PharmAthene was awarded a contract for the advanced development of Valortim® from the National Institute of Allergy and Infectious diseases ("NIAID") and the Biomedical Advanced Research and Development Authority ("BARDA"). This approximately $13.9 million contract supports the development of Valortim® for use as an anti-toxin therapeutic to treat inhalation anthrax infection. The contract will be incrementally funded through fiscal year 2009. The Company recognized $1.4 million and $0.1 million of revenue on this contract for the years ended December 31, 2008 and 2007, respectively.

Table of Contents

On September 25, 2008, PharmAthene was awarded a contract by the National Institutes of Health, NIAID for additional development work on its third generation rPA anthrax vaccine. NIAID has allocated $13.2 million for the initial stages of development work. 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 under this contract. The Company recognized $0.1 million of revenue on this contract for the year ended December 31, 2008.

As part of the Avecia Acquisition, the Company acquired contracts for the development of a anthrax vaccine SparVax™ and for the advanced development of a plague vaccine RypVax™. The Company has recognized revenue of $9.2 million and $2.7 on these programs, respectively for year ended December 31, 2008.

Research and Development and 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 December 31, 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. Acquired in-process research and development had no alternative future use and was expensed for $16.1 million as fully disclosed in Note 3.

Share-Based Compensation

The Company accounts for its stock-based compensation plans using the fair value recognition provisions of Statement of Financial Accounting Standards No. 123 (R), *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.

Table of Contents

Employee share-based compensation expense recognized in the years ended December 31, 2008 and 2007 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures at a rate of approximately 17% and 19%, respectively, for stock options, and 7% for restricted shares, 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 years ended December 31, 2008 and 2007, respectively, was:

	Year ended December 31,	
	2008	2007
Research and development	$ 587,957	$ 431,847
General and administrative	2,453,189	1,351,762
Total share-based compensation expense	$ 3,041,146	$ 1,783,609
Share-based compensation expense, per common share		
Basic and diluted	$ 0.13	$ 0.19

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 19,014,000 and 14,673,000 shares for the years ended December 31, 2008 and 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:

	Year ended December 31,	
	2008	2007
Numerator:		
Net loss	$ (36,415,113)	$ (13,587,303)
Dividends on and accretion of convertible preferred stock	—	(4,133,733)
Net loss available to common stockholders	$ (36,415,113)	$ (17,721,036)
Denominator:		
Weighted-average shares of common stock outstanding-basic and diluted	22,944,066	9,442,885

Table of Contents

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 ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes- and Interpretation of FASB Statement No. 109* ("FIN 48") on January 1, 2007. The Company has analyzed tax positions in all jurisdictions where we are required to file an income tax return and we have concluded that we do not have any material unrecognized tax benefits. As a result, there were no material effects on our financial position or results of operations due to the implementation of FIN 48. As of December 31, 2008, the Company had 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 U.S. 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 by any tax jurisdiction since its inception. Accordingly, all income tax returns filed by the Company are subject to examination by taxing jurisdictions.

The Company's 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 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.

Reclassifications

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

Table of Contents

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 as early adoption is not allowed. The Company will adopt SFAS 141R for business combinations entered into after December 31, 2008.

In June 2008, the FASB issued EITF 07-5, "*Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*" ("EITF 07-5"). EITF 07-5 provides guidance in assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock for purposes of determining whether the appropriate accounting treatment falls under the scope of SFAS 133, "Accounting For Derivative Instruments and Hedging Activities" and/or EITF 00-19, "Accounting For Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock". EITF 07-5 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and early application is not permitted. We have not yet determined what, if any, effect EITF 07-5 will have on our results of operations or financial condition.

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 Financial 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 purchase price was allocated as follows:

(in thousands)		
Current assets	$	5,340
Current liabilities		(5,418)
Goodwill		2,503
In-process research and development		16,131
Total purchase consideration	$	18,556

In connection with the transaction, the Company recorded, a charge of $16.1 million for acquired research projects associated with products in development for which, at the

Table of Contents

acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed.

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 year ended December 31, 2007 combines the historical results for PharmAthene for the year ended December 31, 2007 and the historical results for Avecia for the same period. The audited financial information for the year ended December 31, 2008 reflects the operations of the consolidated company post-acquisition.

	Year ended December 31,			
(in thousands, except per share data)	**2008**		**2007**	
	(audited)		**(unaudited)**	
Total revenue	$	32,911	$	50,170
Net loss attributable to common stockholders		36,415		17,542
Basic and diluted net loss per share	$	1.59	$	1.86

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.

Table of Contents

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. 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 December 31, 2008, financial assets and liabilities subject to fair value measurements were as follows:

	As of December 31, 2008			
	Level 1	Level 2	Level 3	Balance
Assets				
Available-for-sale securities	$ 3,190,912	$ —	$ —	$ 3,190,912
Liabilities				
Derivative	$ —	$ 6,405	$	$ 6,405

Note 5 - Short-Term Investments — Available for Sale

The amortized cost, gross unrealized gains, gross unrealized losses and fair value of available-for-sale investments by security classification, all of which are short term, at December 31, 2008 and 2007 were as follows:

December 31, 2008	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Corporate debt securities	$ 3,183,461	$ 7,451	$ —	$ 3,190,912
Government debt securities	—	—	—	—
Total Securities	$ 3,183,461	$ 7,451	$ —	$ 3,190,912
December 31, 2007				
Corporate debt securities	$ 8,084,453	$ 80,450	$ —	$ 8,164,903
Government debt securities	3,970,242	18,800	—	3,989,042
Total Securities	$ 12,054,695	$ 99,250	$ —	$ 12,153,945

During the years ended December 31, 2008 and 2007, respectively, the Company realized loss of approximately $8,700 and $0 on sales of available-for-sale securities. The gains and losses on available-for-sale securities are based on the specific identification method.

Note 6 - Property and Equipment

Property and equipment consisted of the following:

	December 31,	
	2008	2007
Land	$ 449,787	$ 560,081
Building and leasehold improvements	4,841,800	5,670,628
Furniture, farm and office equipment	222,892	219,855
Laboratory equipment	643,332	866,084
Computer equipment	841,185	556,601
	6,998,996	7,873,249
Less accumulated depreciation	(1,685,777)	(1,302,225)
Property and equipment, net	$ 5,313,219	$ 6,571,024

Table of Contents

Depreciation expense for the years ended December 31, 2008 and 2007 was $643,890 and $542,076, respectively.

Note 7 - 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 11 years. The gross carrying value and accumulated amortization, adjusted based on current foreign currency rates, was $1,414,479 and $488,990, respectively, at December 31, 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 years ended December 31, 2008 and 2007, the Company has recorded amortization expense of

$170,001 and $163,294, respectively. Amortization expense related to the above intellectual property is expected to be approximately $128,000 per year for the next five years.

Note 8 - Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following:

	December 31, 2008	December 31, 2007
Accrued development expenses	$ 4,140,072	$ 1,486,918
Accrued professional services	1,149,622	552,098
Accrued employee expenses	936,282	856,659
Deferred consideration - Avecia Acquisition	7,000,000	—
Restructuring liability	—	498,596
Other	1,398,781	208,615
Accrued expenses and other liabilities	$ 14,624,757	$ 3,602,886

Note 9 - Long Term Debt

Convertible 8% Notes

In connection with the Merger, the Company issued convertible 8% notes (the "Notes") in the aggregate principal amount of $12.3 million to Former PharmAthene's noteholders replacing the existing $12.8 million (principal and accrued interest of 8%) Bridge Notes. The original Bridge Notes were entered into in June and August 2006 with certain investors in Former PharmAthene's Series B Redeemable Convertible Preferred Stock and Series C Redeemable Convertible Preferred Stock. The transaction was treated as a debt extinguishment under Emerging Issues Task Force No. 96-19 ("EITF 96-19"). Debtor's Accounting for a Modification or Exchange of Debt Instruments. Under EITF 96-19, the new debt was recorded at fair value with the difference between the new and the old debt recorded as an extinguishment

Table of Contents

in the income statement. This resulted in a gain of approximately $0.9 million for the year ended December 31, 2007. In accordance with EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock, the Company analyzed the conversion feature and determined that it was an embedded derivative that required bifurcation due to the potential for adjustment to the conversion price and considering the contract does not have a fixed or determinable maximum number of shares that may be required to be issued there is the potential that an infinite number of share could be required to settle the contract. The Company is marking to market the derivative and recorded the changes in other income and expense. For the years ended December 31, 2008 and 2007, the Company recorded $0.1 million and $0.6 million, respectively, as a mark-to-market gain relating to the convertible debt.

The 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 $1.7 million and $632,900 on the Notes for the years ended December 31, 2008 and 2007, respectively. The Company recognized interest expense of approximately $557,900 for the year ended December 31, 2007 related to Former PharmAthene's Bridge Notes.

In connection with the Merger, the Company agreed to pay off two of the holders of the Bridge Notes rather than issue new Notes to them. The Company paid $242,694, in the aggregate, to such holders in fulfillment of this obligation in October 2007.

$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 $3.97 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.

Table of Contents

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 $1.3 million in short-term and long-term restricted cash, respectively, in connection with provision (i) above.

The Company has recognized interest expense of approximately $867,600 and $923,400, respectively, for the years ended December 31, 2008 and 2007.

Note 10 - 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:

2009	$	606,800
2010		583,300
2011		404,300
2012		416,400
2013		428,900
2014 and thereafter		1,567,300
	$	4,007,000

For the years ended December 31, 2008 and 2007, total rent expense under operating lease agreements approximated $753,800 and $589,900, 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.

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 U.S. 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 years ended December 31, 2008 and 2007, respectively.

Table of Contents

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 years ended December 31, 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 U.S. 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, and recently amended in February 2009, 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 plague vaccine 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 royalty payments on these licenses have been incurred.

Note 11 - Related Party Transactions

Through July 2007, the Company leased its office space from an entity that was affiliated with the organization to which Former PharmAthene had issued warrants for 263,296 shares of common stock in August 2003. The Company paid $93,386 in rent expense related to this operating lease for the year ended December 31, 2007. The Company relocated to its new office space and the lease with the affiliate entity was terminated. Additionally, in conjunction with the Merger as further discussed is Note 1, these warrants were assumed and converted into 14,180 common stock warrants with an exercise price of $0.19 per share.

Several directors and officers of the Company invested in Former PharmAthene's Bridge Notes in the second and third quarters of 2006. Additionally, an investor in the Company's new office space also invested in Former PharmAthene's Bridge Notes in the second and third quarters of 2006. In connection with the Merger, these Bridge Notes were converted into approximately $248,000 of Notes.

For the year ended December 31, 2007 in connection with the Merger, the Company paid approximately $1.3 million to an investment bank affiliated with one of its directors.

Table of Contents

Note 12 - 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 Valortim® to be used as a therapeutic for individuals with active disease as well as for prophylactic treatment of individuals exposed to anthrax. For the years ended December 31, 2008 and 2007, PharmAthene recorded research and development expenses of approximately $353,700 and $685,700 related to the development activities for Valortim®. 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.

Note 13 - Stockholders' Equity

Common Stock

On October 10, 2008 Kelisia Holdings Ltd., an indirect wholly-owned subsidiary of Panacea Biotec Limited, 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 net proceeds from this transaction of approximately $12.7 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.

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, consultants, officers and directors. 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 each year on the 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 December 31, 2008, an aggregate of 399,682 shares of common stock are reserved for issuance upon the exercise of outstanding assumed awards. The 2002 Plan was not assumed by the Company following the Merger; therefore, no further grants may be made under the 2002 Plan.

Table of Contents

The following tables summarize the activity of the 2002 Plan:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Term
Outstanding, January 1, 2007	404,314	$ 3.64	
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
Exercisable, December 31, 2007	255,444	$ 3.54	7.3 years
Outstanding, January 1, 2008	441,857	$ 3.67	
Granted	—		
Exercised	—		
Forfeited	(42,175)	$ 3.85	
Outstanding, December 31, 2008	399,682	$ 3.57	6.4 years
Exercisable, December 31, 2008	312,324	$ 3.50	6.1 years
Vested and expected to vest, December 31, 2008	333,574		

Range of Exercise Price	Number Outstanding at 12/31/08	Weighted-Average Remaining Term	Weighted Average Exercise Price	Number Exercisable at 12/31/08	Weighted Average Exercise Price
$0.00-$3.00	110,301	4.7 years	$ 2.96	110,301	$ 2.96
$3.01-$5.36	289,381	7.1 years	$ 3.80	202,023	$ 3.80
Total	399,682	6.4 years	$ 3.57	312,324	$ 3.50

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2008 which was $2.30 and (ii) the exercise price of the underlying awards, multiplied by the number of options that had an exercise price less than the closing price on the last trading day of 2008. The aggregate intrinsic value of options outstanding was zero as of December 31, 2008.

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 of which are generally four years, and the exercise price. Options may have a maximum term of no more than ten years.

Table of Contents

As of December 31, 2008, the Company had remaining 791,257 shares available to be granted under the 2007 Plan. The following tables summarize the activity of the 2007 Plan:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Term
Options			
Outstanding, January 1, 2007	—	$ —	
Granted	2,356,867	$ 5.25	
Exercised	—	$ —	
Forfeited	(54,717)	$ 5.20	
Outstanding, December 31, 2007	2,302,150	$ 5.25	9.5 years
Exercisable, December 31, 2007	348,680	$ 5.21	9.5 years
Outstanding January 1, 2008	2,302,150	$ 5.25	
Granted	1,353,250	$ 2.71	
Exercised	—	$ —	
Forfeited	(92,459)	$ 4.80	
Outstanding, December 31, 2008	3,562,941	$ 4.30	9.0 years
Exercisable, December 31, 2008	949,466	$ 5.23	8.8 years
Vested and expected to vest, December 31, 2008	2,973,631		

Range of Exercise Price	Number Outstanding at 12/31/08	Weighted-Average Remaining Term	Weighted Average Exercise Price	Number Exercisable at 12/31/08	Weighted Average Exercise Price
$0.00-$5.00	1,358,500	9.4 years	$ 2.75	11,875	$ 3.78
$5.01-$5.36	2,204,441	8.7 years	$ 5.26	937,591	$ 5.25
Total	3,562,941	9.0 years	$ 4.30	949,466	$ 5.23

The aggregate intrinsic value is calculated as the difference between (i) the closing price of the common stock at December 31, 2008, which was $2.30 per share and (ii) the exercise price of the underlying awards, multiplied by the number of options that had an exercise price less than the closing price on the last trading day of 2008. The aggregate intrinsic value of options outstanding was approximately $15,100 as of December 31, 2008.

The following tables summarize the activity of the 2007 plan for restricted shares:

	Shares	Weighted-Average Grant Price	Weighted-Average Contractual Term
Restricted Shares			
Outstanding, January 1, 2007	—	$ —	
Granted	216,836	$ 5.27	
Vested	—	$ —	

Table of Contents

	Shares	Weighted-Average Grant Price	Weighted-Average Contractual Term
Forfeited	(1,529)	$ 5.20	
Outstanding, December 31, 2007	215,307	$ 5.27	9.9 years
Outstanding, January 1, 2008	215,307	$ 5.27	
Granted	17,500	$ 3.18	
Vested	(69,686)	$ 5.27	
Forfeited	—	$ —	
Outstanding, December 31, 2008	163,121	$ 5.05	8.7 years
Vested and expected to vest, December 31, 2008	151,702	$ 5.05	8.7 years

Range of Exercise Price	Number Outstanding at 12/31/08	Average Remaining Contractual Life in Years	Weighted Average Exercise Price
$ 0.00-$5.00	17,500	9.2	$ 3.18
$ 5.01-$5.36	145,621	8.7	$ 5.28
Total	163,121	8.7	$ 5.05

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:

	December 31, 2008	December 31, 2007
Weighted average volatility	66%	66-72%
Risk-free interest rate	2.2-3.9%	3.7-4.9%
Expected annual dividend yield	—	—
Expected weighted average life, in years	7.0	7.0

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 U.S. 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

Table of Contents

estimate employee exercise and post-vest termination behavior and therefore do not stratify employees into multiple groups.

Determination of Fair Value

Prior to the closing of the Merger, PharmAthene's common stock had never been publicly traded. From inception through the closing of the Merger, the fair value of its common stock was determined by Former PharmAthene's board of directors with input from management. Upon the closing of the Merger on August 3, 2007, PharmAthene's stock price was used as the basis for determining fair value.

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 with 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 offering (i.e., 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 9, the Company issued 100,778 common stock warrants with an exercise price of $3.97 per share. Additionally, in conjunction with the Merger and as discussed in Note 11, the Company issued 14,180 common stock warrants with an exercise price of $0.19 per share.

In connection with the stock purchase by Kelisia Holdings Ltd. in 2008 disclosed above, the Company issued a warrant to purchase up to 2,745,098 additional shares of PharmAthene common stock at an exercise price of $5.10 per share.

	Warrants for Shares of Common Stock	Weighted-Average Exercise Price	Warrants for Shares of Preferred Stock	Weighted-Average Exercise Price
Outstanding at December 31, 2006	10,223,911	5.69	1,179,610	4.07
Granted	—	—	98,300	4.07
Converted	100,778	3.97	(98,300)	4.07
Forfeited	(584,731)	0.19	(1,179,610)	4.07

Table of Contents

	Warrants for Shares of Common Stock	Weighted-Average Exercise Price	Warrants for Shares of Preferred Stock	Weighted-Average Exercise Price
Outstanding at December 31, 2007	9,739,958	$ 6.01	—	—
Granted	2,745,098	5.10	—	—
Forfeited	—	—	—	—
Outstanding at December 31, 2008	12,458,056	$ 5.81	—	—

Note 14 - Income Taxes

For the years ended December 31, 2008 and 2007, there is no current provision for income taxes, and the deferred tax provision has been entirely offset by a valuation allowance. Actual income tax benefit differs from the expected income tax benefit computed at the federal statutory rate as follows:

	December 31, 2008	December 31, 2007
Statutory federal tax benefit	$ (12,375,599)	$ (4,620,323)
State income tax, net of federal benefit	(812,065)	(689,367)
Other permanent differences	(349,219)	602,249
Book gain on warrants	0	(823,936)
Canada deferred rate change	0	682,832

Foreign Rate Differential	1,616,669	—
Jurisdictional difference in book income	4,105,939	—
Increase in valuation allowance	7,814,275	4,848,345
Income tax expense	$ —	$ —

The Company's net deferred tax assets consisted of the following:

	December 31, 2008	December 31, 2007
Deferred tax assets:		
Net operating loss carryforwards	$ 26,045,695	$ 20,819,453
Fixed Assets/Intangibles	7,131,555	3,716,752
Research and development credits/Loss carryforwards	1,022,090	1,384,691
Accrued expenses and other	1,858,109	413,381
Total deferred tax assets	36,057,449	26,522,964
Deferred tax liabilities:		
Bridge Note Revaluation	(166,766)	(411,243)
Total deferred tax liabilities	(166,766)	(411,243)
Net deferred tax assets	35,890,683	25,923,033
Less: valuation allowance	(35,890,683)	(25,923,033)
Net deferred tax assets	$ —	$ —

Table of Contents

The deferred tax amounts discussed above are classified as follows:

	December 31, 2008	December 31, 2007
Current deferred tax assets	$ 163,157	$ 378,620
Non-current deferred tax assets	35,727,526	25,544,413
Less: valuation allowance	(35,890,683)	(25,923,033)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some or all of the deferred tax asset will not be realized. The ultimate realization of the deferred tax asset is dependent upon the generation of future taxable income during the periods in which the net operating loss carryforwards are available. Management considers projected future taxable income, the scheduled reversal of deferred tax liabilities and available tax planning strategies that can be implemented by the Company in making this assessment on a jurisdiction-by-jurisdiction basis. Based upon the level of historical taxable income and projections for future taxable income over the periods in which the net operating loss carryforwards are available to reduce income taxes payable, management has established a full valuation allowance against the net deferred tax asset in 2008 consistent with 2007.

The U.S. federal net operating loss carryforwards of approximately $53 million will begin to expire in various years beginning 2021. The use of the Company's net operating loss carryforwards may be restricted if the Company experienced a change in ownership in accordance with I.R.C. Section 382. The Canadian federal net operating loss carryforwards of approximately $10.9 million will begin to expire in 2014. Certain Canadian federal net operating losses may have an unlimited life. The UK net operating loss carryforwards of approximately $1.2 million have an unlimited life. Additionally, despite the net operating loss carryforwards, the Company may have a future tax liability due to alternative minimum tax or state minimum tax requirements.

The Company adopted the provisions of Financials Accounting Standards Board ("FASB") Interpretation No. 48, *Accounting for Uncertainty in Income Taxes- and Interpretation of FASB Statement No. 109* ("FIN 48") on January 1, 2007. The Company has analyzed tax positions in all jurisdictions where we are required to file an income tax return and we have concluded that we do not have any material unrecognized tax benefits. As a result, there were no material effects on our financial position or results of operations due to the implementation of FIN 48. As such, the Company believes that any of its uncertain tax positions would not result in adjustments to its effective income tax rate.

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.

The following tax years remain subject to examination

Major Jurisdictions	Open Years
U.S. Federal	2005 - 2008
U.S. States	2004 - 2008
Canada	2005 - 2008
United Kingdom	2008

For income tax returns filed by the Company, the Company is no longer subject to U.S. federal, state and local tax examinations by tax authorities for years prior to 2004, although carryforward tax attributes that were generated prior to 2004 may still be adjusted upon examination by tax authorities if they either have been or will be utilized.

The Company intends to indefinitely reinvest the undistributed earnings from its foreign subsidiaries.

Note 15 - Terminated Merger Agreement

On December 20, 2006, the Company filed a complaint against Siga Technologies, Inc. ("SIGA") in the Delaware Chancery Court. The complaint alleges, among other things, that the Company has the right to license exclusively development and marketing rights for SIGA's drug candidate, SIGA-246, pursuant to a merger agreement between the parties that was terminated in October 2006. The complaint also alleges that SIGA failed to negotiate in good faith the terms of such a license pursuant to the terminated merger agreement. The Company is seeking alternatively a judgment requiring SIGA to enter into an exclusive license agreement with the Company for SIGA-246 in accordance with the terms of the term sheet attached to the merger agreement or monetary damages. On January 16, 2008, the Delaware Chancery Court issued a ruling denying a motion by SIGA to dismiss the compliant. The parties are now engaged in discovery.

Note 16 - Subsequent Events

In March 2009 BARDA issued a Broad Agency Announcement (BAA) for the Advanced Research and Development of Chemical, Biological, Radiological, and Nuclear Medical Countermeasures, which included an advanced development solicitation for proposals covering anthrax anti-toxins. The BAA states that research and technical objectives proposed by offerors may include non-clinical research and development, process development, formulation, manufacturing development, and clinical evaluation efforts. In response we submitted an initial proposal providing for further development of Valortim® and are awaiting a response.

Effective March 2009, the lenders under the Company's credit facility agreed to reduce the amount of unrestricted and unencumbered cash or cash equivalents we are required to maintain in the segregated account to one-half times (0.5x) our outstanding obligations to them.

On March 27, 2009, the Company closed on the public sale of an aggregate of 2,116,055 newly issued shares of its common stock at $2.60 per share and warrants to purchase an aggregate of 705,354 shares of its common stock at an exercise price of $3.00 per share, resulting in aggregate net proceeds of $5,501,743. The warrants will be exercisable beginning on September 27, 2009 and will expire on September 27, 2014, five years from the date they become exercisable. The Company intends to use the net proceeds for general corporate purposes, including the satisfaction of existing obligations.

(d) Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated January 19, 2007, by and among Healthcare Acquisition Corp., PAI Acquisition Corp., and PharmAthene, Inc. (6)
2.2	Sale and Purchase Agreement, dated March 20, 2008, by and among the Registrant and Avecia Investments Limited, Avecia Biologics Limited and Avecia Biologics, Inc. (10)
2.3	Amendment Agreement, dated April 2, 2008, by and among, PharmAthene, Inc., PharmAthene UK Limited and PharmAthene US Corporation and Avecia Investments Limited, Avecia Biologics Limited and Avecia Biologics, Inc. (12)

Exhibit No.	Description
3.1.1	Amended and Restated Certificate of Incorporation. (8)
3.1.2	Certification of Amendment to Amended and Restated Certificate of Incorporation. (14)
3.2	By-laws, as amended. (13)
4.1	Specimen Unit Certificate. (1)
4.2	Specimen Common Stock Certificate. (9)
4.3	Specimen Warrant Certificate. (1)
4.4	Form of Warrant Agreement between Continental Stock Transfer & Trust Company and the Registrant. (3)
4.5	Form of Note Exchange Agreement. (6)
4.6	Form of 8% Convertible Note of Healthcare Acquisition Corp. (6)
4.7	Amendment to Unit Purchase Option by and between the Registrant and Maxim Partners, LLC dated January 28, 2007. (7)
4.8	Warrant Clarification Agreement by and between the Registrant and Continental Stock Transfer & Trust Company, dated January 23, 2007. (7)
10.1.1	Letter Agreement among the Registrant, Maxim Group LLC and John Pappajohn dated May 6, 2005. (2)
10.1.2	Letter Agreement among the Registrant, Maxim Group LLC and Derace L. Schaffer, M.D. dated May 6, 2005. (2)
10.1.3	Letter Agreement among the Registrant, Maxim Group LLC and Matthew P. Kinley dated May 6, 2005. (2)
10.1.4	Restated Letter Agreement among the Registrant, Maxim Group LLC and Edward B. Berger dated June 8, 2005. (3)
10.1.5	Letter Agreement among the Registrant, Maxim Group LLC and Wayne A. Schellhammer dated June 8, 2005. (3)
10.2	Form of Investment Management Trust Agreement between Continental Stock Transfer & Trust Company and the Registrant. (3)
10.2.1	Amendment No. 1 to of Investment Management Trust Agreement between Continental Stock Transfer & Trust Company and the Registrant. (5)

Exhibit No.	Description
10.3	Form of Stock Escrow Agreement between the Registrant, Continental Stock Transfer & Trust Company and the Initial Stockholders. (3)
10.4	Form of Registration Rights Agreement among the Registrant and the Initial Stockholders. (1)
10.5.1	Office Services Agreement by and between the Registrant and Equity Dynamics, Inc. (1)
10.5.2	Office Services Agreement by and between the Registrant and The Lan Group. (1)
10.6.1	Promissory Note, dated April 28, 2005, issued to John Pappajohn, in the amount of $70,000. (1)
10.6.2	Promissory Note, dated April 28, 2005, issued to Derace L. Schaffer, M.D., in the amount of $70,000. (1)
10.6.3	Promissory Note, dated April 28, 2005, issued to Matthew P. Kinley, in the amount of $35,000. (1)
10.6.4	Promissory Note, dated July 26, 2005, issued to John Pappajohn, in the amount of $30,000. (4)
10.6.5	Promissory Note, dated July 26, 2005, issued to Derace L. Schaffer, M.D., in the amount of $30,000. (4)
10.6.6	Promissory Note, dated July 26, 2005, issued to Matthew P. Kinley, in the amount of $15,000. (4)
10.7	Form of Unit Option Purchase Agreement between the Registrant and Maxim Group LLC. (3)
10.8	Form of Warrant Purchase Agreement by and between the Registrant, Maxim Group LLC and the Initial Stockholders. (2)
10.9	Form of Registration Rights Agreement by and among Healthcare Acquisition Corp. and the former stockholders and note holders of PharmAthene, Inc. (6)
10.10	Stock Escrow Agreement, dated August 3, 2007, by and among the Registrant, a representative of the former stockholders and option holders of the Registrant and Continental Stock Transfer and Trust Company. (11)
10.11	Advisory Agreement by and among Maxim Group LLC and the Registrant, dated January 8, 2007. (7)
10.12	Amended and Restated 2007 Long-Term Incentive Compensation Plan. (15)
10.13	Employment Agreement, dated August 3, 2007, between the Registrant and David P. Wright. (8)

Exhibit No.	Description
10.14	Employment Agreement, dated December 22, 2006, between the Registrant and Christopher C. Camut. (9)
10.15	Employment Agreement, dated November 3, 2003, between the Registrant and Francesca Marie Cook. (9)
10.16	Employment Agreement, dated November 3, 2003, between the Registrant and Eric Ian Richman. (9)
10.17	Employment Agreement, dated November 3, 2003, between the Registrant and Valerie Dean Riddle. (9)
10.18	Employment Agreement, dated January 31, 2005, between the Registrant and Wayne Morges. (9)
10.19.1	Loan and Security Agreement, dated March 30, 2007, by and among the Registrant, Silicon Valley Bank, Oxford Finance Corporation, and other lenders listed on Schedule 1.1 thereof. (9)
10.19.2	Consent and First Loan Modification Agreement, dated March 20, 2008, by and among the Registrant, Silicon Valley Bank and Oxford Finance Corporation (10).
10.20	U.S. Army Space & Missile Defense Command—"Development and Licensure of Bioscavanger Increment II (Recombinant Drug Candidate)" Award/Contract No. W9113M-06-C-0189, dated September 22, 2006, by and between the Company and the U.S. Army Space & Missile Defense Command. (9)+
10.21	Cooperative Research and Development Agreement, dated September 12, 2006, by and between the Company and the U.S. Army Medical Research Institute of Infectious Diseases. (9)+
10.22	Center for Scientific Review, National Institute of Health, Research Project Cooperative Agreement, Notice of Grant Award No. 1 U01 NS058207-01, dated September 30, 2006, awarded to the Company. (9)+
10.23	Collaboration Agreement, dated November 29, 2004, by and between the Company and Medarex, Inc. (9)+
10.24	Research and License Agreement, dated August 8, 2006, by and between the Company and Nektar Therapeutics AL, Corporation. (9)+
10.25	License Agreement, dated March 12, 2007, by and between the Company and GTC Biotherapeutics, Inc. (9)+
10.26.1	Office Lease, dated September 14, 2006, by and between the Company and Park Place Trust, as amended by First Amendment to Office Lease, dated January 22, 2007. (9)

Table of Contents

Exhibit No.	Description
10.26.2	Second Amendment to Office Lease, by and between the Company and Park Place Trust, dated September 16, 2008. (19)
10.27	Biopharmaceutical Development and Manufacturing Services Agreement, dated June 15, 2007, by and between the Company and Laureate Pharma, Inc. (9)+
10.28	Services Agreement, dated March 2, 2007, by and between the Company and GTC Biotherapeutics, Inc. (9)+
10.29	Transitional Services Agreement, dated April 2, 2008, between Avecia Biologics Limited and PharmAthene UK. (16)
10.30	Form of PharmAthene Inc. Executive Employment Agreement. (17)
10.31	Form of PharmAthene Inc. Confidentiality and Non-Solicitation Agreement. (17)
10.32	Master Services Agreement, dated April 2, 2008, between PharmAthene UK Limited and Avecia Biologics Limited. (17) +
10.33	Master Service Agreement, dated December 15, 2004, between Avecia Limited and the Secretary of State for Defence, acting through the Defence Science and Technology Laboratory (DSTL). (18)+
10.34	Master Service Agreement, dated August 18, 2005, between Avecia Limited and DSTL. (18) +
10.35	Manufacturing Licence Agreement, dated June 20, 2006, between Avecia Limited and DSTL. (18) +
10.36	Manufacturing and Marketing Licence Agreement, dated December 4, 2006, between Avecia Limited and DSTL. (18) +
10.37	Letter Agreement, dated March 20, 2008, between Avecia Biologics Limited and DSTL. (18)+
10.38	Contract Award by the National Institute of Allergy and Infectious Diseases (NIAID), dated September 25, 2008. (19)+
10.39	Securities Purchase Agreement, dated September 30, 2008, between PharmAthene, Inc. and Kelisia Holdings Ltd. (19)
10.40	Letter Agreement, dated September 30, 2008, between PharmAthene, Inc. and Panacea Biotec, Ltd. (19)
10.41	Investor Rights Agreement, dated October 10, 2008, between PharmAthene Inc. and Kelisia Holdings Ltd. (19)
10.42	Common Stock Purchase Warrant, dated October 10, 2008 in favor of Kelisia Holdings Ltd. (19)

Table of Contents

Exhibit No.	Description
10.43	Deed of Confidentiality between PharmAthene UK Limited, and its employees. (19)
10.44	Contract with the National Institutes of Health for the Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine (#N01-AI-30052) (“NIH Prime Contract-Anthrax”), dated September 29, 2003 *, +
10.45	Amendments 1 through 13 to the NIH Prime Contract-Anthrax *, **, +
10.46	Contract with the National Institutes of Health for the Development, Testing and Evaluation of Candidate Vaccines Against Plague (#HSSN266200400034C) (“NIH Prime Contract-Plague”), dated September 30, 2004 *, +
10.47	Amendments 1 through 10 to the NIH Prime Contract-Plague *, **, +
14	Code of Ethics. (3)
21	Subsidiaries. *
23	Consent of Ernst & Young LLP Independent Registered Public Accounting Firm *
31.1	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a).*
31.2	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a).*
32.1	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.*
32.2	Certification of Chief Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.*

(1) Incorporated by reference to the Registration Statement on Form S-1 of the Registrant filed on May 6, 2005.

(2) Incorporated by reference to the Registration Statement on Form S-1/A of the Registrant filed on June 10, 2005.

(3) Incorporated by reference to the Registration Statement on Form S-1/A of the Registrant filed on July 12, 2005.

(4)	Incorporated by reference to the Registration Statement on Form S-1/A of the Registrant filed on July 27, 2005.

Table of Contents

(5)	Incorporated by reference to the Quarterly Report on Form 10-Q filed by the Registrant on November 14, 2005.
(6)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on January 22, 2007.
(7)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on January 25, 2007.
(8)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on August 9, 2007.
(9)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on September 24, 2007.
(10)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on March 26, 2008.
(11)	Incorporated by reference to the Annual Report on Form 10-K filed by the Registrant on March 31, 2008.
(12)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on April 8, 2008.
(13)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on May 2, 2008.
(14)	Incorporated by reference to the Current Report on Form 8-K filed by the Registrant on June 19, 2008.
(15)	Incorporated by reference to Appendix B to the Proxy Statement on Schedule 14A filed by the Registrant on May 15, 2008.
(16)	Incorporated by reference to the Current Report on Form 8-K/A filed by the Registrant on June 18, 2008.
(17)	Incorporated by reference to the Quarterly Report on Form 10-Q filed by the Registrant on August 14, 2008.
(18)	Incorporated by reference to the Amendment to the Quarterly Report on Form 10-Q/A filed by the Registrant on August 19, 2008.
(19)	Incorporated by reference to the Quarterly Report on Form 10-Q filed by the Registrant on November 14, 2008.
*	Filed herewith.

Table of Contents

**	Amendments No. 2 and 5 to the NIH Prime Contract-Anthrax have been superseded in full by subsequent amendments filed herewith and are therefore omitted. Amendment No. 12 to the NIH Prime Contract-Anthrax and Amendment No. 8 to the NIH Prime Contract-Plague were never executed and are therefore omitted.
+	Certain confidential portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)

RATING N/A | PAGE OF **1** | PAGES **28**

2. CONTRACT (Proc. Inst. Ident.) NO.
N01-AI-30052

3. EFFECTIVE DATE
September 30, 2003

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
VR075

5. ISSUED BY CODE 2606-30052

National Institute of Health
Contract Management Branch, NIAID
Room 2230
8700-B Rockridge Dr. MSC 7612
Belhasda, Maryland 20892-7612

6. ADMINISTERED BY *(If other than Item 5)* CODE

DMID-VR
RFP NIH-NIAID-DMID-03-29

7. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

Avecia Limited
PO Box 42, Hexagon House
Blackley
Manchester M9 6ZS
England

8. DELIVERY

o FOB ORIGIN x OTHER *(See below)*
FOB Destination

9. DISCOUNT FOR PROMPT PAYMENT
N/A

10. SUBMIT INVOICES ADDRESS SHOWN IN ITEM G.3.

CODE FACILITY CODE

11. SHIP TO/MARK FOR CODE N/A

Article F.1.

12. PAYMENT WILL BE MADE BY CODE N/A

See Article G.3.

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:

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

14. ACCOUNTING AND APPROPRIATION DATA

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Title: Production and Testing of Anthrax Recombinant Protective Antigen (rPA) Vaccine Period, September 30, 2003 through October 12, 2006 Amount Allotted: $29,410,000 Contact Type: Cost Plus Fixed Fee/Completion			FY 03 FY 04	$29,410,000 $41,882,000

15Q TOTAL AMOUNT OF CONTRACT $71,292,000

16. TABLE OF CONTENTS

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. x CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign 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 condition 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)*

David Greensmith
Chief Operating Officer (COO)

20A. NAME OF CONTRACTING OFFICER

Elizabeth Ozinski
Contracting Officer, CMB, NIAID, NIH

19B. NAME OF CONTRACTOR

BY /s/ David Greensmith
(Signature of person authorized to sign)

19C. DATE SIGNED
29 SEPTEMBER 2003

20B. UNITED STATES OF AMERICA

BY /s/ Elizabeth Ozinski
(Signature of Contracting Officer)

20C. DATE SIGNED
9/23/03

NSN 7640-01-152-8089
PREVIOUS EDITION UNUSABLE

M-107
Computer Generated

STANDARD FORM 26 (Rev. 4-A5)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

Contract No. N01-AI-30052

DETAILED TABLE OF CONTRACT CONTENTS

PART I - THE SCHEDULE

SECTION B - - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this contract is to continue development of the rPA vaccine and produce, test and release three million doses made from at least three cGMP consistency lots.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is [***].

b. The fixed fee for this contract is [***]. The fixed fee shall be paid in installments based on the negotiated milestones set forth in ARTICLE B.4.h. and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE 1.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee, is [***].

d. Total funds currently available for payment and allotted to this contract are: [***], of which [***] represents the estimated costs, and of which [***] represents the fixed fee. These funds cover the start dates for Milestones 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through September 29, 2004.

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

g. Future increments to be allotted to this contract are estimated as follows:

FY	PERIOD	ESTIMATED COST	FIXED FEE	TOTAL AMOUNT
04	9/30/04 - 10/13/06	[***]	[***]	[***]

These funds cover continuation of Milestones 7, 9, 10, 11, 12, 13, and 17.

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;

(5) Foreign travel - See Paragraph b.(2) 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), 1990, regardless of acquisition value.

b. **Travel Costs**

(1) Travel

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

(b) The Contractor shall invoice and be reimbursed fur all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.205-46.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

a. **Subcontract**

To negotiate a firm fixed price type subcontract with Baxter Healthcare Corporation (BHC) for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation and the draft subcontract as required by the Subcontracts clause of the General Clauses incorporated in this contract. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

b. **Subcontract**

To negotiate a firm fixed price type subcontract with Baxter Pharmaceutical Solutions LLC (BPS) for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation and the draft subcontract as required by the Subcontracts clause of the General Clauses incorporated in this contract. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

c. **Subcontract**

To negotiate a cost plus fixed fee type subcontract with DSTL for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation and the draft subcontract as required by the Subcontracts clause of the General Clauses incorporated in this contract. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

d. **Subcontract**

To negotiate a firm fixed price type subcontract with Parexel International Corporation (PxI) for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation and the draft subcontract as required by the Subcontracts clause of the General Clauses incorporated in this contract. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

e. **Subcontract**

To negotiate a firm fixed price type subcontract with Inveresk Ltd. for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation and the draft subcontract as required by the Subcontracts clause of the General Clauses incorporated in this contract. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

f. **Subcontract**

To negotiate a firm fixed price type subcontract with SRI International (SRI) for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract. After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.

g. **Ceilings**

(1) In no event shall the final amount reimbursable for the Overhead R&D Burn Rate using a base of Scientific Labor exceed a ceiling of 99% for the entire performance period of this contract.

(2) In no event shall the final amount reimbursable for Labor Overhead using a base of Direct Scientific Labor, plus R&D Burn on scientific labor, plus Direct Project Management Labor exceed a ceiling of 66% for the entire performance period of this contract.

(3) In no event shall the final amount reimbursable for Fringe Benefits exceed a ceiling of 38% for the entire performance period of this contract.

(4) In no event shall the final amount reimbursable for ABC 5000 facility daily rate exceed [***]. The contractor must submit to the Financial Advisory Services Branch, NIH the actual costs, excluding profit, for the ABC 5000 facility as of 12/31/03 and 12/31/04. The actual costs will be evaluated and the contractor will be required to make adjustments to the facility costs that have been reimbursed to the contractor based on the funded amount.

(5) This is authorization to charge as a direct cost to the contract a daily cost not to exceed [***] per day for office leasing space for the first year of the contract in a total amount not to exceed a ceiling of [***].

(6) The Government is not obligated to pay any additional amount should the final indirect cost rates exceed these negotiated ceiling rates. In the event that the final indirect cost rates are less than these negotiated ceiling rates, the Government's obligation shall be reduced to conform to the lower rates. Any costs over and above this cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement.

(7) The Contractor shall complete all work in accordance with the Statement of Work, terms and conditions of this contracts.

h. **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 milestone based installments and payment of this fee is determined by the Project Officer's written certification that the milestone has been satisfactorily performed and that the technical requirements have been met regarding the completion of the following milestones: If the Contractor meets the milestones earlier than the dates set forth below, then the fee will be paid at the earlier date after completion of the milestone.

	MILESTONES	ESTIMATED COST	FIXED FEE	TOTAL CPFF
	Milestones for Avecia			
1	Submit refined preclinical testing plan on/before [***].	[***]	[***]	[***]
2	Submit refined clinical testing plan on/before [***].	[***]	[***]	[***]
3	Submit refined regulatory plan on/before [***].	[***]	[***]	[***]

4	Complete development and validation of assays on/before [***].	[***]	[***]	[***]
5	Demonstrated suitability of facility on/before [***].	[***]	[***]	[***]
6	Demonstrated tech transfer on/before [***].	[***]	[***]	[***]
7	Submit inventory storage/maintenance plan on/before [***].	[***]	[***]	[***]
8	Phase 2 trial completed on/before [***]. Reporting to NIAID and subsequent payment to be broken into three distinct phases: (1) initiation of enrollment (first patient enrolled) (2) Last patient out; and (3) delivery of final report to NIAID. Reports should include all data collected during the various phases of the study. Fee for this milestone shall be paid in 3 equal installments of the total fee for this milestone based on the completion of phases (1), (2), and (3) above.	[***]	[***]	[***]
9	Stockpile manufacturing feasibility plan on/before [***].	[***]	[***]	[***]
10	Manufacture all bulk rPA on/before [***] and fee will be paid after receipt of Certificate of Analysis.	[***]	[***]	[***]
11	Fill/Finish 3 million doses on/before [***] and fee will be paid after receipt of Certificate of Analysis.	[***]	[***]	[***]
12	Release of 3d cGMP lot, deliver or store 3 million doses on/before [***] and fee will be paid after receipt of Certificate of Analysis.	[***]	[***]	[***]
13	Second Phase 2 trial completed on/before [***]. Reporting to NIAID and subsequent payment to be broken into three distinct phases: (1) initiation of enrollment (first patient enrolled) (2) Last patient out; and (3) delivery of final report to NIAID. Reports should include all data collected during the various phases of the study. Fee for this milestone shall be paid in 3 equal installments of the total fee for this milestone based on the completion of phases (1), (2), and (3) above.	[***]	[***]	[***]
14	Preclinical studies completed on/before [***].	[***]	[***]	[***]
15	Complete regulatory plan on/before [***].	[***]	[***]	[***]

	MILESTONES	ESTIMATED COST	FIXED FEE	TOTAL CPFF
	Milestones for Avecia			
16	Complete stability plan on/before [***]. Upon completion of 1st year, and 2nd year and 3rd year of stability testing and reporting, fee will be paid in partial payments.	[***]	[***]	**[***]**
17	Complete inventory storage/maintenance plan on/before [***].	[***]	[***]	**[***]**

i. **Scientific Meetings**

Travel to general scientific meetings as follows:

Authorization to expend contract funds for general scientific meeting travel is not provided herein. The Contractor shall request approval to expend contract funds for general scientific meeting travel, in writing, 4 weeks in advance of the proposed travel. The Contractor's written request shall include the name(s) and title(s) of personnel proposed to travel, the meeting dates and location, details of proposed costs (airfare, per diem/subsistence, other), and a description of the benefit to be derived (to this contract) from the proposed travel.

j. **Protocol Approvals**

a. The Contractor shall not commence work on any clinical or preclinical protocol unless the Contractor has received written approval of that protocol from the NIAID Project Officer. The NIAID Project Officer will approve the clinical and preclinical protocols in consultation with an advisory group. It is understood that the protocols may be modified and may not be implemented as proposed. It is further understood that any costs incurred in the conduct of any clinical or preclinical protocol that has not received the written approval of the NIAID Project Officer shall not be reimbursed through this contract.

b. The Contractor shall not commence work on any protocol until the NIAID has informed the Contractor that it has been found exempt from OMB clearance procedures by the Clinical Exemption Committee of the NIH.

k. **Subcontractor Estimated Expenditures**

The Contractor shall include in their monthly invoice a list of estimated Subcontractor monthly expenditures for Subcontractors that have not submitted invoices for that respective month. If the Subcontractor(s) did not work and therefore did not incur costs during that respective month, then this should also be indicated on the monthly invoice.

l. **Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget**

(1) The contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

(a) Direct Labor- List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
(b) 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) Subcontracts - Attach subcontractor invoice(s).
(g) Equipment - Cite authorization and amount.
(h) Total Cost
(i) Fixed Fee
(j) Total CPFF

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

(2) The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

m. FAR Clause 52.223-6 Drug Free Workplace is included in this contract, however, FAR 23.501 (c) provides that the clause does not apply to work that is "(c) Performed outside of the United States and its outlying areas or any part of a contract performed outside the United States and its outlying areas."

n. **Understanding regarding FAR 52.222-36**

FAR 22.1408(a) requires the Contracting Officer to "Insert the clause at 52.222-36, Affirmative Action for Workers with Disabilities, in solicitations and contracts that exceed or are expected to exceed $ 10,000, except when - -

"(1) Both performance of the work and the recruitment of workers will occur outside the United States, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island; or

"(2) The agency head has waived, in accordance with 22.1403(a) or 22.1403(b) all the terms of the clause."

It is the mutual understanding of the contracting officer and Avecia that a significant portion of the work, including all self-performed work, under this contract will be performed outside the United States and the other named territories by workers recruited from outside the United States and the named territories. However, it is also mutually understood that some subcontracted work will be performed in the United States. Therefore both parties agree that FAR 52.222-36(a) (b) and (c) will not apply to Avecia and that FAR 52122-36 (d) "Subcontracts" will only apply to subcontracts that will be performed in the United States or by workers recruited from the United States and the named territories; i.e., FAR 52.222-36 would apply in its entirety to any subcontractor that performs work in the United States. It is also agreed that Avecia will flow-down language similar to that in this paragraph to its subcontracts not performed in the United Stales; i.e., FAR 52.222-36 would apply in its entirety to any second-tier (or lower) subcontracts performed in the United States.

o. **Understanding regarding FAR 52.222-37**

FAR 22.1310(a)(1)(i) provides that FAR 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, is required to be in contracts over $25,000, except when "Work is performed outside the United States by employees recruited outside the United States". As FAR 52.222-35(d) contains an "Applicability" clause that limits its reach to the listing of employment openings within the United States and named territories, no additional understanding beyond that applicability clause is necessary.

FAR 22.1310(b) provides that 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, in solicitations and contracts containing the clause at 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans. Therefore, if "Work is performed outside the United States by Employees recruited outside the United States," FAR 52.222-37 would not be required.

It is the mutual understanding of the contracting officer and Avecia that a significant portion of the work, including all self-performed work, under this contract will be performed outside the United States and the other named territories by workers recruited from outside the United States and the named territories. However, it is also mutually understood that some subcontracted work will be performed in the United States. Therefore both parties agree that FAR 52.222-37(a) through (c) will not apply to Avecia and that FAR 52.222-37 (f) will only apply to subcontracts that will be performed in the United States or by workers recruited from the United States; i.e., FAR 52.222-37 would apply in its entirety to any subcontractor that performs work in the United States It is also agreed that Avecia will flow-down language similar to that in this paragraph to its subcontracts not performed in the United States; i.e., FAR 52.222-37 would apply in its entirety to any second-tier (or lower) subcontracts performed in the United States.

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 accomplish the tasks and milestones in the Statement of Work, SECTION J, ATTACHMENT I, dated September 30, 2003, attached hereto and made a part of this contract. Performance and expenditures under this contract will be consistent with the work plans, schedule and budget described in the Contractor's initial proposal dated June 30, 2003, and the Final Proposal Revision dated September 8, 2003, which includes the answers provided in Response to the Technical and Administrative Questions.

ARTICLE C.2. REPORTING REQUIREMENTS

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 the technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following:

b. Technical Reports

The Contractor shall prepare and submit the following reports in the manner stated below:

(1) Monthly Technical Progress Reports - On the fifteenth of each month for the previous calendar month, the Contractor shall submit six (6) copies of a Monthly Technical Progress Report, comprising five (5) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall include the following specific information:

a. A cover page that lists the contract number and title, the period of performance being reported, the contractor's names and address, the author(s), and the date of submission;

b. SECTION I - An introduction covering the purpose and scope of the contract effort;

c. SECTION II - - The report shall detail, document, and summarize the results of work done during the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. Also to be included in the report is a summary of work proposed for the next reporting period. Specific requirements are set forth in the Work Statement. A summary of each ongoing and completed protocol shall be submitted at this time. A monthly report will not be required for the period when the final report is due. Preprints and reprints of papers and abstracts shall be submitted with the Annual Report.

d. SECTION III - - Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with resolution or proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and if behind planned progress what corrective steps are planned.

e. SECTION IV - - Estimated and Actual Expenses

This report shall also contain a narrative statement as to whether there is any discrepancy at this time between the % of work completed and the cumulative costs incurred to date. Section IV of this report shall also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. These shall be listed for each Subcontractor. If the Subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

(2) Milestone Reports - - A milestone report will be provided after the completion of each Milestone unless otherwise agreed upon by the Principal Investigator and the Project Officer. Milestone reports and monthly reports may be combined if agreed by the Contracting Officer and the Project Officer. For those months when milestone reporting requirements are extensive, the monthly Technical Progress Report may not be required if agreed by the Project Officer, Contracting Officer and Contractor. Cost information for the month will be required in all cases.

(3) Final Report - By the expiration date of the contract, the Contractor shall submit five (5) copies of a comprehensive Final Report, as above, comprising four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. Specific requirements are set forth in the Work Statement. Preprints and reprints not submitted previously shall be submitted.

(4) Summary of Salient Results - With the final report the Contractor shall submit a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer within 90 days after the expiration date of the contract to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases, CMB
6700-B Rockledge Drive, Room 2230
Bethesda, Maryland 20892 -7612

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

To assist Contractors in complying with invention reporting requirements of the clause, the NTH 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 is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the address listed in Article G.1. 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 No. 52.246-8, INSPECTION OF RESEARCH AND DEVELOPMENT- COST REIMBURSEMENT (MAY 2001)

SECTION F - - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duty authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in SECTION C, ARTICLE C. 2 . will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below:

Item	Description	Delivery Schedule
1	Monthly Progress Reports	Fifteenth of each month
2	Milestone Reports	On the fifteenth day after completion of each milestone
3	Final Report	Expiration Date of the Contract
4	Summary of Salient Results	With the Final Report

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

Addressee	Deliverable Item	Quantity
Contracting Officer CMB, NIAID, NIH Room 2230, MSC 7612 6700-B Rockledge Drive Bethesda, MD 20892-7612	Monthly Progress Reports Milestone Reports Final Report Summary of Salient Results	Original Original Original Original
Project Officer DMID/NIAID/NIH 6610 Rockledge Dr., Room 5002 Bethesda, MD 20892-7630	Monthly Progress Reports Milestone Reports Final Report Summary of Salient Results	5 Copies 5 Copies 5 Copies 5 Copies

c. Other Reports/Deliverables

The following are considered deliverables under this contract:

5. All Technical Reports, Milestone Reports, preprints, and protocols as described in paragraph A, above. These deliverables are due as indicated.

6. All milestones indicated in the Statement of Work.

If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delay, the reasons for the delay, and the expected date of delivery for the report.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

SECTION G - - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

Ed Nuzum, DVM, Ph.D.
Project Officer
Office of Biodefense Research Affairs (OBRA)/DMID/NIAID/NIH
Mail Stop Code 6604
6610 Rockledge Drive, Room 5117
Bethesda, MD 20892-6604
Phone: (301) 451-6737
Fax: (301) 480-1263
Email: enuzum@niaid.nih.gov

Eileen Flynn
Co-Project Officer
Office of Biodefense Research Affairs (OBRA)/DMID/NIAID/NIH
Mail Stop Code 7630
6610 Rockledge Drive, Room 5002
Bethesda, MD 20892-7630
Phone: (301) 451-6737
Fax: (301) 480-1263
Email: eflynn@niaid.nih.gov

The Project Officer is responsible for: (I) 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: (l) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individual is considered to be essential to the work being performed hereunder:

Name	Title
Matthew G. Duchars, BSc, PhD	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 instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

An original and two copies to the following designated billing office:

Contracting Officer
Contract Management Branch
National Institute of Allergy and Infectious Diseases, NIH
Room 2230
6700-B ROCKLEDGE DRIVE, MSC 7612
BETHESDA, MD 20892-7612

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301)496-0612.

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.11. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. 108-7 and ARTICLE H.11. of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in Part II, Section 1, 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 DHHS Publication, Contractor's Guide for Control of Government Property, 1990, which is incorporated into this contract by reference. 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 BLVD MSC 7670
BETHESDA MD 20852-7670
(301) 496-6466

b. Notwithstanding the provisions outlined in the DHHS Publication, Contractor's Guide for Control of Government Property, 1990 which is incorporated in this contract in paragraph a. above, the contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for performing annual inventories required under this contract. This form is included as an attachment in SECTION J of this contract.

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 will be prepared annually to coincide with the anniversary date of the contract.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

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. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H.2. HUMAN SUBJECTS

RESEARCH INVOLVING HUMAN SUBJECTS SHALL NOT BE CONDUCTED UNDER THIS CONTRACT UNTIL THE PROTOCOL DEVELOPED IN PHASE II 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).

ARTICLE H.3. 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.4. 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 I07
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, the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/clinical/default_human.htm), 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 and Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.5. HUMAN MATERIALS

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

ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-7, Division G, Title V-General Provisions, Section 510	2003	10/1/02 - 9/30/03

ARTICLE H.7. NEEDLE EXCHANGE

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-7, Division G, Title V-General Provisions, Section 505	2003	10/1/02 - 9/30/03

ARTICLE H.8. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. "This document may be accessed on the Internet at the following URL: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm.

ARTICLE H.9. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NIAID environment (NIH) directly, or through collaborative research or holding facilities under contract to NIAID except by permit. Direct shipments to NIH from a commercial colony will be considered exempt. Non-exempt sources must be approved by permit issued through the National Center for Research Resources (NCRR). The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, NIAID environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted not less than 30 days prior to shipping date to: NIH Veterinary Resources Branch (VRP), National Center for Research Resources (NCRR), Scientific Services Branch, Laboratory Sciences Section, Building 28A, Room 111, 28 LIBRARY DR MSC 5210, BETHESDA MD 20892-5210, (301)496-2527.

ARTICLE H.10. 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.11. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

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

ARTICLE H.12. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limit 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 exceeds any salary rate ceiling established in future HHS appropriation acts.

b.

Public Law No.	Fiscal Year	Dollar Amount of Salary Limitation*
P.L. 108-7, Division G, Title II-General Provisions, Section 204	2003	Executive Level 1

b. Direct salaries which will be paid with FY-03 funds are limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

**For contract expenditures using FY-03 funds, the period 10/1/02 - 12/31/02 the Executive Level rate is $166,700. Effective 1/1/03, for contract expenditures using FY-03 funds, the Executive Level 1 rate is increased to $171,900 and will remain at that level until such time as it is determined to raise the Executive Schedule annual rates. See the web site listed below for Executive Schedule rates of pay.*

LINK to EXECUTIVE LEVEL SALARIES: http://opm.gov.oca/PAYRATES/index.htm
(Click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years.)

ARTICLE H.13. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health Department of Health and Human Services, under Contract No. N01-AI- 30052."

ARTICLE H.14. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-7, Division G, Title V-General Provisions, Section 507	2003	10/1/02 - 9/30/03

ARTICLE H.15. 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.dh.hs.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.16. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c, below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Public Law and Section No.	Fiscal Year	Period Covered
for a., above: P.L. 108-7, Division G, Title V-General Provisions, Section 503a	2003	10/1/02 - 9/30/03
for b., above: P.L. 108-7, Division G, Title V. General Provisions, Section 503b	2003	10/1/02 - 9/30/03

ARTICLE H.17. 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.18. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORISM ACTIVITIES

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

ARTICLE H.19. OFFICE OF HEALTH AND SAFETY - LABORATORY REGISTRATION/SELECT AGENT TRANSFER PROGRAM

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including DCDs that can be found at http://www.cdc.gov/od/ohs/1rsat.htm and NTH's OBA that can be found at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.htm.

ARTICLE H.20. SELECT AGENT AWARDS TO FOREIGN CONTRACTORS STATUS

This award includes research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens). Before using contract funds for any work directly involving the Select Agents, the contractor must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 for US institutions is in place and will be administered for all Select Agent work covered by the contract. The contractor must address the following key elements for their institution: safety; security; training; procedures for ensuring that only approved/appropriate individuals have access to the Select Agents; and any applicable laws, regulations and policies equivalent to 42 CFR 73.

ARTICLE H.21. POSSESSION, USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For possession, use and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to: 1) public health and safety; 2) both human and animal health; animal health, or animal products; and/or 3) plant health or plant products, registration information must be submitted to the Centers for Disease Control and Prevention,

Department of Health and Human Services (DHHS) or the Animal and Plant Health inspection Service (APHIS), U.S. Department of Agriculture (USDA) as applicable.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap.

PART II - CONTRACT CLAUSES

SECTION I - - CONTRACT CLAUSES

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

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

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government’s Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications

52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities

52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Jun 2003	Toxic Chemical Release Reporting
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Jun 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(1) through (iv). The frequency of reporting in (I) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment, Alternate I (Feb 2002)
52.232-34	May 1999	Payment by Electronic Funds Transfer-Other Than Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs

52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jun 2003	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principals
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings

352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 6/2003].

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

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

FAR Clause 52.232-20, LIMITATION OF COST, 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 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

(2) FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference……

[ ] Offeror elects to waive the evaluation preference."

(3) FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUNE 2003).

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 10% to the price of all offers, except—…"

(4) FAR 52.224- 1, Privacy Act Notification (APRIL 1984)

(5) FAR 52.224-2, Privacy Act (APRIL 1984)

(6) FAR 52.225-5, Trade Agreements Act

(7) FAR 52.227-14, Rights in Data - General (JUNE 1987)

(8) FAR 52.242-3, Penalties for Unallowable Costs (MAY 2001).

(9) FAR 52.247-63, Preference for U.S. Flag Air Carriers (JUNE 2003)

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

(1) HHSAR 352.223-70, Safety and Health (JANUARY 2001). [This clause is provided in full text in SECTION J - ATTACHMENTS.]

(2) HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National institutes of Health (NIH) wherever it appears in this clause.

(3) HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

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

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

(1) NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

(2) NIH(RC) [ ], 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 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (APRIL 2003)

(a) Definitions. As used in this clause-

Commercial item, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).

(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).

(v) 52.247-64, Preference for Privately Owned U.S. - Flag Commercial Vessels (APR 2003) (46 U.S.C. Appx 1241 and 10 U.S.C. 2631) (flow down required in accordance with paragraph (d) of FAR clause 52.247 64).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III

SECTION J - - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, September 30, 2003, 3 pages.
2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (5/97), 5 pages.
3. Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.
4. Annual Technical Progress Report Format for Each Study, July 1994, 1 page.
5. Safety and Health, HHSAR Clause 352.223-70, (1/01), 1 page.
6. Procurement of Certain Equipment, NIH(RC)-7, 4/1/84, 1 page.
7. Research Patient Care Costs, NIH(RC)-11, 4/1/84, 1 page.
8. Report of Government Owned, Contractor Held Property, 1 page.

PART IV

SECTION K - - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Representations and Certifications, dated September 4, 2003
2. Human Subjects Assurance Identification Number FWA00004876, dated June 6, 2003
3. Animal Welfare Assurance Number for Subcontractor DSTL, A5537-01, dated October 7, 2002.

END of the SCHEDULE
(CONTRACT)

Statement of Work

[***]

Contract No. N01-AI-30052

Statement of Work

[***]

Contract No. N01-AI-30052

Statement of Work

[***]

Contract No. N01-AI-30052

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

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

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

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

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall he submitted monthly unless otherwise authorized by the contracting officer.

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

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

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

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

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

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

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

(b) **Completion Invoice -** The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The

completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.

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

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) **Designated Billing Office Name and Address** - Enter the designated billing office and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number** - Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared** - Insert the date the invoice/financing request is prepared.

(d) **Contract Number and Date** - Insert the contract number and the effective date of the contract.

(e) **Payee's Name and Address** - Show the contractors name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract** - Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

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

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

(i) **Incurred Cost - Current** - Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.

(j) **Incurred Cost - Cumulative** - Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

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

(1) **Direct Labor** - - Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.

(2) **Fringe Benefits** - - List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property** - Include permanent research equipment and general purpose equipment having a unit acquisition cost of S1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.
- The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule.
- Be preceded by an asterisk (*) if the equipment is below the approval level.

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

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

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

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

(8) billed separately from domestic travel.

(9) **Subcontract Costs** - List subcontractor(s) by name and amount billed.

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

(l) **Cost of Money (COM)** - Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed_

(m) **Indirect Costs-Overhead** - Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned** - Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) **Total Amounts Claimed** - Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments** - - Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) **Grand Totals**

The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

Column D - Incurred Cost-Current - Enter the costs, which were incurred during the current period.

Column E-Incurred Cost-Cumulative - Enter the cumulative cost to date.

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Billing Office Name and Address

NATIONAL INSTITUTES OF HEALTH
National Institute of Allergy and Infectious Diseases.
Room 2230, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

(b) Invoice/Financing Request No.

(c) Date Invoice Prepared

(d) Contract No.

Effective Date

(e) Payee's Name and Address

ABC CORPORATION
100 Main Street
Anywhere, USA zip code

Attn: Name, Title, & Phone Number of Official to Whom Payment is Sent

(f) Total Estimated Cost

(g) Total Fixed Fee

(h) 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	Incurred Cost (i) Current D	Incurred Cost (j) Cumulative E	Cost at Completion F	Contract Amount G	Variance H
(k) Direct Costs							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property (attach HHS-565)							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(l) Cost of Money							
(m) Overhead							
G&A							
(n) Fixed Fee							
(o) Total Amount Claimed							
(p) Adjustments							
(q) Grand Totals							

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

(Name of Official) (Title)

* Attach details as specified in the contract

NIH(RC)-4
Rev. 5/91

ATTACHMENT 2
Page 5

Contract No. N01-AI-30052

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

	Sex/Gender Females	Males	Unknown or Not Reported	Total
Ethnic Category				
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

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				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				

*These totals must agree
**These totals must agree

Inclusion Enrollment Report
5/2001 (Modified OAMP: 10/2001)

ATTACHMENT 3

Contract No. N01-AI-30052

ANNUAL TECHNICAL PROGRESS REPORT FORMAT

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 Format
July, 1994

ATTACHMENT 4

Contract No. N01-AI-30052

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

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

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

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

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

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

(End of clause)

Safety and Health Clause
HHSAR 352.223-70, (1/01)

ATTACHMENT 5

PROCUREMENT OF CERTAIN EQUIPMENT

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

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

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

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

ATTACHMENT 6

Contract No. N01-AI-30052

RESEARCH PATIENT CARE COSTS

(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.

NIH(RC)-11
(4/1/84)

ATTACHMENT 7

Contract No. N01-AI-30052

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY

CONTRACTOR:

ADDRESS

CONTRACT NUMBER

REPORT DATE:

FISCAL YEAR:

	BEGINNING OF PERIOD		ADJUSTMENTS			END OF PERIOD	
CLASSIFICATION	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND>=$25K							
LAND<$25K							
OTHER REAL>=$25K							
OTHER REAL<$25K							
PROPERTY UNDER CONST>=$25K							
PROPERTY UNDER CONST<$25K							
PLANT EQUIP>=$25K							
PLANT EQUIP<$25K							
SPECIAL TOOLING>=$25K							
SPECIAL TOOLING<$25K							
SPECIAL TEST EQUIP>=$25K							
SPECIAL TEST EQUIP<$25K							
AGENCY PECULIAR>=$25K							
AGENCY PECULIAR<$25K							

MATERIAL>=$25K (CUMULATIVE)
PROPERTY UNDER MFR>=$25K
PROPERTY UNDER MFR<$25K

SIGNED BY:

DATE SIGNED:

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | 1. CONTRACT ID CODE | PAGE OF PAGES 1 2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (*If applicable*)
01	**See 16C**	**VR092**	

ISSUED BY CODE 2668-30052

National Institutes of Health
Contract Management Branch, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE

DMID-VR

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, country, State and ZIP Code*)

Avacia Limited
PO Box 42, Hexagon House
Blackley
Manchester, M9 8ZS
England

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. **NO1-AI-30052**

10B. DATED (*SEE ITEM 13*) September 30, 2003

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
DOC#300N1AI30052A EIN 1-900216013-A1 CAN 3-8460924 SOCC# 25.55 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority)*
Unilateral - Article B.2.f.

E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: The purpose of this modification is to add an increment of funds.

	TOTAL FUNDS ALLOTTED			TOTAL ESTIMATED COST		
AMOUNT	**Cost**	**Fixed Fee**	**CPFF**	**Cost**	**Fixed Fee**	**CPFF**
Total Prior to this MOD:	[***]	[***]	[***]	[***]	[***]	[***]
MOD #01:	[***]	[***]	[***]	[***]	[***]	[***]
TOTAL	[***]	[***]	[***]	[***]	[***]	[***]

COMPLETION DATE: [***]
FUNDED THROUGH: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)*

16A. NAME AND TILE OF CONTRACTING OFFICER (*Type or print)*
[***]
[***]

15B. CONTRACTOR/OFFEROR 15C. DATE SIGNED

(*Signature of person authorized to sign)*

16B. UNITED STATES OF AMERICA 16C. DATE SIGNED
[***]

BY [***]
(Signature of Contracting Officer)

NSN 7540-01-152-8070 **OMB No. 0990-0115** **STANDARD FORM 30** (REV. 10-83)

ARTICLE B.2. ESTIMATED COST AND FIXED FEE - paragraphs d, e and g are modified to read as follows:

d. Total funds currently available for payment and allotted to this contract are increased by [***] from [***] to [***] of which [***] represents the estimated costs, and of which [***] represents the fixed fee. These funds cover the start dates for Milestones 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, and 17. For further provisions on funding see the LIMITATION OF FUNDS clause referenced in Part II, Article 1.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through [***].

g. Future increments to be allotted to this contract are estimated as follows:

FY	PERIOD	ESTIMATED COST	FIXED FEE
[***]	[***]	[***]	[***]

These funds cover continuation of Milestones 7, 9, 10, 11, 12, 13, and 17.

No other terms and conditions are changed by this modification.

[Letterhead of Department of Health and Human Services]

August 9, 2004

Our Reference: Contract No. N01-AI-30052
Modifications 03

Avecia Limited
PO Box 42, Hexagon House
Blackley
Manchester, M9 8ZS
England

[***]

[***]

We are enclosing an executed copy of the referenced modification for your retention. Should you have any questions regarding its administration, please do not hesitate to contact me on (301) 402-6298 or write to:

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

Sincerely,

[***]

[***]
Contracting Officer
Contract Management Branch
National Institute of Allergy
and Infectious Diseases

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES
1 3

2. AMENDMENT/MODIFICATION NO
03

3. EFFECTIVE DATE
See Block 16 C

4. REQUISITION/PURC
N/A

5. PROJECT NO. (*if applicable*)
N/A

6. ISSUED BY CODE

National Institutes of Health
Contract Management Branch, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*if other than Item 6)* CODE

DMID - VRCB

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State, and ZIP Code)*

Avecia, Limited
P.O. Box 42 Hexagon House
Blackleyh
Manchester, M9 8ZS
England

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ ORDER NO.
N01-AI-30052

10B. DATED (*SEE ITEM 13*)
September 29, 2003

CODE FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change maybe made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required)*
N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

{PRIVATE}A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b)

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO THE AUTHORITY OF:
FAR 1.602-1

D. OTHER (*Specify type of modifications and authority*)

E. IMPORTANT: Contractor o is not, o is required to sign this document and return **2** copies to the issuing office.

14. DESCRIPTION OF AMENDMENT MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: To modify ARTICLE G.1- PROJECT OFFICER and ARTICLE B.4 - ADVANCE UNDERSTANDINGS.

Total Estimated Cost Plus Fixed Fee - [***] (Unchanged)
Total Funds Allotted: [***] (Unchanged)

Completion Date: [***] (Unchanged)
Funded Through: [***] (Unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)		16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)	
[***]		[***] [***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
[***]	3August2004	BY [***]	8/6/04
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

NSN 7540-01-152-8070 OMB No. 9009-0115 **STANDARD FORM 30** (REV. 10-83) FAR (48 CFR) 53.243

The following name and address associated with the NIAID contracts organization are modified where they appear in the contract:

DELETE	**REPLACE WITH**
Contract Management Branch **CMB, NIAID, NIH** **Room 2230, MSC 7612** **6700-B Rockledge Drive** **Bethesda, MD 20892-7612**	**Contract Management Program** **CMP, NIAID, NIH** **Room 3214, MSC 7612** **6700-B Rockledge Drive** **Bethesda, MD 20892-7612**

ARTICLE B.4. ADVANCE UNDERSTANDINGS paragraph p. is added to the contract as follows:

p. The Centers for Disease Control and Prevention (CDC) will supply the following to Avecia under this contract as Government furnished information:

Current technical protocols for:

[***]

The Center for Disease Control will also supply uncontrolled copies of all associated quality system documents for the proper implementation of these protocols.

CDC will initiate a separate agreement with Avecia to transfer the above information. The agreement will allow Avecia to share this information with contractors that will be bidding [***].

When Avecia selects their subcontractor, CDC may, pending further discussion and agreement with NIH, provide public domain and proprietary computer software algorithms for the implementation of these protocols, a limited quantity of reagents, and technical or intellectual oversight for a technology transfer activity to the successful subcontractor.

ARTICLE G.1. PROJECT OFFICER is replaced in its entirety with the following:

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

[***]
[***]
[***]
[***]
DHHS/NIH/NIAID
6610 Rockledge Dr, Room 5119, MSC 6604
Bethesda, MD 20892-6604
ph 301-451-4806
fax 301-480-1263
swinram@niaid.nih.gov

[***]

[***]
[***]
[***]
DHHS/NIH/NIAID
6610 Rockledge Dr, Room 5002, MSC 6604
Bethesda, MD 20892-6604

ph 301-451-6737
fax 301-480-1263
eflynn@niaid.nih.gov

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

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

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

The Government may unilaterally change its Project Officer designation.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A — PAGE OF PAGES 1 3

2. AMENDMENT/MODIFICATION NO. 04

3. EFFECTIVE DATE see block 16C, below

4. REQUISITION/PURCHASE REQ. NO. VRCB146

5. PROJECT NO. (*if applicable*)

6. ISSUED BY — CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Program
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7912

ADMINISTERED BY (*if other than Item 6*) VR — CODE

8. NAME AND ADDRESS OF CONTRACTOR (*No. Street, County, State and ZIP Code*)

Avecia Ltd
P.O. Box 42, Hexagon House
Blackley
Manchester, M9 8ZS

England

CODE — FACILITY CODE

o 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

10A. MODIFICATION OF CONTRACT/ORDER NO. N01-AI-30052

x 10B. DATED (*SEE ITEM 13*) September 29, 2003

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended and set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and the specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning (1) copy of the amendment, (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*
EIN #1-900216013-A1 CAN #4-8460924 - [***] SOC #25.55 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

o A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (***Specify authority***) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER (*Specify type of modification and authority)*

x Article B.2.f.

E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.*)

PURPOSE: To provide incremental funding and to update Section H. articles.

TOTAL FUNDS ALLOTTED

	Estimated Cost	Fixed Fee	Total Allotted Amount
Prior to this mod:	[***]	[***]	[***]
This modification #4:	[***]	[***]	[***]
Total:	[***]	[***]	[***]

Total Funds Allotted: [***]
TOTAL Contract Amount: [***]
Funded Through: [***]
Contract Completion Date: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)*

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED

(Signature of person authorized to sign)

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*) [***]

16B. UNITED STATES OF AMERICA [***]

16C. DATE SIGNED [***]

BY _____ (*Signature of Contracting Officer*)

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (40 CFR) 53.243

ARTICLE B.2. ESTIMATED COST AND FIXED FEE - - paragraphs d., e. and g. are hereby modified to read as follows:

d. Total funds currently available for payment and allotted to this contract are hereby increased by [***] from [***] to [***]; of which [***] represents an increase to the estimated cost from [***] to [***] and of which [***] represents an increase to the fixed fee from [***] to [***]. For further provisions on funding, see the LIMITATION OF FUNDS Clause referenced in Part II, ARTICLE 1.2., Authorized Substitution of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through [***].

g. Future increments to be allotted to this contract are estimated as follows:

PERIOD	ESTIMATED COST	FIXED FEE	TOTAL AMOUNT
[***]	[***]	[***]	[***]

ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH - - paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-199, Title V-General Provisions, Section 510	2004	10/01/2003 -09/30/2004

ARTICLE H.7. NEEDLE EXCHANGE - paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-199, Title V-General Provisions, Section 505	2004	10/01/2003 09/30/2004

ARTICLE H.12. SALARY RATE LIMITATION LEGISLATION PROVISIONS, paragraphs b and c are hereby modified to add the following:

b.

Public Law. No.	Fiscal Year	Dollar Amount of Salary Limitation
P.L. 108-199, Title II - General Provisions, Section 204	2004	Executive Level I

c. Direct salaries which will be paid with FY-04 funds are limited to the Executive Level 1 rate which was in effect on the date(s) the expense was incurred.

**For contract expenditures using FY-04 funds, the Executive Level I rate for the period 10/1/03 - 12/31/03 is $171,900. Effective 1/1/04, for contract expenditures using FY-04 funds, the Executive Level 1 rate was increased to $175,700 and will remain at that level until such time as it is determined to raise the Executive Schedule annual rates. See the web site listed below for Executive Schedule rates of pay.*

LINK to EXECUTIVE LEVEL SALARIES: http://www.opm.gov/oca/PAYRATES/index.htm
(Click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years.)

NOTE: All prior Public Laws and related Executive Levels incorporated in the Basic Award and all previous Modifications shall remain in effect for the applicable fiscal year and related funds.

ARTICLE H.14. PRESS RELEASES, paragraph b., is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-199, Title V - General Provisions, Section 507	2004	10/01/2003-09/30/2004

ARTICLE H.16. ANTI-LOBBYING, paragraph c. is hereby modified to add the following:

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.

Public Law and Section No.	Fiscal Year	Period Covered
for a. above: P.L. 108-199, Title V - General Provisions, Section 503a	2004	10/01/2003 - 09/30/2004
for b. above: P.L. 108-199, Title V - General Provisions, Section 503b	2004	10/01/2003 - 09/30/2004

All other terms and conditions of the contract remain unchanged.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES 1 8

2. AMENDMENT /MODIFICATION NO
Mod #06

3. EFFECTIVE DATE
See Block 16 C

4. REQUISITION/PURC
N/A

5. PROJECT NO. (If applicable)
N/A

6. ISSUED BY CODE

National Institutes of Health
Contract Management Program, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

7. ADMINISTERED BY (If other than Item 6) CODE

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and Zip Code)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9.B. DATED (SEE ITEM 11)

x 10A. MODIFICATION PF CONTRACT/ORDER NO.
N01-AI-30052

10B. DATED (SEE ITEM 13)
September 29, 2003

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

" The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of offers" is extended. " is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing items 8 and 15, and returning copies of the amendment: (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
x FAR 43.202

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 1.602-1 AND 52.243-2, Changes - Cost Reimbursement, Alternate V

D. OTHER (*Specify type of modification and authority*)

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 3 copies to the issuing office

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: To issue a Change Order to the Statement of Work and revise the milestone payment schedule in Article B.4.

TOTAL AMOUNT FUNDED: [***]
TOTAL ESTIMATED COST: [***]
FUNDED THROUGH: [***]
CONTRACT EXPIRATION DATE: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changes, remains unchanges and in full force and effect

15A. NAME AND TITLE OF SIGNER (*Type or Print*)
[***]

15B. CONTRACTOR/OFFEROR

[***]

15C. DATE SIGNED

27JUL05

[***]
(*Signature of person authorized to sign*)

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)

16B. UNITED STATES OF AMERICA

[***]
[***]

16C. DATE SIGNED
[***]

BY [***]
(*Signature of contracting Officer*)

NSN 7540-01-152-8070 **OMB No. 0990-0115** **STANDARD FORM 30** (REV. 10-83) Far (48 CFR) 53.243

ARTICLE B.4. **ADVANCE UNDERSTANDINGS** - - Paragraph h., item 17 is deleted, and items 4-8, and 10-16 are hereby revised as follows:

h. 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 milestone based installments and payment of this fee shall be determined by the Project Officer's written certification that the milestone has been satisfactorily performed and that the technical requirements have been met regarding the completion of the following milestones: If the Contractor meets the milestones earlier than the dates set forth below, then the fee will be paid at the earlier date after completion of the milestone.

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
4	[***]	[***]	[***]	[***]
	a) [***]		a) [***]	
			b) [***]	
	b) [***]		c) [***]	
	c) [***]			

5	[***]	[***]	[***]	[***]
	Fee shall be paid in two installments for this milestone based on the completion of the following items: a) [***] b) [***]		a) [***] b) [***]	
6	[***]	[***]	[***]	[***]
	Fee shall be paid in three installments for this milestone based on the completion of the following items: a) [***]		a) [***]	

	b) [***] c) [***]		b) [***] c) [***]	
7	[***]	[***]	[***]	[***]
8	[***]	[***]	[***]	[***]
	Fee shall be paid in six installments for this milestone based on the completion of the following items: a) [***] b) [***] c) [***] d) [***] e) [***] f) [***]		a) [***] b) [***] c) [***] d) [***] e) [***] f) [***]	

10	[***]	[***]	[***]	[***]
	Fee shall be paid in three installments for this milestone based on the completion of the following items: a) [***] b) [***] c) [***]		a) [***] b) [***] c) [***]	
11	[***]	[***]	[***]	[***]
	Fee shall be paid in three installments for this milestone based on the completion of the following items: a) [***] b) [***] c) [***]		a) [***] b) [***] c) [***]	

12	[***]	[***]	[***]	[***]
	Fee shall be paid in two installments for this milestone based on the completion of the following items: a) [***] b) [***]		a) [***] b) [***]	
13	[***]	[***]	[***]	[***]
	Fee shall be paid in six installments for this milestone based on the completion of the following items: a) [***] b) [***]		a) [***] b) [***]	

	c) [***] d) [***] e) [***] f) [***]		c) [***] d) [***] e) [***] f) [***]	
14	[***] Fee shall be paid in three yearly installments for this milestone based on the completion of the following	[***]	[***]	[***]

	items: a) [***] b) [***] c) [***]		a) [***] b) [***] c) [***]	
15	[***] Fee shall be paid in three equal installments (one each year) on provision of [***] a) [***] b) [***] c) [***]	[***]	[***] a) [***] b) [***] c) [***]	[***]
16	[***] Fee shall be paid in three installments (one each year) upon completion of [***] a) [***] b) [***] c) [***]	[***]	[***] a) [***] b) [***] c) [***]	[***]

ARTICLE B.4. ADVANCE UNDERSTANDINGS - - Paragraph p., is added to read as follows:

p. **Contractor's Statement of Release**

In consideration of the modification agreed to herein as complete equitable adjustments for the Contractor's doses reduction proposal for adjustment, the Contractor hereby releases the Government from any and all liability under this contract for further equitable adjustments attributable to such facts or circumstances giving rise to the proposal for adjustment.

ARTICLE G.1. PROJECT OFFICER - - the second paragraph is hereby modified to replace the Co-Project Officer as follows:

[***]
[***]
[***]
[***]
DHHS/NIH/NIAID/OBRA
Bethesda MD 20892
Ph: (301) 451-6737
Fax: (301) 480-1263/ (301) 480-3235
shrivass@niaid.nih.gov

SECTION J - - List of Attachments

ATTACHMENT 1, Statement of Work, Milestones 4-6, 8, 10-14, and 17 are hereby modified as follows:

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

Milestone 17: DELETED.*

[***]

All other terms and conditions of the contract remain unchanged.

[Letterhead of Department of Health and Human Services]

September 13, 2005

[***]
Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

Subject: Contract No. N01-AI-30052
Modification No. 07

[***]

We are enclosing an executed copy of the subject modification for your retention. If you have any questions regarding its administration, please contact the Undersigned, at (301) 451-2617.

Sincerely,

[***]
[***]
Contract Specialist

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A — PAGE OF PAGES 1 3

2. AMENDMENT/MODIFICATION NO. 07

3. EFFECTIVE DATE [See block 16C, below]

4. REQUISITION/PURCHASE REQ. NO. DMID 2 017

5. PROJECT NO. (*If applicable*) N/A

ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Branch
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID2-RCB

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, country, State and ZIP Code*)

Avacia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. NO1-AI-30052

10B. DATED (*SEE ITEM 13*) 09/30/2003

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes references to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
DOC#300N1AI30052A EIN 1-900216013-A1 CAN 3-8460924 SOCC# 25.55 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority)*
P.L. 1.602-1; Limitation of Funds Clause and P.L. 108-447

E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: Incremental Funding.

	Total Funds Currently Allotted			Total Estimated Cost		
	Cost	Fixed Fee	CPFF	Cost	Fixed Fee	CPFF
Total Prior to this Mod:	[***]	[***]	[***]	[***]	[***]	[***]
Mod #01:	[***]	[***]	[***]	[***]	[***]	[***]
Revised TOTAL	[***]	[***]	[***]	[***]	[***]	[***]

COMPLETION DATE: [***]
FUNDED THROUGH: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)*

16A. NAME AND TILE OF CONTRACTING OFFICER (*Type or print)*
[***]
[***]

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED
[***]

BY [***]
(*Signature of person authorized to sign)*
(Signature of Contracting Officer)

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)STANDARD FORM 30
(REV. 10-83 Prescribed by GSA
FAR (48 CFR) 53.243

ARTICLE B.2. ESTIMATED COST AND FIXED FEE, paragraphs d. and e., are hereby modified to read as follows and paragraph g. is deleted in its entirety:

d. Total funds currently available for payment and allotted to this contract are hereby increased by [***] from [***] to [***]; of which [***] represents an increase to the estimated cost from [***] to [***]; and of which [***] represents an increase to the fixed fee from [***] to [***]. For further provisions on funding, see the LIMITATION OF COST Clause referenced in Part II, ARTICLE 1.1., General Clauses for a Cost-Reimbursement Research and Development Contract.

e. It is estimated that the amount currently allotted will cover performance of the contract through [***]. By virtue of this action, this contract is hereby fully funded.

ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-447, Title V General Provisions, Section 509	2005	10/01/04-09/30/05

ARTICLE H.7. NEEDLE EXCHANGE, paragraph b, is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-447, Title V - General Provisions, Section 505	2005	10/01/04-09/30/05

ARTICLE H.12. SALARY RATE LIMITATION LEGISLATION PROVISIONS, paragraphs b. and c. are hereby modified to add the following:

b.

Public Law No.	Fiscal Year	Dollar Amount of Salary Limitation*
P.L. 108-447. Title II, General Provisions, Section 204	2005	Executive Level I

c. Direct salaries are limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

**For the period 10/1/04-12/31/04, the Executive Level I rate is $175,700. Effective 1/1/05, the Executive Level I rate increased to $180,100 and will remain at that rate until it is revised. See the web site listed below for Executive Schedule rates of pay.*

LINK to EXECUTIVE LEVEL SALARIES: http://www.opm.gove/oca/05tables/html/ex.asp *(For previous years, go to: http://www.opm.gove/oca/05tables/index.asp and click on the year to locate the Executive Level salary rates.)*

NOTE: All prior Public Laws and related Executive Levels incorporated in the Basic Award and all previous Modifications shall remain in effect for the applicable fiscal year and related funds.

HHS-556

ARTICLE H.14. PRESS RELEASES, paragraph b., is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-447, Title V - General Provisions, Section 506	2005	10/01/04-09/30/05

ARTICLE H.16. ANTI-LOBBYING, paragraph c., is hereby modified to add the following:

c. Public Law and Section No.	Fiscal Year	Period Covered
for b., above: P.L. 108-447, Title V - General Provisions, Section 503b	2005	10/1/04-9/30/05
for a., above: P.L. 108-447, Title V - General Provisions, Section 503a	2005	10/1/04-9/30/05

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES, is hereby modified to delete FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984), reinstating the applicability of FAR Clause 52.232-20, LIMITATION OF COST (APRIL 1984) of **ARTICLE 1.1**.

HHS-556

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A

PAGE OF PAGES 1 4

2. AMENDMENT/MODIFICATION NO 08

3. EFFECTIVE DATE [See block 16C, below]

4. REQUISITION/PURCHASE REQ. NO.

5. PROJECT NO. (*If applicable*) N/A

ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Branch
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID-RCB-B

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avacia Limited
PO Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. N01-AI-30052

10B. DATED (*SEE ITEM 13*) 09/30/2003

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, ois not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes references to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN 1-900216013-A1 SOCC# 25.55 CAN 6-846701 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority)*
P.L. 1.602-1; Limitation of Cost Clause and P.L. 109-149

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: To increase the Total Estimated Cost of the contract and obligate funds in the amount of the increase.

	Total Funds Currently Allotted			Total Estimated Cost		
	Cost	Fee	Total	Cost	Fee	Total
Total Prior to this Mod:	[***]	[***]	[***]	[***]	[***]	[***]
This Mod #	[***]	[***]	[***]	[***]	[***]	[***]
Revised Total	[***]	[***]	[***]	[***]	[***]	[***]

COMPLETION DATE: [***]
FUNDED THROUGH: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)* [***]

16A. NAME AND TILE OF CONTRACTING OFFICER (*Type or print)*

15B. CONTRACTOR/OFFEROR [***]

15C. DATE SIGNED 30 August 2006

16B. UNITED STATES OF AMERICA [***]

16C. DATE SIGNED [***]

(*Signature of person authorized to sign)*

BY (*Signature of Contracting Officer)*

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83
Prescribed by GSA
FAR (48 CFR) 53.243

ARTICLE B.2. ESTIMATED COST AND FIXED FEE, paragraphs a., c., d., and e., are hereby modified to read as follows:

a. The estimated cost of this contract is increased by [***] from [***] to [***].

c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee, is increased [***] from [***] to [***].

d. Total funds currently available for payment and allotted to this contract are hereby increased by [***] from [***] to [***]; of which [***] represents an increase to the estimated cost from [***] to [***] and of which [***] represents and increase to the fixed fee remaining unchanged at [***] For further provisions on funding, see the LIMITATION OF COST Clause referenced in Part II, ARTICLE 1.1., General Clauses for a Cost-Reimbursement Research and Development Contract.

e. It is estimated that the amount currently allotted will cover performance through contract completion.

ARTICLE B.3. ADVANCE UNDERSTANDINGS, paragraphs h., is hereby modified to revise the submilestone estimated cost, fixed fee and total cost plus fixed fee detail as follows (all other aspect and descriptions of the milestone chart remains inchanged):

Milestone	Submilestone	Estimated Cost	Fixed Fee	Total CPFF
[***]		[***]	[***]	[***]
[***]		[***]	[***]	[***]
[***]		[***]	[***]	[***]
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	

	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	

[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
[***]	[***]	[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]
	[***]		[***]	
	[***]		[***]	
	[***]		[***]	
[***]		[***]	[***]	[***]

HHS-556

CONTRACT No: N01-AI-30052 **SPECIAL PROVISIONS** **Page 4 of pages 4**
Modification No: 08

ARTICLE H.6. **CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**, paragraph b. is hereby modified to add the following:

b. Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V - General Provisions, Section 509	2006	10/01/05-09/30/06

ARTICLE H.7. **NEEDLE EXCHANGE**, paragraph b. is hereby modified to add the following:

b. Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V - General Provisions, Section 505	2006	10/01/05-09/30/06

ARTICLE H.12. **SALARY RATE LIMITATION LEGISLATION PROVISIONS**, paragraphs b. and c. are hereby modified to add the following:

b. Public Law No.	Fiscal Year	Dollar Amount of Salary Limitation*
P.L. 109-149	2006	Executive Level I

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

---

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

FOR FY06 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2006:

http://www.opm.gove/oca/06tables/html/ex.asp

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

NOTE: All prior Public Laws and related Executive Levels incorporated in the Basic Award and all previous Modifications shall remain in effect for the applicable fiscal year and related funds.

ARTICLE H.14. **PRESS RELEASES**, paragraph b., is hereby modified to add the following:

b. Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V - General Provisions, Section 506	2006	10/01/05-09/30/06

ARTICLE H.16. **ANTI-LOBBYING**, paragraph c., is hereby modified to add the following:

b. Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V - General Provisions, Section 503a	2006	10/01/05-09/30/06
P.L. 109-149, Title V - General Provisions, Section 503b	2006	10/01/05-09/30/06

HHS-556

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT 1. CONTRACT ID CODE N/A PAGE OF PAGES 1 2

2. AMENDMENT/MODIFICATION NO 09 | 3. EFFECTIVE DATE [See block 16C, below] | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (*If applicable*) N/A

ISSUED BY	CODE	7. ADMINISTERED BY (*If other than Item 6*)	CODE N/A
National Institutes of Health, HHS National Institute of Allergy and Infectious Diseases DEA, Contract Management Branch 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612		MID RCB-B	

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)		
Avacia Limited PO Box 42, Hexagon House Blackley, Manchester, M9 8ZS, UK	x	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (*SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. N01-AI-30052
		10B. DATED (*SEE ITEM 13*)
CODE FACILITY CODE		09/30/2003

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes references to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN 1-900216013-A1; SOCC 25-55

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority)*
P.L. 1.602-1; Limitation of Cost Clause and P.L. 109-149

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: Modify Invoice Payment Procedures under ARTICLE G.3.

COMPLETION DATE: [***] FUNDED THROUGH: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)*		16A. NAME AND TILE OF CONTRACTING OFFICER (*Type or print)*	
[***] [***]		[***] [***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
[***]	14JUN07	[***]	[***]

BY _____
(*Signature of person authorized to sign)* (*Signature of Contracting Officer)*

NSN 7540-01-152-8070 30-105 STANDARD FORM 30 (REV. 10-83
PREVIOUS EDITION UNUSABLE Computer Generated Prescribed by GSA
FAR (48 CFR) 53.243

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT - is hereby modified to read as follows:

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

(1) Payment requests shall be submitted as follows:

On original to follow 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

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

(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 **NIAID OA Invoices**.

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

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

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

b. Inquiries regarding payment shall be directed to the designated billing office, (301) 496-6088.

SECTION J - - Attachment 2, Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 is hereby replaced with the following updated attachment.

HHS-556

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 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 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.

(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, VIN, 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. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contract, VIN, and DUNS).

(c) **Invoice/financing Request Number**: Insert the appropriate serial number of the payment request.

(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 Instruction in Section G of the Contract Schedule.

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

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

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

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

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

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

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

· hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and

---

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

(2) **Fringe Benefits**: List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(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 costs (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 request. 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 for 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, 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 for computation or fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

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

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

(u) **Grand Totals**

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

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

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

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

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B432, MSC 8500
Bethesda, MD 20692-8500

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

ABC CORPORATION
100 Main Street
Anywhere, USA Zip Code
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
VIN:
DUNS or DUNS+4

(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) o Two-Way Match o Three-Way Match

(j) Office of Acquisitions:

(k) Central Point of Distribution:

(l) This invoice /financing request represents reimbursable costs for the period 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 Amount G	Variance H
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials and 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) adjustments							
(t) adjustments							
(u) Grand Totals							

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

(Name of Official) (Title)

* Attach details as specified in the contract

NIH(RC)-4
Rev. 05/2007

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A

PAGE OF PAGES 1 8

2. AMENDMENT/MODIFICATION NO 10

3. EFFECTIVE DATE [see block 16C, below]

4. REQUISITION/PURCHASE REQ. NO. DMIO 2 017

5. PROJECT NO. (*If applicable*) N/A

ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Branch
Room 3214 MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID2-RCB

8. NAME AND ADDRESS OF CONTRACTOR (*No., Street, county, State and ZIP Code*)

Avecia Limited
PO Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

o 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. NO1-AI-30052

10B. DATED (*SEE ITEM 13*) 09/30/2003

CODE FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

oThe above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ois extended, ois not extended

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes references to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN 1-900216013 - A1 SOCC 25.55

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

o A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
P.L. 1.602-1

D. OTHER (*Specify type of modification and authority)*

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: To increase the Total Estimated Cost and Fixed Fee; clarify Part B Statement and Work and the corresponding milestones; and to extend the contract completion date.

	TOTAL FUNDS ALLOTTED			TOTAL ESTIMATED COST		
AMOUNT	**Cost**	**Fee**	**Total**	**Cost**	**Fee**	**Total**
Prior to this Mod:	[***]	[***]	[***]	[***]	[***]	[***]
This Mod #01:	[***]	[***]	[***]	[***]	[***]	[***]
Revised TOTAL	[***]	[***]	[***]	[***]	[***]	[***]

FUNDED THROUGH DATE: [***] COMPLETION DATE: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (T*ype or print)*
[***]
[***]

16A. NAME AND TILE OF CONTRACTING OFFICER (*Type or print)*
[***]
[***]

15B. CONTRACTOR/OFFEROR
[***]

15C. DATE SIGNED
20 August 2007

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED

BY _____
(*Signature of person authorized to sign)* *(Signature of Contracting Officer)*

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR 53 243)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE
N/A

PAGE OF PAGES
1 8

2. AMENDMENT/MODIFICATION NO
10

3. EFFECTIVE DATE
[see block 16C, below]

4. REQUISITION/PURCHASE REQ. NO.
DMIO 2 017

5. PROJECT NO. (*If applicable*)
N/A

ISSUED BY CODE

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Branch
Room 3214, MSC 7812
6700-B Rockledge Drive
Bethesda, MD 20892-7612

MID2-RCB

8. NAME AND ADDRESS OF CONTRACTOR (*No., Street, County, State and ZIP Code*)

Avecia Limited
PO Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

o 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO.
NO1-AI-30052

10B. DATED (*SEE ITEM 13*)
09/30/2003

CODE FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ois extended, ois not extended

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes references to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN 1-900216013-A1 SOCC 25.55

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

o A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
P.L. 1.602-1

D. OTHER (*Specify type of modification and authority)*

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: Fixed fee; clarify font B statement of Work and the corresponding miles tones; and to extend the contract completion date.

	TOTAL FUNDS ALLOTTED			TOTAL ESTIMATED COST		
AMOUNT	**Cost**	**Fee**	**Total**	**Cost**	**Fee**	**Total**
Prior to this MOD:	[***]	[***]	[***]	[***]	[***]	[***]
This Mod #:	[***]	[***]	[***]	[***]	[***]	[***]
Revised TOTAL	[***]	[***]	[***]	[***]	[***]	[***]

FUNDED THROUGH DATE: August 31, 2009 (Unchanged) COMPLETION DATE: August 31, 2013 (Unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (T*ype or print)*
[***]

16A. NAME AND TILE OF CONTRACTING OFFICER (*Type or print)*
[***]

[***] [***]

15B. CONTRACTOR/OFFEROR [***] | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA [***] | 16C. DATE SIGNED [***]

20 August 2007 | BY

(*Signature of person authorized to sign*) | (*Signature of Contracting Officer*)

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

ARTICLE B.2. ESTIMATED COST AND FIXED FEE, - - paragraphs a., b., and c. are hereby modified to read as follows:

a. The estimated cost of this contract is increased by [***] from [***] to [***].

b. The fixed fee for this contract is increased by [***] from [***] to [***].

c. The Government's obligation, represented by the sum of the estimated cost plus fixed fee, is increased by [***] from [***] to [***].

ARTICLE B.4. ADVANCE UNDERSTANDINGS, paragraph h., is hereby modified to revise the submilestone estimated cost, fixed fee, total cost plus fixed fee, and clarification of the work to be completed per milestone; detail as follows (all other aspects and descriptions of the milestone chart remain unchanged):

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
4	[***]	[***]	[***]	[***]
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
5	[***]	[***]	[***]	[***]
	Fee shall be paid in two installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	

6	[***]	[***]	[***]	[***]
	Fee shall be paid in three installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
7	[***]	[***]	[***]	[***]
8	[***]	[***]	[***]	[***]
	Fee shall be paid in six installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	

10	[***]	[***]	[***]	[***]
	Fee shall be paid in three installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	
	g) [***]		g) [***]	
	h) [***]		h) [***]	

11	[***]	[***]	[***]	[***]
	Fee shall be paid in five installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	

12	[***]	[***]	[***]	[***]
	Fee shall be paid in two installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
13	[***]	[***]	[***]	[***]
	Fee shall be paid in six installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	
14	[***]	[***]	[***]	[***]
	Fee shall be paid in three yearly installments for this milestone based on the completion of the following items:			
	a) [***]		a) [***]	

	b) [***]		b) [***]
	c) [***]		c) [***]

15	[***]	[***]	[***]	[***]
	Fee shall be paid in three equal installments (one each year) on provision of			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
16	[***]	[***]	[***]	[***]
	Fee shall be paid in three installments (one each year) upon completion			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	

	g) [***]		g) [***]
	h) [***]		h) [***]
	i) [***]		i) [***]
	j) [***]		j) [***]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A — PAGE OF PAGES 1 3

2. AMENDMENT/MODIFICATION NO 11

3. EFFECTIVE DATE [see block 16C, below]

4. REQUISITION/PURCHASE REQ. NO. 182712

5. PROJECT NO. (*If applicable*) N/A

ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Branch
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID2-RCB

VIN: 1109979

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, country, State and ZIP Code*)

Avecia Limited
PO Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

o 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. N01-AI-30052

10B. DATED (*SEE ITEM 13*) 09/30/2003

CODE FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ois extended, ois not extended

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes references to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN 1-900216013-A1 SOCC 25.55 CAN: 8475593 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

o A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority)*
FAR 1.602-1 and FAR 52.232-11, Limitation of Funds

E. IMPORTANT: Contractor x is not, o is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: The purpose of this modification is to add an increment of funds.

	TOTAL FUNDS ALLOTTED			TOTAL ESTIMATED COST		
AMOUNT	**Cost**	**Fee**	**Total**	**Cost**	**Fee**	**Total**
Total Prior to this MOD:	[***]	[***]	[***]	[***]	[***]	[***]
MOD #01:	[***]	[***]	[***]	[***]	[***]	[***]
TOTAL	[***]	[***]	[***]	[***]	[***]	[***]

FUNDED THROUGH DATE: [***] COMPLETION DATE: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)*

16A. NAME AND TILE OF CONTRACTING OFFICER (*Type or print)*
[***]
[***]

15B. CONTRACTOR/OFFEROR 15C. DATE SIGNED 16B. UNITED STATES OF AMERICA 16C. DATE SIGNED
[***]

BY [***]
(*Signature of person authorized to sign)* *(Signature of Contracting Officer)*

NSN 7540-01-152-8070 30-105 STANDARD FORM 30 (REV. 10-83)
PREVIOUS EDITION UNUSABLE Computer Generated Prescribed by GSA
FAR (48 CFR) 53 243

ARTICLE B.2. **ESTIMATED COST AND FIXED FEE**, - paragraphs d. and e., are hereby modified to read as follows:

d. Total funds currently available for payment and allotted to this contract are hereby increased by [***] from [***] to [***]; of which [***] represents an increase to the estimated cost from [***] to [***]; and of which [***] represents an increase to the fixed fee from [***] to [***]. For further provisions on funding, see the LIMITATION OF FUNDS Clause referenced in Part II, ARTICLE I.1., General Clauses for a Cost-Reimbursement Research and Development Contract.

e. It is estimated that the amount currently allotted will cover performance through January 31, 2011.

ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 110-005, Section 509 *	2007	10/01/06 - 09/30/07

*Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007.

ARTICLE H.7. NEEDLE EXCHANGE, paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 110-005, Section 505 *	2007	10/01/06 - 09/30/07

*Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007.

ARTICLE H.12. SALARY RATE LIMITATION LEGISLATION PROVISIONS, paragraphs b. and c. are hereby modified to add the following:

b.

Public Law and No.	Fiscal Year	Dollar Amount of Salary Limitation*
P.L. 110-005, Section 204 *	2007	Executive Level I

**Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007. Therefore, the provision that restricts the amount of direct salary to Executive Level I of the Federal Executive Pay Scale continues through FY 2007. The Executive Level I annual salary rate was $183,500 for the period January 1 through December 31, 2006. Effective January 1, 2007, the Executive Level I salary rate increased to $186,600.*

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

FOR FY -07 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2007:
http://www.opm.gov/oca/07tables/html/ex.asp
(Note: This site shows the FY-07 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the pages and click on the year to locate the desired Executive Level salary rates.)

NOTE: All prior Public Laws and related Executive Levels incorporated in the Basic Award and all previous Modifications shall remain in effect for the applicable fiscal year and related funds.

ARTICLE H.14. PRESS RELEASES, paragraph b., is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 110-005, Section 506 *	2007	10/01/06 - 09/30/07

*Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007.

ARTICLE H.16. ANTI-LOBBYING, paragraph c., is hereby modified to add the following:

c.

Public Law and Section No.	Fiscal Year	Period Covered
for a., above: P.L. 110-005, Section 503(a)*	2007	10/01/06 - 9/30/07
for b., above: P.L. 110-005, Section 503(b)*	2007	10/01/06 - 9/30/07

**Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007.*

[Letterhead of Department of Health and Human Services]

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Room 6111, 6610 Rockledge Drive
Bethesda, MD 20892-6603
Ph: 301-496-1884

[***]
Avecia Biotechnology
PO Box 2, Belasis Avenue
Billingham
TS23 1 YN United Kingdom

June 12, 2006

Re: [***]

Dear Dr. Duchars,

[***]

[***]

1. Not to further modify the CDC approved modified code
2. To use the routines exclusively for government purposes within the scope of the DMID contract.
3. To contact the CDC for a commercial use license in the event the routines are required for any private or commercial purposes.

If Avecia Biotechnology agrees with the terms of this LoA please have an authorized signatory sign below.

[***]

[***]
[***]
Division of Microbiology and Infectious Diseases

Accepted and Agreed on behalf of Avecia Biotechnology:

[***] Date: [***]

[***]
[***]

[Letterhead of Department of Health and Human Services]

[***]
Avecia Biotechnology
Belasis Avenue
Billingham, Cleveland
TS23 1YN, United Kingdom

6610 Rockledge Dr
Room 5119
Bethesda, MD 20892-6604
Ph 301-451-4806
Fax 301-496-8030
swinram@niaid.nih.gov

RE: Letter of Agreement - NIAID's Clinical Trials using Avecia's rPA Vaccine Candidate

Dear Matthew,

[***]

[***]

NIAID agrees that Avecia may have the following involvement in the DMID sponsored clinical trial:

[***]

Data generated by studies using Avecia's vaccine candidate will be owned by NIAID but will be made available to Avecia, at no cost. Once a clinical trial has been completed, the data obtained may be published with the prior written permission of NIAID. NIAID will provide Avecia an opportunity to review and comment on proposed publications.

Please indicate your acceptance of these terms by having an authorized representative from Avecia Biotechnology sign below. At your earliest convenience, kindly return a copy of this letter to my attention, and then please mail the signed original using the contact information above.

Sincerely,

[***]
[***]
[***]
[***]
July 2, 2007

Authorized Representative for Avecia Biotechnology:

[***] 30th June 2004
Signature & Date

Name: [***]

Title: [***]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE **N/A**

PAGE OF PAGES 1 2

2 AMENDMENT/MODIFICATION NO 13

3 EFFECTIVE DATE **[see block 16C, below]**

4 REQUISITION/PURCHASE REQ. NO.

5 PROJECT NO (*If applicable*) **N/A**

6 ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Branch
Room 3214, MSC 7612
5700-B Rockledge Drive
Bethesda, MD 20892-7612

7 ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID - RCB-B

8. NAME AND ADDRESS OF CONTRACTOR (*No Street County State and ZIP Code*)

PharmAthene UK, Limited VIN: 1148448
Johnson Matthey Building
PO Box 88, Haverton Hill Road
Billingham TS23 1XN

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO **NO1-AI-30052**

10B. DATED (*SEE ITEM 13*) **09/30/2003**

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
SOCC 25.55

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(C) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
FAR 42,12 and FAR 1.502-1

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14 DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: To recognize the Contractor's successor in Interest from Avecia Biologica Limited to Pharmothene UK, Limited, to revise ARTICLE B.4. ADVANCED UNDERSTANDINGS and ARTICLE G.1. PROJECT OFFICER.

	Total Funds Currently Allotted			Total Estimated Cost			
	Cost	Fee	Total	Cost	Fee		Total
Prior to this Mod:	[***]	[***]	117,736,200	[***]	[***]	$	118,036,200
This Mod #	[***]	[***]	-0-	[***]	[***]	$	-0-
Revised Total	[***]	[***]	117,736,200	[***]	[***]	$	118,036,200

FUNDED THROUGH DATE: January 31, 2001 (Unchanged) COMPLETION DATE: August 31, 2013 (Unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)*
Chris Camut, VP, CFO/UK Board of Directors

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print)*
Karen M. Gamble
Contracting Officer, DEA, NIAID, HIH

15B. CONTRACTOR/OFFEROR 15C. DATE SIGNED 12/4/08

/s/ Chris Camut
(*Signature of person authorized to sign)*

16B. UNITED STATES OF AMERICA 16C. DATE SIGNED 12/4/08

BY /s/ Karen Gamble
(Signature of Contracting Officer)

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)
Prescribed by GRA
FAR (48 CPR) 53.243

Contract No: N01-A1-30052
Modification No: 13

SPECIAL PROVISIONS

Pursuant to FAR 42.12, Block 8 of the Standard Form 30 shall read as follows:

PharmAthene UK, Limited VIN: 1148448
Johnson Matthey Building
PO Box 88, Haverton Hill Road
Billingham TS23 1XN

The following is attached and made part of this modification:

Novation Agreement
Exhibit A, List of all Affected Contracts

ARTICLE B.4. ADVANCED UNDERSTANDINGS, paragraph g. Ceilings, is modified to add the following:

(8) As a result of this novation, it is agreed that the Total Estimated Cost of this Contract shall not exceed the current value of $118,036,200, due to any variances in the indirect costs.

ARTICLE G.1. PROJECT OFFICER, is modified to add the following:

The Alternate Project Officer named below will represent the Government for the purpose of this contract:

Nancy Wilkie
Office of Biodefense Research Affairs (OBRA)
Division of Microbiology and Infectious Diseases
DHHS/NIH/NIAID
Room 5004, MSC 6604
6610 Rockledge Drive
Bethesda, MD 20892-6604
wilkien@niaid.nih.gov

HHS-556

NOVATION AGREEMENT

AVECIA BIOLOGICS LIMITED (Transferor), a corporation duly organized and existing under the laws of England and Wales with its principal office in Manchester United Kingdom; **PHARMATHENE UK LIMITED** (Transferee), a corporation duly organized and existing under the laws of England and Wales with its principal office in Billingham, UK; and the **UNITED STATES OF AMERICA** (Government) enter into this Agreement as of 2nd April, 2008.

(a) The parties agree to the following facts:

(1) The Government, represented by various Contracting Officers of the National Institute for Allergies and Infectious Diseases, has entered into certain contracts with the Transferor as shown in the attached list marked 'Exhibit A' and incorporated in this Agreement by reference. The term "the contracts," as used in this Agreement, means the above contracts and purchase orders and all other contracts and purchase orders, including all modifications, made between the Government and the Transferor before the effective date of this Agreement (whether or not performance and payment have been completed and releases executed if the Government or the Transferor has any remaining rights, duties, or obligations under these contracts and purchase orders). Included in the term "the contracts" are also all modifications made under the terms and conditions of these contracts and purchase orders between the Government and the Transferee, on or after the effective date of this Agreement.

(2) As of 2nd April, 2008, the Transferor has transferred to the Transferee all the assets of the Transferor by virtue of a Sale and Purchase Agreement between the Transferor and the Transferee.

(3) The Transferee has acquired all the assets of the Transferor by virtue of the above transfer.

(4) The Transferee has assumed all obligations and liabilities of the Transferor under the contracts by virtue of the above transfer.

(5) The Transferee is In a position to fully perform all obligations that may exist under the contracts.

(6) It is consistent with the Government's interest to recognize the Transferee as the successor party to the contracts.

(7) Evidence of the above transfer has been filed with the Government.

(b) In consideration of these facts, the parties agree that by this Agreement—

(1) The Transferor confirms the transfer to the Transferee, and waives any claims and rights against the Government that it now has or may have in the future in connection with the contracts.

(2) The Transferee agrees to be bound by and to perform each contract in accordance with the conditions contained in the contracts. The Transferee also

---

assumes all obligations and liabilities of, and all claims against, the Transferor under the contracts as if the Transferee were the original party to the contracts.

(3) The Transferee ratifies all previous actions taken by the Transferor with respect to the contracts, with the same force and effect as if the action had been taken by the Transferee.

(4) The Government recognizes the Transferee as the Transferor's successor in interest in and to the contracts. The Transferee by this Agreement becomes entitled to all rights, titles, and interests of the Transferor in and to the contracts as if the Transferee were the original party to the contracts. Following the effective date of this Agreement, the term "Contractor," as used in the contracts, shall refer to the Transferee.

(5) Except as expressly provided in this Agreement, nothing in it shall be construed as a waiver of any rights of the Government against the Transferor.

(6) All payments and reimbursements previously made by the Government to the Transferor, and all other previous actions taken by the Government under the contracts, shall be considered to have discharged those parts of the Government's obligations under the contracts. All payments and reimbursements made by the Government after the date of this Agreement in the name of or to the Transferor shall have the same force and effect as if made to the Transferee, and shall constitute a complete discharge of the Government's obligations under the contracts, to the extent of the amounts paid or reimbursed.

(7) The Transferor and the Transferee agree that the Government is not obligated to pay or reimburse either of them for, or otherwise give effect to, any costs, taxes, or other expenses, or any related increases, directly or indirectly arising out of or resulting from the transfer or this Agreement, other than those that the Government in the absence of this transfer or Agreement would have been obligated to pay or reimburse under the terms of the contracts.

(8) The Transferor guarantees payment of all liabilities and the performance of all obligations that the Transferee—

(i) Assumes under this Agreement; or

(ii) May undertake in the future should these contracts be modified under their terms and conditions. The Transferor waives notice of, and consents to, any such future modifications.

(9) The contracts shall remain in full force and effect, except as modified by this Agreement. Each party has executed this Agreement as of the day and year first above written.

UNITED STATES OF AMERICA,

Signed [***]

Name and Title [***]

AVECIA BIOLOGICS LIMITED,

Signed /s/ Duncan McLellan

Name and Title **Duncan McLellan - Director and Chief Financial Officer**

PHARMATHENE UK LIMITED,

Signed /s/ David P. Wright

Name and Title **David P. Wright - CEO**

CERTIFICATE

I, **Richard Clements**, certify that I am the Company Secretary of AVECIA BIOLOGICS LIMITED, that Duncan McLellan, who signed this Agreement for this corporation, was then a Director and the Chief Financial Officer of this corporation; and that this Agreement was duly signed for and on behalf of this corporation by authority of its governing body and within the scope of its corporate powers. Witness my hand this day of 2nd June 2008.

Signed /s/ Richard Clements

CERTIFICATE

I, **Christopher C. Camut**, certify that I am the Company Secretary of PHARMATHENE UK LIMITED, that David P. Wright, who signed this Agreement for this corporation, was then a Director of this corporation; and that this Agreement was duly signed for and on behalf of this corporation by authority of its governing body and within the scope of its corporate powers. Witness my hand this day of 23 June 2008.

Signed /s/ Christopher C. Camut

Exhibit A

The Contracts

Contract number N01-AI-25492

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Development and Testing of Vaccines Against Anthrax."

Contract number N01-AI-30052

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Production and Testing of Anthrax Recombinant Protective Antigen."

Contract number HHSN266200400034C, N01-AI-40034

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Development, Testing and Evaluation of Candidate Vaccines Against Plague."

List of Affected Contracts

Contract number N01-AI-25492

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Development and Testing of Vaccines Against Anthrax."

This contract is substantially complete. As at 15th January 2008, the total contract amount was $10,155,120 and there was an [***] which is under discussion between Avecia Biologics Limited and NIAID.

Contracting Office: National Institutes of Health
Office of Acquisitions, NIAID
Room 3214
6700-B Rockledge Dr., MSC 7612
Bethesda, Maryland 20892-7612

Contract number N01-AI-30052

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Production and Testing of Anthrax Recombinant Protective Antigen."

As at 15th April 2008, the total contract value was $118,036,200 and the total estimated costs remaining to complete were [***].

Contracting Office: National Institutes of Health
Office of Acquisitions, NIAID
Room 3214
6700-B Rockledge Dr., MSC 7612
Bethesda, Maryland 20892-7612

Contract number HHSN266200400034C, N01-AI-40034

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Development, Testing and Evaluation of Candidate Vaccines Against Plague."

As at 15th April 2008, the total contract value was $50,701,714 and the total estimated costs remaining to complete were [***].

Contracting Office: National Institutes of Health
Office of Acquisitions, NIAID
Room 3214
6700-B Rockledge Dr., MSC 7612
Bethesda, Maryland 20892-7612

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE OF PAGES
			1 25

2. CONTRACT (*Proc. Inst. Ident.*) NO. HSSN266200400034C
3. EFFECTIVE DATE 9/30/04
4. REQUISITION/PURCHASE REQUEST/PROJECT NO. VRCB149

5. ISSUED BY CODE

National Institutes of Health, DHHS
Contract Management Program, NIAID
Room 3214
8700B Rockledge Drive, MSC 7812
Bethesda, Maryland 20892-7612

6. ADMINISTERED BY (*If other than Item 5*) CODE

7. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

8. DELIVERY
o FOB ORIGIN **x** OTHER (*See below*)
FOB Destination

9. DISCOUNT FOR PROMPT PAYMENT
N/A

10. SUBMIT INVOICES (*4 copies unless other-wise specified*) TO THE ADDRESS SHOWN IN ITEM G.3

CODE FACILITY CODE

11. SHIP TO/MARK FOR CODE

See Article F.1

12. PAYMENT WILL BE MADE BY CODE

See Article G.3

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:

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

14. ACCOUNTING AND APPROPRIATION DATA
E/N # 1-900216013-A1 SOC #25.55 ADB # N01-AI-40034
CAN # 4-8480924 Amount: $21,067,201
4-8461247 Amount: $8,595,999

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Title-Development, Testing and Evaluation of Condition Vaccined Against Plague Period: September 30, 2004 through March 29, 2007 Amount Alotted: $27,664,200 Type: Cost Reimbursement Completion	FY 2004			$27,664,200

15G. TOTAL AMOUNT OF CONTRACT $27,664,200

16. TABLE OF CONTENTS

(ü)	SEC.	DESCRIPTION	PAGE(S)	(ü)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
x	A	SOLICITATION/CONTRACT FORM	1	x	I	CONTRACT CLAUSES	19
x	B	SUPPLIES OR SERVICES AND PRICES/COST	2			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
x	C	DESCRIPTION/SPECS./WORK STATEMENT	7	x	J	LIST OF ATTACHMENTS	24
x	D	PACKAGING AND MARKING	8			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
x	E	INSPECTION AND ACCEPTANCE	8	x	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	25
x	F	DELIVERIES OR PERFORMANCE	9				
x	G	CONTRACT ADMINISTRATION DATA	10	o	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
x	H	SPECIAL CONTRACT REQUIREMENTS	12	o	M	EVALUATION FACTORS FOR AWARD	

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 condition 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)*
Derrick Nicholson
Chief Financial Officer

20A. NAME OF CONTRACTING OFFICER
Janet M. Mattson
Contracting Officer
Contract Management Program, NIAID, NIH, DHHS

19B. AVECIA LIMITED
/s/ Derrick Nicholson
(Signature of person authorized to sign)

19C. DATE SIGNED
29/09/04

20B. UNITED STATES OF AMERICA
BY /s/ Janet M. Mattson
(Signature of Contracting Officer)

20C. DATE SIGNED
9/30/04

MAN 7540-01-152-0208
PREVIOUS EDITION UNUSABLE

M-107
Computer Generated

STANDARD FORM 28 (REV. d-85)12/2002)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

SECTION B - - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this contract is to begin early advanced product development for pilot lot manufacture, release and animal testing, and initial human clinical trials of a recombinant plague vaccine.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of Part A of this contract is [***].

b. The fixed fee for Part A of this contract is [***]. The fixed fee shall be paid in installments based on the negotiated milestones set forth in ARTICLE B.4.h. and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE 1.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The Government's obligation, represented by the sum of the estimated cost plus the fixed fee for Part A of this contract is [***].

d. If the Government exercises its option pursuant to ARTICLE H.10. of this contract, the Government's total obligation 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 - Part A	**[***]**	**[***]**	**[***]**
Option Period - Part B	**[***]**	**[***]**	**[***]**
Total (Base Period and Option)	**[***]**	**[***]**	**[***]**

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 Contacting Officer, the costs of the following items or activities shall be unallowable as direct costs:

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

(2) Special rearrangement or alteration of facilities;

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

(4) Travel to attend general scientific meetings;

(5) Consultant costs;

(6) Subcontracts;

(7) Patient care costs;

(8) 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), 1990, regardless of acquisition value.

b. **Travel Costs**

(1) Travel

(a) Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of Part A of this contract shall not exceed [***] without the prior written approval of the Contracting Officer. Total expenditures for travel incurred in direct performance of Option Part B, if exercised, shall not exceed [***] without the prior written approval of the Contracting Officer.

(b) The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.205-46.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

a. **Subcontract**

To negotiate a firm fixed price type subcontract with Baxter Pharmaceutical Solutions LLC for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract and a copy of the draft subcontract agreement. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.)

b. **Subcontract**

To negotiate a cost plus fixed fee type subcontract with the Defence Science and Technology Laboratory (DSTL) for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract and a copy of the draft subcontract agreement. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.)

c. **Subcontract**

To negotiate a fixed price type subcontract with Parexel International Ltd. for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract and a copy of the draft subcontract agreement. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.)

d. **Subcontract**

To negotiate a fixed price type subcontract with Inveresk Research International Ltd. for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract and a copy of the draft subcontract agreement. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.)

e. **Subcontract**

To negotiate a fixed price type subcontract with Battelle for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract and a copy of the draft subcontract agreement. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.)

f. **Subcontract**

To negotiate a fixed price type subcontract with Huntingdon Research Centre Ltd. for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract and a copy of the draft subcontract. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer.)

g. **Subcontract**

To negotiate a fixed price type subcontract with Cylex, Inc. for an amount not to exceed [***]. Award of the subcontract shall not proceed without the prior written approval of the Contracting Officer upon review of the supporting documentation as required by the Subcontracts clause of the General Clauses incorporated in this contract and a copy of the draft subcontract agreement. (After written approval of the subcontract by the Contracting Officer, a copy of the signed, approved subcontract shall be provided to the Contracting Officer).

h. **Consultants**

Consultant fee(s) to be paid to the following individual(s):

Name	Rate Per Day	Number of Days	Including Travel	Total Cost Not to Exceed
TBD				

i. **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 milestone based installments and payment of this fee is determined by the Project Officer's written certification that the milestone has been satisfactorily performed and that the technical requirements have been met regarding the completion of the following milestones. If the contractor meets the milestones earlier than the dates set forth below, then the fee will be paid at the earlier date after completion of the milestone.

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
1	Produce a cGMP pilot lot, sufficient for 2000 doses and capable of supporting an IND on or before February 21, 2005	[***]	[***]	[***]
2	Release 2000 doses and file an IND on or before October 13, 2000	[***]	[***]	[***]
3	Assess safety and efficacy to aerosol challenge in animal models on or before October 13, 2005	[***]	[***]	[***]
4	Produce a protocol for Phase I clinical trial on or before December 31, 2004 and Phase II clinical trial on or before August 22, 2006	[***]	[***]	[***]
5	Conduct Phase I clinical trial on or before December 8, 2005	[***]	[***]	[***]
6	Feasibility to manufacture 3 million doses and put into inventory on or before September 30, 2005	[***]	[***]	[***]
7	Interim report on Phase I trial on or before June 8, 2006	[***]	[***]	[***]
8	Final report on Phase I trial on or before January 4, 2007	[***]	[***]	[***]

j. **Scientific Meetings**

Travel to general scientific meetings as follows:

Authorization to expend contract funds for general scientific meeting travel is not provided herein. The Contractor shall request approval to expend contract funds for general scientific meeting travel, in writing, 4 weeks in advance of the proposed travel. The Contractor's written request shall include the name(s) and title(s) of personnel proposed to travel, the meeting dates and location, details of proposed costs (airfare, per diem/subsistence, other), and a description of the benefit to be derived (to this contract) from the proposed travel.

k. **Invoices - - Cost and Personnel Reporting, and Variances from the Negotiated Budget**

(1) The contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

(a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
(b) 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.
(g) Subcontracts - Attach subcontractor invoice(s).
(h) Equipment - Cite authorization and amount.
(i) G&A - Cite rate and amount.
(j) Total Cost
(k) Fixed Fee
(l) Total CPFF

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

(2) The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

l. **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. HHSN266200400034C
ADB Contract No. N01-AI-40034

m. **Understanding regarding FAR 52.223-6**

FAR Clause 52.223-6 Drug Free Workplace is included in this contract, however, FAR 23.501(c) provides that the clause does not apply to work that is "(c) Performed outside of the United States and its outlying areas or any part of a contract performed outside the United States and its outlying areas."

n. **Understanding regarding FAR 52.222-36**

FAR 22.1408(a) requires the Contracting Officer to "Insert the clause at 52.222-36, Affirmative Action for Workers with Disabilities, in solicitations and contracts that exceed or are expected to exceed $10,000, except when -

"(1) Both performance of the work and the recruitment of workers will occur outside the United States, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island; or

"(2) The agency head has waived, in accordance with 22.1403(a) or 22.1403(b) all the terms of the clause."

It is the mutual understanding of the contracting officer and Avecia that a significant portion of the work, including all self-performed work, under this contract will be performed outside the United States and other named territories by the workers recruited from outside the United States and the named territories. However, it is also mutually understood that some subcontracted work will be performed in the United States. Therefore both parties agree that FAR 52.222-36(a), (b), and (c) will not apply to Avecia and that FAR 52.222-36 (d) "Subcontracts" will only apply to subcontracts that will be performed in the United States or by workers recruited from the United States and the named territories; i.e., FAR 52.222-36 would apply in its entirety to any subcontractor that performs work in the United States. It is also agreed that Avecia will flow-down language similar to that in this paragraph to its subcontracts not performed in the United States; i.e., FAR 52.222-36 would apply in its entirety to any second-tier (or lower) subcontracts performed in the United States.

o. **Understanding regarding FAR 52.222-37**

FAR 22.1310(a)(1)(i) provides that FAR 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, is required to be in contracts over $25,000, except when "Work is performed outside the United States by employees recruited from outside the United States. As FAR 52.222-35(d) contains an "Applicability" clause that limits its reach to the listing of employment openings within the United States and named territories, no additional understanding beyond that applicability clause is necessary.

FAR 22.1310(b) provides that 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans, in solicitations and contracts containing the clause at

FAR 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans. Therefore, if "Work is to be performed outside the United States by Employees recruited outside the United States," FAR 52.222-37 would not be required.

It is the mutual understanding of the contracting officer and Avecia that a significant portion of the work, including all self-performed work, under this contract will be performed outside the United States and the other named territories by workers recruited from outside the United States and the named territories. However, it is also mutually understood that some subcontracted work will be performed in the United States. Therefore, both parties agree that FAR 52.222-37(a) through (e) will not apply to Avecia and that FAR 52.222-37(f) will only apply to subcontracts that will be performed in the United States or by workers recruited from the United States; i.e., FAR 52.222-37 would apply in its entirety to any subcontractor that performs work in the United States. It is also agreed that Avecia will flow-down language similar to that in this paragraph to its subcontracts not performed in the United States; i.e., FAR 52.222-37 would apply in its entirety to any second-tier (or lower) subcontracts performed in the United States.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT 1, dated September 30, 2004, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period, a detailed forecast of work planned for the next 30 day reporting period, and an assessment of how this reconciles with work proposed for the upcoming 90 days. These reports are subject to the technical inspection and requests for clarification by the Project Officer. Execution of the 30 day work plan will be contingent upon NIAID review and approval. These shall be brief and factual and prepared in accordance with the following format:

A. Technical Reports

The Contractor shall prepare and submit the following reports in the manner stated below:

(1) Monthly Technical Progress Reports - On the due date specified in the contract of each month for the previous calendar month, the Contractor shall submit five (5) copies of a Monthly Technical Progress Report, comprising four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall include the following specific information:

a. A cover page that lists the contract number and title, the period of performance being reported, the contractor's names and address, the author(s), and the date of submission;

b. SECTION I - - An introduction covering the purpose and scope of the contract effort;

c. SECTION II - - The report shall detail, document, and summarize the results of work done during the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. Also to be included in the report is a summary of work proposed for the next reporting period. Specific requirements are set forth in the Work Statement. A one-page summary of each ongoing and completed protocol shall be submitted at this time. A monthly report will not be required for the period when the final report is due. Preprints and reprints of papers and abstracts shall be submitted with the Annual Report.

d. SECTION III - - Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and if behind planned progress what corrective steps are planned. The report should include an assessment of percent effort compared to percent complete for each major category.

(2) Milestone Reports - A milestone report will be provided after the completion of each Milestone unless otherwise agreed upon by the Principal Investigator and the Project Officer. Milestone reports and monthly reports may be combined if agreed by the Contracting Officer and the Project Officer.

(3) Final Report - By the expiration date of the contract, the Contractor shall submit four (4) copies of a comprehensive Final Report, as above, comprising three (3) copies to the Project Officer and one (1) copy to the Contracting Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. Specific requirements are set forth in the Work Statement. Preprints and reprints not submitted previously shall be submitted.

(4) Summary of Salient Results - With the monthly report nearest the anniversary date of contract award, and with the final report, the Contractor shall submit a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

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 the address listed for the Project Officer in Article G.1. 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 No 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 30, 2004 through March 29, 2007.

b. If the Government exercises its option(s) pursuant to Article H.10. of this contract, the period of performance will be increased as listed below:

Option Part B **Option Period: 30 months**

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Type of report	No. Copies	Addressee	Due Dates
Monthly Progress	4	Project Officer (PO) DMID/NIAID/NIH 6610 Rockledge Dr. MSC 6605, Room 5117 Bethesda, MD 20892-6605	Fifteenth of each month
Monthly Progress	1	Contracting Officer (CO) CMB/NIAID/NIH 6700-B Rockledge Dr. MSC 7612, Room 3214 Bethesda, MD 20892-7612	Same as above
Milestone Reports	4	Submitted after Milestone completion (3 to Project Officer and 1 to Contracting Officer)	On the fifteenth day after completion of each milestone
Final	4	Submitted with Final Report (3 to Project Officer and 1 to Contracting Officer)	Expiration date of the contract
Summary of Salient Results	4	Same as above	Anniversary and expiration date

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

Project Officer
Office of Biodefense Research Affairs
Division of Microbiology and Infectious Diseases
DHHS/NIH/NIAID
Room 5001, MSC 6604
6610 Rockledge Drive
Bethesda, MD 20892

Contracting Officer
Contract Management Program
DHHS/NIH/NIAID
6700B Rockledge Dr., Rm. 3214, MSC 7612
Bethesda, MD 20892-7612

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.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

Vicki L. Pierson, Ph.D.
Office of Biodefense Research Affairs
Division of Microbiology and Infectious Diseases
DHHS/NIH/NIAID
Room 5001, MSC 6604
6610 Rockledge Drive
Bethesda, MD 20892-6604

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section 1 of this contract, the following individual are considered to be essential to the work being performed hereunder:

Name	Title
Mark Carver, Ph.D.	Principal Investigator

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

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

(a) To be considered a "proper" invoice in accordance with FAR 32.9, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. HHSN266200400034C
ADB Contract No. N0l-AI-40034

(b) An original and two copies to the following designated billing office:

Contracting Officer
Contract Management Program
National Institute of Allergy and Infectious Diseases, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
BETHESDA MD 20892-7612

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-0612.

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.12. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year Funds were initially charged through the final billing period utilizing the applicable Fiscal Year Funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. 108-199 and ARTICLE H.12. of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

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

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE 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 DHHS Publication, **Contractor's Guide for Control of Government Property,** 1990, which is incorporated into this contract by reference. 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 BLVD MSC 7670
BETHESDA MD 20852-7670
(301) 496-6466

b. Notwithstanding the provisions outlined in the DHHS Publication, **Contractor's Guide for Control of Government Property**, 1990 which is incorporated in this contract in paragraph a. above, the contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for performing annual inventories required under this contract. This form is included as an attachment in SECTION J of this contract.

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, an interim evaluation will be prepared mid-point in the contract to coincide with the anniversary date of the contract.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

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. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant office for review. Since these projects may

be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

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.htm. 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 Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.4. 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.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-199, Title V-General Provisions, Section 510	2004	10/l/03 - 9/30/04

ARTICLE H.6. NEEDLE EXCHANGE

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-199. Title V-General Provisions, Section 505	2004	10/1/03 - 9/30/04

ARTICLE H.7. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as Attachment 4.

ARTICLE H.8. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at http://grants1.nih.gov/grants/olaw/references/phspol.htm

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

UNDER GOVERNING POLICY, FEDERAL FUNDS ADMINISTERED BY THE PUBLIC HEALTH SERVICE (PHS) SHALL NOT BE EXPENDED FOR RESEARCH INVOLVING LIVE VERTEBRATE ANIMALS

WITHOUT PRIOR APPROVAL BY THE OFFICE FOR LABORATORY ANIMAL WELFARE (OLAW), OF AN ASSURANCE TO COMPLY WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES WITHOUT OLAW-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.

ARTICLE H.10. 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 Part A of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-9 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform Part B of the Statement of Work as 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 expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in ARTICLE B.2.

ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limit 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 exceeds any salary rate ceiling established in future HHS appropriation acts.

b.

Public Law No.	Fiscal Year	Dollar Amount of Salary Limitation*
P.L. 108-199 Title II, General Provisions, Section 204	2004	Executive Level I

c. Direct eateries which will be paid with FY-04 funds are limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

**For contract expenditures using FY-04 funds, the Executive Level I rate for the period 10/1/03 - 12/31/03 is $171,900. Effective 1/1/04, for contract expenditures using FY-04 funds, the Executive Level I rate is $175,700 and will remain at that level until such time as it is determined to raise the Executive Schedule annual rates. See the web site listed below for Executive Schedule rates of pay.*

LINK to EXECUTIVE LEVEL SALARIES*: *http://www.opm.gov/oca/PAYRATES/index.htm
(Click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll dawn to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years.)

ARTICLE H.12. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN266200400034C."

ARTICLE H.13. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (l) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-199, Title V-General Provisions, Section 507	2004	10/1/03 - 9/30/04

ARTICLE H.14. 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.15. ANTI -LOBBYING

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

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.

Public Law and Section No.	Fiscal Year	Period Covered
for a., above: P.L. 108-199, Title V- General Provisions, Section 503a	2004	10/1/03 - 9/30104
for b., above: P.L. 108-199, Title V- General Provisions, Section 503b	2004	10/1/03 - 9/30/04

ARTICLE H.16. 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.17. SHARING RESEARCH DATA

The contractor's data sharing plan, dated June 4, 2004 is hereby incorporated by reference. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

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

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

ARTICLE H.18. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the contractor should provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/gap/

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

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

FAR CLAUSE NO.	DATE	TITLE
52.202-l	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Oct 2003	Central Contractor Registration
52.209-6	Jul 1995	Protecting the Government’s Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Jan 2004	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data — Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities

52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-l	Jun 2003	Buy American Act - Supplies
52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
52.227-l	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments

52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer—Central Contractor Registration
52.233-l	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *lf written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

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

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 07/2004].

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

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

None.

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 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

(2) FAR 52.217-8, Option to Extend Services (NOVEMBER 1999).

"…The Contracting Officer may exercise the option by written notice to the Contractor within at least 30 days before the contract expires?'

(3) FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference….

[ ] Offeror elects to waive the evaluation preference."

(4) ALTERNATE I (OCTOBER 1998), FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (OCTOBER 1999).

(5) FAR 52.224-l, Privacy Act Notification (APRIL 1984).

(6) FAR 52.224-2, Privacy Act (APRIL 1984).

(7) FAR 52.229-8, Taxes-Foreign Cost-Reimbursement Contracts (MARCH 1990).

(8) FAR 52.229-9, Taxes-Cost-Reimbursement Contracts with Foreign Governments (MARCH 1990).

(9) FAR 52.242-3, Penalties for Unallowable Costs (MAY 2001).

(10) FAR 52.247-63, Preference for U.S. Flag Air Carriers (JUNE 2003).

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

(1) HHSAR 352.223-70, Safety and Health (JANUARY 2001). [This clause is provided in full text in SECTION J - ATTACHMENTS.]

(2) HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the

Protection of Human subjects and should replace office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

(3) HHSARS 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

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

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

(1) NIH(RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

(2) NIH(RC)- 11, Research Patient Care Costs (4/l/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 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (JULY 2004)**

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

Commercial item, has the meaning contained in Federal Acquisition Regulation 52.201-1, Definitions.

Subcontract, includes a transfer of commercial item between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (MAY 2004) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).

(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).

(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (APR 2003) (46 U.S.C. Appx 1241 and 10 U.S.C. 2631) (flow down required in accordance with paragraph (d) of FAR clause 52.247-64).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d.) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, September 30, 2004, 2 pages.

2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (5/97), 5 pages.

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

4. Privacy Act System of Records, Number 09-25-0200, as cited in the Federal Register Notice issued in Volume 62, Number 66, pages 16596-16602, dated April 7, 1997, 9 pages.

5. Safety and Health, HHSAR Clause 352.223-70, (l/01), 1 page.

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

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

8. Report of Government Owned, Contractor Held Property, 1 page.

STATEMENT OF WORK

[***]

Contract No. HHSN2662004000034C
ADB NO. N01-AI-400034

STATEMENT OF WORK

[***]

Contract No. HHSN2662004000034C
ADB NO. N01-AI-400034

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

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

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

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

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the contracting officer.

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

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

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

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

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

Invoice/Financing Request identification: Each invoice/financing request shall be identified as either:

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

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

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

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) **Designated Billing Office Name and Address** — Enter the designated billing office and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request

(c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.

(d) **Contract Number, ADB Number and Date** — Insert both the contract number and the ADB number (which appears in the upper left hand corner of the face page of the contract), and the effective date of the contract.

(e) **Payee's Name and Address** — Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

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

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

(i) **Incurred Cost — Current** - Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.

(j) **Incurred Cost** — Cumulative - Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

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

(1) **Direct Labor** — Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.

(2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach the NIH Form entitled, "Report of Government Owned, Contractor Held Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.
- The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule.
- An asterisk (*) shall precede the item if the equipment is below the approval level.

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

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

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

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

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

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

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

(m) **Indirect Costs-Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned** — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments** — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) **Grand Totals**

The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

Column D—Incurred Coat-Current - - Enter the costs, which were incurred during the current period.

Column E—Incurred Cost-Cumulative - Enter the cumulative cost to date.

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

Column G—Contract Amount - Enter the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Billing Office Name and Address

NATIONAL INSTITUTES OF HEALTH NIAID, CMP
6700B Rockledge Dr., Rm. 3214, MSC 7612
Bethesda, MD 20892-7612

(b) Invoice/Financing Request No.

(c) Date Invoice Prepared

(d) Contract No.

ADB No.

Effective Date

(e) Payee's Name and Address

ABC CORPORATION
100 Main Street
Anywhere, USA zip code

Attn: Name, Title, & Phone Number of Official to Whom Payment is Sent

(f) Total Estimated Cost

(g) Total Fixed Fee

(h) 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	Incurred Cost (i) Current D	Incurred Cost (j) Cumulative E	Cost at Completion F	Contract Amount G	Variance H
(k) Direct Costs							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property (attach HHS-565)							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(l) Cost of Money							
(m) Overhead							
G&A							
(n) Fixed Fee							
(o) Total Amount Claimed							
(p) Adjustments							
(q) Grand Totals							

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

(Name of Official) (Title)

*Attach details as specified in the contract

Contract No. HHSN2662004000034C
ADB NO. N01-AI-400034

INCLUSION ENROLLMENT REPORT

This report formal 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

	Sex/Gender			
	Female	Males	Unknown or Not	Total
Ethnic Category				
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaskan Native				
Asian				
Native Hawaiian or Other Pacific Islander				

Black or African American
White
More than one race
Unknown or not reported
Racial Categories: Total of All Subjects*

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/Alaskan Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of Hispanic or Latinos				

*These totals must agree
**These totals must agree

PRIVACY ACT SYSTEM OF RECORDS

09-25-0200

SYSTEM NAME:

Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adults and/or children who arc the subjects of clinical, basic, or population-based research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: name, study identification number, address, relevant telephone numbers, social security number (voluntary), drives license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curricula vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

“Research and Investigation,” “Appointment and Authority of the Directors of the National Research Institutes,” “National Cancer Institute,” “National Eye Institute,” “National Heart, Lung and Blood Institute,” “National Institute on Aging,” “National Institute on Alcohol Abuse and Alcoholism,” “National Institute on Allergy and Infectious Diseases,” “National Institute of Arthritis and Musculoskeletal and Skin Diseases,” “National Institute of Child Health and Human Development,” “National Institute on Deafness and Other Communication Disorders,” “National Institute of Dental and Craniofacial Research,” “National Institute of Diabetes, and Digestive and Kidney Diseases,” “National Institute of Drug Abuse,” “National Institute of Environmental Health Sciences,” “National Institute of Mental Health,” “National Institute of Neurological Disorders and Stroke, and the “National Human Genome Research Institute” of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b,

285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 2851, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S):

To document, track, monitor and evaluate NIH clinical, basic, and population-based research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

(3) A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR Part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR Part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

(4) Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

(5) The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is, therefore, deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

(6) Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

(7) Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social security numbers, date of birth and other identifiers may be disclosed: (I) to the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain

---

morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

(8) Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in research studies.

(9) PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.
PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

(10) Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of Stale or Federal Government as required by State or Federal law.

(11) Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

(12) The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

(13) Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY:

During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, social security number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

(1) Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.

(2) Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

(3) Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

(4) Implementation Guidelines: These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, “Safeguarding Records Contained in Systems of Records,” supplementary Chapter PHS hf: 45-13, and the HHS Automated Information Systems Security Program Handbook.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1B “Keeping and Destroying Records” (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS(ES):

See Appendix I for a listing of current System Managers. This system is for use by all NIH Institutes and Centers.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate IC Privacy Act Coordinator listed below. In cases where the requester knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: individual’s name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the

individual’s identity). A requester must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be wilting to review the record and inform the subject individual of its contents at the representative’s discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child’s or incompetent person’s medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.

If the requester does not know which Institute or Center Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, 6011 Executive Blvd., Room 601L, Rockville, MD 20852.

NIH Privacy Act Coordinators

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Clinical Center (CC), Building 10, Room 1N208, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center for Complementary and Alternative Medicine (NCCAM), Building 31, Room 2B11, 31 Center Drive, Bethesda, MD 20892-2182.

Privacy Act Coordinator, National Cancer Institute (NCI), Building 31, Room 10A34, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892-5465.

Privacy Act Coordinator, National Center for Research Resources (NCRR), Rockledge 1, Room 5140, 6705 Rockledge Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Eye Institute (NEI), Building 31, Room 6A32, 31 Center Drive, Bethesda, MD 20892-2510.

Privacy Act Coordinator, National Human Genome Research Institute (NHGRI), Building 10, 3C710, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Heart, Lung, and Blood Institute (NHLBI), Building 31, Room 5A33, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National institute on Aging (NIA), Gateway Building 31, Room 2C234, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 400, 6000 Executive Boulevard, Bethesda, MD 20892-7003.

Privacy Act Coordinator, National Institute of Allergy and Infectious Diseases (NIAID), 6700-B Rockledge Drive, Room 2143, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Natcher Building, Room 5AS49, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1B37, 31 Center Drive, Bethesda, MD 20892-2077.

Privacy Act Coordinator, National Institute of Child Health and Human Development (NICHD), Building 31, Room 2A11, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), Neuroscience Center, 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892-9547.

Privacy Act Coordinator, National Institute on Deafness and Other Communication Disorders (NIDCD), Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Dental and Craniofacial Research (NIDCR), Natcher Building, Room 4AS25, 45 Center Drive, Bethesda, MD 20892-6401.

Privacy Act Coordinator, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Building 31, Room 9A47, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Research Triangle Park, NC 27709.

Privacy Act Coordinator, National Institute of General Medical Sciences (NIGMS), Natcher Building, Room 2AN32, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, 6001 Executive Boulevard, Room 8102, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Nursing Research (NINR), Rockledge II, Room 710, 6701 Rockledge Drive, Bethesda, MD 20892.

RECORD ACCESS PROCEDURE:

Same as Notification Procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:

Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I: System Manager(s) and Address(es)

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Computer Systems Analyst, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 344, 6130 Executive Boulevard, Bethesda, MD 20892.

American Burkitt's Lymphoma Registry, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Suite 434, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Genetic Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI). Executive Plaza South, Room 7122, 6120 Executive Boulevard, Bethesda, MD 20892-7236.

Program Director, Research Resources, Biological Carcinogenesis Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 540, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Environmental Epidemiology Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 443, 6130 Executive Boulevard, Bethesda, MD 20892.

Associate Director, Surveillance Program, Division of Cancer Prevention, National Cancer Institute (NCI), Executive Plaza North, Room 343K, 6130 Executive Boulevard, Bethesda, MD 20892.

Head, Biostatistics and Data Management Section, Center for Cancer Research, National Cancer Institute (NCI), Building 6116, Room 702, 6116 Executive Boulevard, Bethesda, MD 20892.

Chief, Clinical Research Branch, Center for Cancer Research, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), 501 W. 7th Street, Room 3, Frederick, MD 21702.

Deputy Branch Chief, Navy Hospital, NCI-Naval Medical Oncology Branch, Center for Cancer Research, National Cancer Institute (NCI), Building 8, Room 5101, Bethesda, MD 20814.

Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 804, 6130 Executive Boulevard, Bethesda, MD 20892.

Director, Extramural Clinical Studies, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), Fort Detrick, Frederick, MD 21702.

Clinical Operations Manager, National Eye Institute (NEI), Building 10, Room 10S224, 10 Center Drive, Bethesda, MD 20892.

Director, Division of Biometry and Epidemiology, National Eye Institute (NEI), Building 31, Room 6A52, 31 Center Drive, Bethesda, MD 20892.

Associate Director, Office of Clinical Affairs, National Heart, Lung, and Blood Institute (NHLBI), Building 10, Room 8C104,10 Center Drive, Bethesda, MD 20892-1754.

Senior Scientific Advisor, Office of the Director, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI), Federal Building, Room 220, 7550 Wisconsin Avenue, Bethesda, MD 20892.

Chief, Laboratory of Epidemiology, Demography and Biometry, National Institute on Aging (NIA), Gateway Building, Room 3C309, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Chief, Research Resources Branch, Intramural Research Program, National Institute on Aging (NIA), 5600 Nathan Shock Drive, Baltimore, MD 21224.

Clinical Director, National Institute on Aging (NIA), 5600 Nathan Shock Drive, Baltimore, MD 21224.

Deputy Director, Division of Biometry and Epidemiology, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 514, 6000 Executive Boulevard, Bethesda, MD 20892-7003.

Deputy Director, Division of Clinical and Prevention Research, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco) Building, Room 505, 6000 Executive Boulevard, Bethesda, MD 20892-7003.

Chief, Respiratory Viruses Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), Building 7, Room 106, 7 Memorial Drive, Bethesda, MD 20892.

Chief, Hepatitis Virus Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), Building 7, Room 202, 7 Memorial Drive, Bethesda, MD) 20892.

Chief, Biometry Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (MAID), 6700-B Rockledge Drive, Room 3120, Bethesda, MD) 20892.

Clinical Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Building 10, Room 9S205, 10 Center Drive, Bethesda, MD 20892.

Chief, Contracts Management Branch, National Institute of Child Health and Human Development (NICHD), Executive Plaza North, Room 7A07, 6130 Executive Boulevard, Bethesda, MD 20892.

Director of Intramural Research, National Institute on Deafness and Other Communication Disorders (NIDCD), Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.

Chief, Scientific Programs Branch, National Institute on Deafness and Other Communication Disorders (NIDCD), Executive Plaza South, Room 400C, 6120 Executive Boulevard, Bethesda, MD 20892-7180.

Clinical Director, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room INl17, 10 Center Drive, Bethesda, MD 20892-1191.

Chief, Scientific Review Branch, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room IN117, 10 Center Drive, Bethesda, MD 20892-1191.

Research Psychologist, Gene Therapy and Therapeutics Branch, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room 1N105, 10 Center Drive, Bethesda, MD 20892-1190.

Chief, Clinical Investigations, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Building 10, Room 9N222, 10 Center Drive, Bethesda, MD 20892.

Chief, Phoenix Clinical Research Section, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Phoenix Area Indian Hospital, Room 541, 4212 North 16th Street, Phoenix, AZ 85016.

Chief, Diabetes Research Section, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Natcher Building, Room 5AN18G, 45 Center Drive, Bethesda, MD 20892-6600.

Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892-9547.

Chief, Epidemiology Branch, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Research Triangle Park, NC 27709.

Director, Intramural Research Program, National Institute of Mental Health (NIMH), Building 10, Room 4N224, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, Room 8102, 6001 Executive Boulevard, Bethesda, MD) 20982.

Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.

Chief, Epilepsy Branch, National Institute of Neurological Disorders and Stroke (NINDS), Neuroscience Center, 6001 Executive Boulevard, Suite 2110, Bethesda, MD 20892-9523.

Assistant Director, Clinical Neurosciences Program, Division of Intramural Research, National Institute of Neurological Disorders and Stroke (NINDS), Building 10, Room 5N234, 10 Center Drive, Bethesda, MD 20892.

Acting Chief, Laboratory of Central Nervous Systems Studies, Intramural Research Program, National Institute of Neurological Disorders and Stroke (NINDS), Building 36, Room 4A21, 36 Convent Drive, Bethesda, MD 20892-4123.

Clinical Director, National Human Genome Research Institute (NHGRI), Building 10, Room 10C101D, 10 Center Drive, Bethesda, MD 20892.

Deputy Director, Division of Extramural Research, National Institute of Neurological Disorders and Stroke (NINDS), Neuroscience Center, Room 3307, 6001 Executive Boulevard, Bethesda, MD 20892.

Director, Office of Clinical and Regulatory Affairs, Division of Extramural Research and Training, Democracy Plaza II, Room 401, 6707 Democracy Boulevard, Bethesda, MD 20892-5475.

Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1837, 31 Center Drive, Bethesda, MD 20892-2077.

Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892-5465.

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

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

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

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

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

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

(End of clause)

Safety and Health Clause
HHSAR 352.223-70 (1/01)

ATTACHMENT 5

Contract No. HHSN2662004000034C
ADB NO. N01-AI-400034

PROCUREMENT OF CERTAIN EQUIPMENT

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

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

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

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

ATTACHMENT 6

Contract No. HHSN2662004000034C
ADB NO. N01-AI-400034

RESEARCH PATIENT CARE COSTS

(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.

NIH (RC)-11
(4/1/84)

ATTACHMENT 7

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY

CONTRACTOR:

CONTRACTOR NUMBER

ADDRESS

REPORT DATE:

FISCAL YEAR:

	BEGINNING OF PERIOD		ADJUSTMENTS			END OF PERIOD	
CLASSIFICATION	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND>=$25K							
LAND<$25K							
OTHER REAL>=$25K							
OTHER REAL<$25K							
PROPERTY UNDER CONST>=$25K							
PROPERTY UNDER CONST<$25K							
PLANT EQUIP>=$25K							
PLANT EQUIP<$25K							
SPECIAL TOOLING>=$25K							
SPECIAL TOOLING<$25K							
SPECIAL TEST EQUIP>=$25K							
SPECIAL TEST EQUIP<$25K							
AGENCY PECULIAR>=$25K							
AGENCY PECULIAR<$25K							
MATERIAL>=$25K (CUMULATIVE)							
PROPERTY UNDER MFR>=$25K							
PROPERTY UNDER MFR<$25K							

SIGNED BY:

DATE SIGNED:

Report of Government Owned, Contractor Held Property

ATTACHMENT 8

Contract No. HHSN2662004000034C
ADB NO. N01-AI-400034

PART IV

[***]

END of the SCHEDULE
(CONTRACT)

Exhibit 10.47

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | 1. CONTRACT ID CODE | PAGE OF PAGES 1 1

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURC	5. PROJECT NO. (*If applicable*)
Mod #01	See Block 16 C	N/A	N/A

6. ISSUED BY CODE

National Institutes of Health
Contract Management Program, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Billingham TS23 1YN, UK
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. N01-AI-40034

10B. DATED (SEE ITEM 13) September 30, 2004

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN#: 1-900216013-A1 SOC#: 25.55 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

x B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriate date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

D. OTHER (*Specify type of modification and authority*)

E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: To deobligate funds on the Contract Award from the Common Account Number (CAN) 8421247.

TOTAL AMOUNT FUNDED: [***]
TOTAL ESTIMATED COST: [***]
FUNDED THROUGH: [***]
CONTRACT EXPIRATION DATE: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)

15B. CONTRACTOR/OFFEROR 15C. DATE SIGNED

(*Signature of person authorized to sign*)

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
[***]
[***]

16B. UNITED STATES OF AMERICA
BY
[***]
(*Signature of Contracting Officer*)

16C. DATE SIGNED
[***]

NSN 7540-01-152-8070 OMB No. 0990-0115 **STANDARD FORM 30** (REV. 10-83)
FAR (48 CFR) 53.243

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | 1. CONTRACT ID CODE | PAGE OF PAGES 1 5

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURC	5. PROJECT NO. (*If applicable*)
Mod #02	See Block 16 C	N/A	N/A

6. ISSUED BY CODE

National Institutes of Health
Contract Management Program, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. N01-AI-40034

10B. DATED (SEE ITEM 13) September 30, 2004

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO

THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriate date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 1.602-1

D. OTHER (*Specify type of modification and authority*)

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 3 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: To update Article B.2., to revise the milestone payment schedule in Article B.4. and to replace Limitation of Cost Clause with Limitation of Funds in Article I.2.

TOTAL AMOUNT FUNDED: [***] (unchanged)
TOTAL ESTIMATED COST: [***] (unchanged)
FUNDED THROUGH: [***] (unchanged)
CONTRACT EXPIRATION DATE: March 29, 2007 (unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)
[***]

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
[***]
[***]

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED
5thJan2005

[***]
(*Signature of person authorized to sign*)

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED
[***]

BY [***]
(*Signature of Contracting Officer*)

NSN 7540-01-152-8070

OMB No. 0990-0115

STANDARD FORM 30 (REV. 10-83)
FAR (48 CFR) 53.243

ARTICLE B.2. ESTIMATED COSTS AND FIXED FEE - paragraphs e., f. and g. are added as follows:

e. Total funds currently available for payment and allocated to Part A of this contract are hereby decreased by [***] from [***]to [***], of which [***] represents a decrease to the estimated cost from [***] to [***]; and of which [***] represents a decrease to the fixed fee from [***] to [***]. For further provisions on funding, see the LIMITATION OF FUNDS Clause referenced in Part II, Article I.2., Authorized Substitution of Clauses.

f. It is estimated that the amount currently allotted will cover performance of the contract through [***].

g. Future increments to be allotted to the contract are estimated as follows:

PERIOD	ESTIMATED COST	FIXED FEE	TOTAL AMOUNT
[***]	[***]	[***]	[***]

ARTICLE B.4. ADVANCE UNDERSTANDINGS - paragraph i., is revised to read as follows:

i. 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 milestone based installments and payment of this fee shall be determined by the Project Officer's written certification that the milestone has been satisfactorily performed and that the technical requirements have been met regarding the completion of the following milestones: If the Contractor meets the milestones earlier than the dates set forth below, then the fee will be paid at the earlier date after completion of the milestone.

	MILESTONE FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
1	**[***]**	[***]	[***]	[***]
	Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items:			
	a) [***] b) [***] c) [***] d) [***] e) [***]		a) [***] b) [***] c) [***] d) [***] e) [***]	
	Total Fee for Milestone		[***]	

2	**[***]**	[***]	[***]	[***]

	Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items: a) [***] b) [***] c) [***] d) [***] e) [***] Total Fee for Milestone		a) [***] b) [***] c) [***] d) [***] e) [***] [***]	
3	**[***]**	[***]	[***]	[***]
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items: a) [***] b) [***] c) [***] [***] Total Fee for Milestone		a) [***] b) [***] c) [***] [***]	
4	**[***]**	[***]	[***]	[***]
	Fee shall be paid in two installments of the total fee for this milestone based on the completion of the following two items: a) [***]		a) [***]	

	b) [***] Total Fee for Milestone		b) [***] [***]	
5	**[***]**	[***]	[***]	[***]
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items: a) [***] b) [***] c) [***] Total Fee for Milestone		a) [***] b) [***] c) [***] [***]	
6	**[***]**	[***]	[***]	[***]
	Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items: a) [***] b) [***] c) [***] d) [***] Total Fee for Milestone		a) [***] b) [***] c) [***] d) [***] [***]	

7	**[***]**	[***]	[***]	[***]
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following two items: a) [***] b) [***]		a) [***] b) [***]	

Total Fee for Milestone		[***]	
8			
[***]	[***]	[***]	[***]
Fee shall be paid in two installments of the total fee for this milestone based on the completion of the following three items: a) [***] b) [***] c) [***]		a) [***] b) [***] c) [***]	
Total Fee for Milestone		[***]	

** Milestone 3 was subject to discussion regarding the progress of this project prior to NIAID involvement. At the time of the RFP, Avecia described their current projects status and it was agreed funds from this milestone should be channeled towards [***] if needed.*

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES, is hereby modified to include the following:

ARTICLE I.1. of this section is modified as follows:

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefore.
Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATIONS OF FUNDS, will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.

All other terms and conditions of the contract remain unchanged.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES 1 3

2. AMENDMENT/MODIFICATION NO
Mod #03

3. EFFECTIVE DATE
See Block 16 C

4. REQUISITION/PURC
N/A

5. PROJECT NO. (*If applicable*)
N/A

6. ISSUED BY CODE

National Institutes of Health
Contract Management Program, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than item 6*) CODE

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO.
N01-AI—40034

10B. DATED (*SEE ITEM 13*)
September 30, 2004

CODE FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended.o is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods

(a) By competing Items 8 and 15, and returning copies of the amendment; (b) By acknowledge receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitations and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
FAR 1.602-1

D. OTHER (*Specify type of modification and authority*)

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 3 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: To revise the milestone 1 payment schedule, to add an Advance Understanding containing DMID's approval of data sharing between Avecia and the UK Medicines Supply Agency in Article B.4. and to update Section H. articles.

TOTAL AMOUNT FUNDED: [***] (unchanged)
TOTAL ESTIMATED COST: [***] (unchanged)
FUNDED THROUGH: [***] (unchanged)
CONTRACT EXPIRATION DATE: [***] (unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)
[***]

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
[***]
[***]

15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED

[***] 23-06-05 | BY [***] 7/20/05

(*Signature of person authorized to sign*) | (*Signature of Contracting Officer*)

NSN 7540-01-152-8070 | OMB No. 0990-0115 | **STANDARD FORM 30** (REV. 10-83) FAR (48 CFR) 53.243

ARTICLE B.4. ADVANCE UNDERSTANDINGS - paragraph i., item No. 1, is revised to read as shown below and paragraph p. is added as follows:

i. 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 milestone based installments and payment of this fee shall be determined by the Project Officer's written certification that the milestone has been satisfactorily performed and that the technical requirements have been met regarding the completion of the following milestones: If the Contractor meets the milestones earlier than the dates set forth below, then the fee will be paid at the earlier date after completion of the milestone.

	MILESTONE FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
1	[***]	[***]	[***]	[***]
	Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	
	Total Fee for Milestone		[***]	

p. [***]

[***]

All other terms and conditions of the contract remain unchanged.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A | PAGE OF PAGES 1 3

2. AMENDMENT/MODIFICATION NO 04 | 3. EFFECTIVE DATE See Block 16 C, below | 4. REQUISITION/PURCHASE REQ. NO. DMID 2 018 | 5. PROJECT NO. (*If applicable*) N/A

6. ISSUED BY CODE

National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Contract Management Branch
Room 2230, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID2 - RCB

ADB Contract No. N01-AI-40034

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSN266200400034C

10B. DATED (*SEE ITEM 13*) September 30, 2004

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN#: 1-900216013-A1 SOCC 25.55 CAN 5-8460924 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriate date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority)*
P.L. 1.602-1, Limitation of Funds Clause; FAR 52.217-8; and P.L. 108-447

E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: To fund the final increment of funds for the base portion of the contract and to exercise and incrementally fund Option Period - Part B.

	Total Funds Currently Allotted			Total Estimated Cost		
	Cost	Fee	Total	Cost	Fee	Total
Prior to this Mod	[***]	[***]	[***]	[***]	[***]	[***]
This Mod #	[***]	[***]	[***]	[***]	[***]	[***]
Revised Total	[***]	[***]	[***]	[***]	[***]	[***]

FUNDED THROUGH DATE: [***] COMPLETION DATE: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print)*

15B. CONTRACTOR/OFFEROR

(*Signature of person authorized to sign)*

15C. DATE SIGNED

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print)*
[***]
[***]

16B. UNITED STATES OF AMERICA

BY [***]
(Signature of Contracting Officer)

16C. DATE SIGNED
[***]

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

ARTICLE B.2. ESTIMATED COST AND FIXED FEE - paragraphs b. and c., are hereby modified to read as follows:

a. The estimated cost of this contract is increased by [***] from [***] to [***].

b. The fixed fee of this contract is increased by [***] from [***]. The fixed fee shall be paid in installments based on the negotiated milestones set forth in ARTICLE B.4., paragraph i, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE 1.1., of this contract. Payment shall not be made in less than monthly installments.

c. The Government's obligation, represented by the sum of the estimated cost plus the fixed fee of this contract is increased by [***] from [***] to [***]

e. Total funds currently available for payment and allotted to this contract are hereby increased by [***] from [***] to [***]; of which [***] represents an increase to the estimated cost from [***] to [***]; and of which [***] represents an increase to the fixed fee from [***] to [***]. For further provisions on funding, see the LIMITATION OF FUNDS Clause referenced in Part II, ARTICLE I.2., Authorized Substitutions of Clauses.

f. It is estimated that the amount currently allotted will cover performance of the contract through [***].

g. The total of future increments to be allotted to the contract are estimated as follows:

PERIOD	ESTIMATED COST	FIXED FEE	TOTAL AMOUNT
[***]	[***]	[***]	[***]

ARTICLE F.1. PERIOD OF PERFORMANCE , paragraph a. is hereby modified to read as follows:

a. The period of performance of this contract shall be from [***] through September [***].

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-447, Title V - General Provisions, Section 509	2005	10/01/04 - 09/30/05

ARTICLE H.6. NEEDLE EXCHANGE, paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-447, Title V - General Provisions, Section 505	2005	10/01/04 - 09/30/05

ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS, paragraphs b. and c. are hereby modified to add the following:

b.

Public Law No.	Fiscal Year	Dollar Amount of Salary Limitation*
P.L. 108-447, Title II - General Provisions, Section 204	2005	Executive Level I

c. Direct salaries are limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

HHS-556

** For the period 10/1/04-12/31/04, the Executive Level I rate is $175,700. Effective 1/1/05, the Executive Level I rate increased to $180,100 and will remain at that rate until it is revised. See the web site listed below for Executive Schedule rates of pay.*

***LINK to EXECUTIVE LEVEL SALARIES**: http://www.opm.gov/oca/05tables/html/ex.asp (For previous years, go to: http://www.opm.gov/oca/05tables/index.asp and click on the year to locate the Executive Level salary rates.)*

NOTE: All prior Public Laws and related Executive Levels incorporated in the Basic Award and all previous Modifications shall remain in effect for the applicable fiscal year and related funds.

ARTICLE H.13. PRESS RELEASES, paragraph b., is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 108-447, Title V - General Provisions, Section 506	2005	10/01/04 - 9/30/05

ARTICLE H.15. ANTI-LOBBYING, paragraph c., is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
for a., above: P.L. 108-447, Title V - General Provisions, Section 503a	2005	10/01/04 - 9/30/05
for b., above: P.L. 108-447, Title V - General Provisions, Section 503b	2005	10/01/04 - 9/30/05

HHS-556

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE: N/A

PAGE OF PAGES: 1 16

2. AMENDMENT/MODIFICATION NO: 05

3. EFFECTIVE DATE: See Block 16 C, below

4. REQUISITION/PURCHASE REQ NO.: 2006-0361

5. PROJECT NO. (*If applicable*): N/A

6. ISSUED BY CODE

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

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID RCB-B

ADB Contract No. N01-AII40034

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSN266200400034C

10B. DATED (*SEE ITEM 13*) September 30, 2004

CODE FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN#: 1-900216013-A1 SOCC 25.55 CAN 5-8467101 [***]

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriate date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority*)
FAR 1.602-1

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible)*

PURPOSE: To add an increment of funds, thus fully funding the contract; to clarify the Part B Option Statement of Work, required Deliverables, and revise the related Milestone Estimated Cost and Fixed Fee distributions; to add the Alternate Project Officer; to change the Principal Investigator; and make other administrative changes..

	Total Funds Currently Allotted			Total Estimated Cost		
	Cost	Fee	Total	Cost	Fee	Total
Prior to this Mod	[***]	[***]	[***]	[***]	[***]	[***]
This Mod #	[***]	[***]	[***]	[***]	[***]	[***]
Revised Total	[***]	[***]	[***]	[***]	[***]	[***]

FUNDED THROUGH DATE: [***] COMPLETION DATE: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)
[***]

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
[***]
[***]

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED
21SEP06

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED
[***]

[***]
(*Signature of person authorized to sign*)

BY [***]
(*Signature of Contracting Officer*)

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

ARTICLE B.2. ESTIMATED COSTS AND FIXED FEE - paragraphs e. and f., are hereby modified to read as follows and g. is deleted in its entirety:

e. Total funds currently available for payment and allocated to Part A of this contract are hereby increased by [***] from [***]to [***], of which [***] represents an increase to the estimated cost from [***] to [***]; and of which [***] represents an increase to the fixed fee from [***] to [***]. For further provisions on funding, see the LIMITATION OF COST Clause referenced in Part II, ARTICLE I.1., General Clauses for a Cost Reimbursement Research and Development Contract.

f. By virtue of the fact that this contract is fully funded, it is estimated that the amount currently allotted will cover performance through the completion date of the contract.

ARTICLE B.4. ADVANCE UNDERSTANDINGS - paragraph i., is hereby modified as follows to update the Milestone Schedule:

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
1	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in six installments of the total fee for this milestone based on the completion of the following six items: a) [***] b) [***] c) [***] d) [***] e) [***] f) [***]		a) [***] b) [***] c) [***] d) [***] e) [***] f) [***]	

2	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items: a) [***] b) [***] c) [***] d) [***] e) [***]		a) [***] b) [***] c) [***] d) [***] e) [***]	
3	**[***]**	**[***]**	**[***]**	**[***]**

	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items: a) [***] b) [***] c) [***] [***]		a) [***] b) [***] c) [***]	

4	**[***]** Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following two items: a) [***] b) [***]	**[***]**	**[***]** a) [***] b) [***]	[***]
5	**[***]** Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items: a) [***] b) [***] c) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***]	[***]
6	**[***]** Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items: a) [***] b) [***] c) [***] d) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***] d) [***]	[***]

7	**[***]** Fee shall be paid in two installments of the total fee for this milestone based on the completion of the following two items. a) [***] b) [***]	**[***]**	**[***]** a) [***] b) [***]	[***]
8	**[***]** Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items. a) [***] b) [***] c) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***]	[***]
9	**[***]** Fee shall be paid in six installments of the total fee for this milestone based on	**[***]**	**[***]**	[***]

	the completion of the following six items: a) [***] b) [***] c) [***] d) [***] e) [***] f) [***]		a) [***] b) [***] c) [***] d) [***] e) [***] f) [***]	

10	**[***]** Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items: a) [***] b) [***] c) [***] d) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***] d) [***]	[***]
11	**[***]** Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following fouritems: a) [***] b) [***] c) [***] d) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***] d) [***]	[***]

12	**[***]** Fee shall be paid in nine installments of the total fee for this milestone based on the completion of the following nine items: a) [***] b) [***] c) [***] d) [***] e) [***] f) [***] g) [***] h) [***] i) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***] d) [***] e) [***] f) [***] g) [***] h) [***] i) [***]	[***]

13	**[***]** Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items: a) [***] b) [***] c) [***] d) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***] d) [***]	[***]
14	**[***]** Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items: a) [***] b) [***] c) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***]	[***]

15	**[***]** Fee shall be paid in two installments of the total fee for this milestone based on the completion of the following two items: a) [***] b) [***]	**[***]**	**[***]** a) [***] b) [***]	[***]
16	**[***]** Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items: a) [***] b) [***] c) [***] d) [***]	**[***]**	**[***]** a) [***] b) [***] c) [***] d) [***]	[***]

17	[***] **Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items:** **a) [***]** **b) [***]** **c) [***]** **d) [***]** **e) [***]**	**[***]**	**[***]** **a) [***]** **b) [***]** **c) [***]** **d) [***]** **e) [***]**	**[***]**

ARTICLE C.1 STATEMENT OF WORK, is hereby modified to read as follows:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT 1, dated September 30, 2004, and as clarified by Modification No. 5 of the contract, attached hereto and made a part of this contract.

ARTICLE C.3 OTHER DELIVERABLES, is hereby added as follows:

In addition to the deliverables required by ARTICLE C.2. and ARTICLE F.2, or otherwise described by the Statement of Work of this contract, the following are to be delivered per the direction of the Project Officer prior to the completion date of the contract:

1. Materials, supplied, and equipment purchased for this contract but not expended in the execution of the Statement of Work.

2. Drug Substance not allocated for retains (in amounts needed to maintain GMP compliance), reference standard, clinical trials, or stability studies as defined in the SOW.

3 Drug Product not allocated for retains (in amounts needed to maintain GMP compliance), reference standard, clinical trials, or stability studies as defined in the SOW.

4 Consented clinical specimens collected during the course of any clinical trial and not used in the protocol-specific studies or held as retains (in amounts described in the clinical trial documentation).

5. Copies of regulatory submissions.

6. Analytical methods and models developed as part of the execution of this SOW.

7. Quality audit reports subject to Avecia's confidentiality obligations to its contractors.

ARTICLE F.2. DELIVERIES paragraph a., is hereby modified to include the following table of deliverables in addition to those deliveries currently required by the contract:

Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
1.	[***]	[***]	[***]	[***]
2.	[***]	[***]	[***]	[***]
3.	[***]	[***]	[***]	[***]
4.	[***]	[***]	[***]	[***]
6.	[***]	[***]	[***]	[***]
7.	[***]	[***]	[***]	[***]
8.	[***]	[***]	[***]	[***]
9.	[***]	[***]	[***]	[***]
10.	[***]	[***]	[***]	[***]
11.	[***]	[***]	[***]	[***]
12.	[***]	[***]	[***]	[***]
13.	[***]	[***]	[***]	[***]
14.	[***]	[***]	[***]	[***]
15.	[***]	[***]	[***]	[***]

Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
16.	[***]	[***]	[***]	[***]
17.	[***]	[***]	[***]	[***]
18.	[***]	[***]	[***]	[***]
19.	[***]	[***]	[***]	[***]

ARTICLE G.1. PROJECT OFFICER, is hereby modified to include the following:

The following will represent the Government as the Alternate Project Officer for the purposes of this contract:

[***]
[***]
[***]

[***]
Room 5006, MSC 6604
6610 Rockledge Drive
Bethesda, MD 20892-6604

ARTICLE G.2. KEY PERSONNEL, is hereby modified to delete Mark Carver as the Principal Investigator and to insert Matthew Duchars as the Principal Investigator.

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V – General Provisions, Section 509	2006	10/01/05 – 9/30/06

ARTICLE H.6. NEEDLE EXCHANGE, paragraph b. is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V – General Provisions, Section 505	2006	10/01/05 – 9/30/06

ARTICLE H.11 SALARY RATE LIMITATION LEGISLATION PROVISIONS, paragraphs b. and c. are hereby modified to add the following:

b.

Public Law No.	Fiscal Year	Dollar Amount of Salary Limitation*
P.L. 109149	2006	Executive Level I

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

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

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

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

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

NOTE: All prior Public Laws and related Executive Levels incorporated in the Basic Award and all previous Modifications shall remain in effect for the applicable fiscal year and related funds.

ARTICLE H.13. PRESS RELEASES. paragraph b., is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 109-149, Title V – General Provisions, Section 506	2006	10/01/05 – 9/30/06

ARTICLE H.15. ANTI-LOBBYING. paragraph c., is hereby modified to add the following:

b.

Public Law and Section No.	Fiscal Year	Period Covered
for a., above: P.L. 109-149, Title V – General Provisions, Section 503a	2006	10/1/05 – 9/30/06
for b., above: P.L. 109-149, Title V – General Provisions, Section 503a	2006	10/1/05 – 9/30/06

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES, is hereby modified to delete FAR Clause 52.232-22, LIMITATION OF FUNDS (April 1984), reinstating the applicability of FAR Clause 52.232-20, LIMITATION OF COST (April 1984) of ARTICLE I.1.

SECTION J — LIST OF ATTACHMENTS, item no. 1., is hereby modified to read as follows:

1. Statement of Work, [***] (and as clarified by Modification No. 5), 5 pages.

ATTACHMENT 1 — STATEMENT OF WORK, is hereby modified to include the following under the Part B Option section for clarification purposes:

[***]
[***]
[***]
[***]

[***]
[***]
[***]
[***]

[***]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A

PAGE OF PAGES 1 2

2. AMENDMENT/MODIFICATION NO 06

3. EFFECTIVE DATE See Block 16 C, below

4. REQUISITION/PURCHASE REQ NO.

5. PROJECT NO. (*If applicable*) N/A

6. ISSUED BY CODE

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

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

MID RCB-B

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSN266200400034C

10B. DATED (*SEE ITEM 13*) September 30, 2004

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)

EIN#: 1-900216013-A1 SOCC 25.55

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriate date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

x D. OTHER (*Specify type of modification and authority*)
FAR 1.602-1

E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office.

DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: Modify Invoice Payment Procedures under ARTICLE G.3.

FUNDED THROUGH DATE: [***](Unchanged)

COMPLETION DATE: [***] (Unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)
[***]

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
[***]
[***]

15B. CONTRACTOR/OFFEROR

15C. DATE SIGNED
14JUN07

[***]
(*Signature of person authorized to sign*)

16B. UNITED STATES OF AMERICA

16C. DATE SIGNED
[***]

BY [***]
(*Signature of Contracting Officer*)

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT — is hereby modified to read as follows:

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

(1) Payment requests shall be submitted as follows:

One original to the following designated billing office:

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

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

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

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

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

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

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

b. Inquires regarding payment shall be directed to the designated office, (301) 496-6088.

SECTION J — Attachment 2, Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 is hereby replaced with the following updated attachment.

HHS-556

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 request 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 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 costs 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 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.

(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, VIN, 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. Provide the Contractor's vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

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

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

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

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

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

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

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

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

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

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

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

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

---

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

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

· hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and

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

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(u) **Grand Totals**

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

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

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

Column E — Amount Billed — Cumulative: enter the cumulative amounts to date.

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address

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

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

ABC Corporation
100 Main Street
Anywhere, USA Zip Code

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.

VIN:
DUNS or DUNS+4:

(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) o Two-Way Match o Three-Way Match

(j) Office of Acquisitions:

(k) Central Point of Distribution:

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

	Cumulative Percentage of Effort/Hrs.		Amount Billed				
Expenditure Category* **A**	**Negotiated B**	**Actual C**	**(m) Current D**	**(n) Cumulative E**	**Cost of Completion F**	**Contract Amount 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 are for appropriate purposes and in accordance with the contract.

(Name of Official) (Title)

*Attach details as specified in the contract.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE N/A

PAGE OF PAGES 1 20

2. AMENDMENT/MODIFICATION NO 07

3. EFFECTIVE DATE See Block 16 C, below

4. REQUISITION/PURCHASE REQ NO.

5. PROJECT NO. (*If applicable*) N/A

6. ISSUED BY CODE

7. ADMINISTERED BY (*If other than Item 6*) CODE N/A

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

MID RCB-B

VIN: 1109979

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code*)

Avecia Limited
P.O. Box 42, Hexagon House
Blackley, Manchester, M9 8ZS, UK

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO.
HHSN266200400034C

10B. DATED (*SEE ITEM 13*)
September 30, 2004

CODE FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment, you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*)
EIN#: 1-900216013-A1 SOCC 25.55

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS,
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

x A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriate date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
FAR 1.602-1

D. OTHER (*Specify type of modification and authority*)

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: To clarify the Part B Option Statement of Work, required Deliverables; and revise the related Milestone Estimated Cost and Fixed Fee distributions, as well as change the contract funded through and completion dates:

TOTAL ESTIMATED COST:[***]
TOTAL ALLOTTED TO DATE: [***]

CONTRACT COMPLETION DATE: [***]
FUNDED THROUGH DATE: [***]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)

[***]

16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
[***]
[***]

15B. CONTRACTOR/OFFEROR

[***]
(*Signature of person authorized to sign*)

15C. DATE SIGNED
9July'07

16B. UNITED STATES OF AMERICA

BY [***]
(*Signature of Contracting Officer*)

16C. DATE SIGNED
[***]

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30
(REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

ARTICLE B.2. ESTIMATED COST AND FIXED FEE, paragraph f., is hereby modified to read as follows:

f. It is estimated that the amount currently allotted will cover performance of the contract through [***].

ARTICLE B.4. ADVANCED UNDERSTANDINGS, paragraph i., is hereby modified as follows to update the Milestone Schedule:

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
1	[***]	[***]	[***]	[***]
	Fee shall be paid in six installments of the total fee for this milestone based on the completion of the following six items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	

	f) [***]		f) [***]	
	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
2	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	
	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
3	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	[***]			
	Total Fee for Milestone		**[***]**	
4	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following two items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	Total Fee of Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
5	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items:			

	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	Total Fee for Milestone		**[***]**	
6	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	Total Fee of Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
7	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in two installments of the total fee for this milestone based on the completion of the following two items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	Total Fee for Milestone		**[***]**	
8	**[***]**	**[***]**	**[***]**	**[***]**
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	Total Fee of Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
9	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in six installments of the total fee for this milestone based on the completion of the following six items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	

	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
10	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items:			
	a) [***]		[***]	
	b) [***]		[***]	
	c) [***]		[***]	
	d) [***]		[***]	
	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
11	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items:			
	a) [***]		[***]	
	b) [***]		[***]	
	c) [***]		[***]	
	d) [***]		[***]	
	[***]			
	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
12	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in nine installments of the total fee for this milestone based on the completion of the following nine items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	
	g) [***]		g) [***]	

	h) [***]		h) [***]	
	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
13	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in eight installments of the total fee for this milestone based on the completion of the following eight items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	f) [***]		f) [***]	
	g) [***]		g) [***]	
	h) [***]		h) [***]	
	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
14	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	Total Fee for Milestone		**[***]**	

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
15	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in five installments of the total fee for this milestone based on the completion of the following five items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	

	d) [***]		d) [***]	
	e) [***]		e) [***]	
	Total Fee for Milestone		**[***]**	

HHS-556

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
16	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in four installments of the total fee for this milestone based on the completion of the following four items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	d) [***]		d) [***]	
	e) [***]		e) [***]	
	Total Fee for Milestone		**[***]**	

HHS-556

	MILESTONES FOR AVECIA	ESTIMATED COST	FIXED FEE	TOTAL CPFF
17	[***]	**[***]**	**[***]**	**[***]**
	Fee shall be paid in three installments of the total fee for this milestone based on the completion of the following three items:			
	a) [***]		a) [***]	
	b) [***]		b) [***]	
	c) [***]		c) [***]	
	Total Fee for Milestone		**[***]**	

ARTICLE C.1. STATEMENT OF WORK, is hereby modified to read as follows:

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 Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT 1, dated September 30, 2004, and as clarified by Modification No. 7 of the contract, attached hereto and made part of this contract.

HHS-556

ARTICLE F.1. PERIOD OF PERFORMANCE, paragraph a, is hereby modified to read as follows:

a. The period of performance of this contract shall be from [***] through [***].

ARTICLE F.2. DELIVERIES, paragraph a., is hereby modified to include the following table of deliverables in addition to those deliveries currently required by the contract.

Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
1.	[***]	[***]	[***]	[***]
2.	[***]	[***]	[***]	[***]
3.	[***]	[***]	[***]	[***]
4.	[***]	[***]	[***]	[***]
5.	[***]	[***]	[***]	[***]

6.	[***]	[***]	[***]	[***]
7.	[***]	[***]	[***]	[***]
8.	[***]	[***]	[***]	[***]
9.	[***]	[***]	[***]	[***]
10.	[***]	[***]	[***]	[***]
11.	[***]	[***]	[***]	[***]
12.	[***]	[***]	[***]	[***]
13.	[***]	[***]	[***]	[***]

Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
14.	[***]	[***]	[***]	[***]
15.	[***]	[***]	[***]	[***]
16.	[***]	[***]	[***]	[***]
17.	[***]	[***]	[***]	[***]
18.	[***]	[***]	[***]	[***]
19.	[***]	[***]	[***]	[***]
20.	[***]	[***]	[***]	[***]

SECTION J — LIST OF ATTACHMENTS, items no. 1., is hereby modified to read as follows:

1. [***] (and as clarified by Modification No. 7), 5 pages.

ATTACHMENT 1 — STATEMENT OF WORK, is hereby modified to include the following under the Part B Option section for clarification purposes:

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO	5. PROJECT NO. (*if applicable*)
09	**See block 16C, below**		**N/A**

6. ISSUED BY CODE

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

7. ADMINISTERED BY (*if other than Item 6*) CODE N/A

MID RCB-B

N01-AI-40034

8. NAME AND ADDRESS OF CONTRACTOR (*No., Street, County, State and ZIP Code*)

Avecia Biologics Limited VIN: 1140323
P.O. Box 42, Hexagon Tower
Blackley, Manchester, M9 8ZS, UK

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO.
HHSN266200400034C

10B. DATED (*SEE ITEM 13*)
September 30, 2004

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment, (b) By acknowledging receipt of this amendment on each copy of the offer submitted or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA (*if required*)

N/A

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS,
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(D) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b)

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF

x D. OTHER (Specify type of modification and authority)
FAR 1.602-1 and Article G.1. Project Officer

E. IMPORTANT: Contractor x is not, o is required to sign this document and return copies to the issuing office

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: To revise ARTICLE G.1. and update Section H and I Articles.

	Total Funds Currently Allotted			Total Estimated Cost		
	Cost	**Fee**	**Total**	**Cost**	**Fee**	**Total**
Prior to this Mod	[***]	[***]	$ 50,701,800	[***]	[***]	$ 50,701,800
This Mod #	[***]	[***]	$ 0	[***]	[***]	$ 0
Revised Total	[***]	[***]	$ 50,701,800	[***]	[***]	$ 50,701,800

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)

15B. CONTRACTOR/OFFEROR 15C. DATE SIGNED

(*Signature of person authorized to sign*)

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
Karen M. Gamble
Contracting Officer, OA, DEA, NIAID

16B. UNITED STATES OF AMERICA 16C. DATE SIGNED
7/11/2008

BY /s/ Karen M. Gamble
(*Signature of Contracting Officer*)

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53 243

ARTICLE G.1. PROJECT OFFICER, Marlene Hammer is deleted as Alternate Project Officer.

The second paragraph is hereby modified to replace the Project Officer as follows:

Freyja Lynn
Office of Biodefense Research Affairs
Division of Microbiology and Infectious Diseases
DHHS/NIH/NIAID
Room 5064, MSC 6604
6610 Rockledge Drive
Bethesda, MD 20892-6604
lynnf@niaid.nih.gov

THE FOLLOWING SECTION H ARTICLES ARE UPDATED IN COMPLIANCE WITH PUBLIC LAW (P.L.) 110-161:

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH is deleted in its entirety and replaced with:

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.6. NEEDLE EXCHANGE is deleted in its entirety and replaced with:

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.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS is deleted in its entirety and replaced with:

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.)*

NOTE: All prior Public Laws and related Executive Levels incorporated in the Basic Award and all previous Modifications shall remain in effect for the applicable fiscal year and related funds.

ARTICLE H.13. PRESS RELEASES is deleted in its entirety and replaced with:

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.

THE FOLLOWING ARTICLE IS DELETED IN COMPLIANCE WITH PUBLIC LAW (P.L.) 110-161:

ARTICLE H.15. ANTI-LOBBYING is deleted in its entirety. It is now covered under HHSAR Clause 352.270¬10, incorporated in ARTICLE 1.1.

ARTICLE H.16. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES, is renumbered to read **ARTICLE H.15**.

ARTICLE H.17. SHARING RESEARCH DATA, is renumbered to read **ARTICLE H.16.**

ARTICLE H.18. POSSESSION USE AN TRANSFR OF SECLECT BIOLOGICAL AGENTS OR TOXINS, is renumbered to read **ARTICLE H.17.**

ARTICLE H.19. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES, is renumbered to read **ARTICLE H.18.**

THE FOLLOWING NEW PROVISIONS ARE HEREBY ADDED TO THIS CONTRACT IN COMPLIANCE WITH THE CONTINUING LEGISLATIVE MANDATES FOR FY2008 (P.L. 110-161).

ARTICLE H.19. 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.20. 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.21. RESTRICTION ON ABORTIONS

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

THE FOLLOWING SECTON H ARTICLE IS ADDED IN COMPLIANCE WITH PUBLIC LAW (P.L.) 110-85:

ARTICLE H.22. 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.

THE FOLLOWING SECTON I ARTICLE IS UPDATED IN COMPLIANCE WITH PUBLIC LAW (P.L.) 110-161:

ARTICLE I.1. GENERAL CONTRACT CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT, subparagraph b., is revised to add the following clause:

HHSAR Clause No. 352.270-10, Jan 2006, Anti-Lobbying

HHS-556

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE **N/A**

PAGE 1 OF PAGES 2

2. AMENDMENT/MODIFICATION NO 10

3. EFFECTIVE DATE **See block 16C, below**

4. REQUISITION/PURCHASE REQ. NO

5. PROJECT NO. (*if applicable*) **N/A**

6. ISSUED BY CODE

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

7. ADMINISTERED BY (*if other than Item 6*) CODE **N/A**

MID RCB-B

8. NAME AND ADDRESS OF CONTRACTOR (*No., Street, County, State and ZIP Code*)

PharmAthene UK Limited VIN: 1148445
Johnson Matthey Building
PO Box 88, Haverton Hill Road
Billingham, T523 1KN

CODE FACILITY CODE

x 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (*SEE ITEM 11*)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. **HHSN266200400034C**

10B. DATED (*SEE ITEM 13*) **September 30, 2004**

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

o The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers o is extended, o is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning one (1) copy of the amendment: (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATA SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and data specified.

12. ACCOUNTING AND APPROPRIATION DATA *(if required)*
SOCC 25.55

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(C) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

x C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF **FAR 42.12 and FAR 1.602-1**

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor o is not, x is required to sign this document and return 2 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible*)

PURPOSE: To recognize the Contractor's successor in interest from Avecia Biologics Limited to PharmAthene UK, Limited; to revise ARTICLE B4 ADVANCE UNDERSTANDINGS and ARTICLE G4. PROJECT OFFICER

	Total Funds Currently Allotted			Total Estimated Cost		
	Cost	Fee	Total	Cost	Fee	Total
Prior to this Mod	[***]	[***]	$ 50,701,800	[***]	[***]	$ 50,701,800
This Mod #	[***]	[***]	$ -0-	[***]	[***]	$ -0-
Revised Total	[***]	[***]	$ 50,701,800	[***]	[***]	$ 50,701,800

FUNDED THROUGH DATE: September 29, 2010 (Unchanged)

CONTRACT COMPLETION DATE: September 29, 2010 (Unchanged)

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (*Type or print*)

Chris Camut, VP, CFO/ UK Board of Directors

15B. CONTRACTOR/OFFEROR

/s/ Chris Camut
(*Signature of person authorized to sign*)

15C. DATE SIGNED 12/4/08

16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*)
Karen M. Gamble
Contracting Officer, MID, RCB, B-OA, DEA, NIAID

16B. UNITED STATES OF AMERICA

BY /s/ Karen M. Gamble
(*Signature of Contracting Officer*)

16C. DATE SIGNED 12/4/2008

NSN 7540-01-152-8070
PREVIOUS EDITION UNUSABLE

30-105
Computer Generated

STANDARD FORM 30 (REV. 10-83)

Pursuant to FAR 42.12, Block 8 of the Standard Form 38 shall read as follows:

PharmAthene UK Limited VIN: 1148448
Johnson Matthey Building
PO Box 88, Haverton Hill Road
Billingham TS23 1XN

The following is attached and made part of this modification:

Novation Agreement
Exhibit A, List of all Affected Contracts

ARTICLE B.4. ADVANCED UNDERSTANDINGS, is modified to add the following:

9. **Ceilings**

As a result of this novation, it is agreed that the Total Estimated Cost of this Contract shall not exceed the current value of $50,701,800, due to any variances in the indirect costs.

ARTICLE G.1. PROJECT OFFICER, is modified to add the following.

The Alternate Project Officer named below will represent the Government for the purpose of this contract:

Nancy Wilkie
Office of Biodefense Research Affaris (OBRA)
Division of Microbiology and Infectious Diseases
DHHS/NIH/NIAID
Room 5004, MSC 6604
6610 Rockledge Drive
Bethesda, MD 20892-6604
wilkien@niaid.nih.gov

HHS-556

NOVATION AGREEMENT

AVECIA BIOLOGICS LIMITED (Transferor), a corporation duly organized and existing under the laws of England and Wales with its principal office in Manchester United Kingdom; **PHARMATHENE UK LIMITED** (Transferee), a corporation duly organized and existing under the laws of England and Wales with its principal office in Billingham, UK; and the **UNITED STATES OF AMERICA** (Government) enter into this Agreement as of 2nd April, 2008.

(a) The parties agree to the following facts:

(1) The Government, represented by various Contracting Officers of the National Institute for Allergies and Infectious Diseases, has entered into certain contracts with the Transferor as shown in the attached list marked 'Exhibit A' and incorporated in this Agreement by reference. The term "the contracts," as used in this Agreement, means the above contracts and purchase orders and all other contracts and purchase orders, including all modifications, made between the Government and the Transferor before the effective date of this Agreement (whether or not performance and payment have been completed and releases executed if the Government or the Transferor has any remaining rights, duties, or obligations under these contracts and purchase orders). Included in the term "the contracts" are also all modifications made under the terms and conditions of these contracts and purchase orders between the Government and the Transferee, on or after the effective date of this Agreement.

(2) As of 2nd April, 2008, the Transferor has transferred to the Transferee all the assets of the Transferor by virtue of a Sale and Purchase Agreement between the Transferor and the Transferee.

(3) The Transferee has acquired all the assets of the Transferor by virtue of the above transfer.

(4) The Transferee has assumed all obligations and liabilities of the Transferor under the contracts by virtue of the above transfer.

(5) The Transferee is in a position to fully perform all obligations that may exist under the contracts.

(6) It is consistent with the Government's interest to recognize the Transferee as the successor party to the contracts.

(7) Evidence of the above transfer has been filed with the Government.

(b) In consideration of these facts, the parties agree that by this Agreement—

(1) The Transferor confirms the transfer to the Transferee, and waives any claims and rights against the Government that it now has or may have in the future in connection with the contracts.

(2) The Transferee agrees to be bound by and to perform each contract in accordance with the conditions contained in the contracts. The Transferee also

assumes all obligations and liabilities of, and all claims against, the Transferor under the contracts as if the Transferee were the original party to the contracts.

(3) The Transferee ratifies all previous actions taken by the Transferor with respect to the contracts, with the same force and effect as if the action had been taken by the Transferee.

(4) The Government recognizes the Transferee as the Transferor's successor in interest in and to the contracts. The Transferee by this Agreement becomes entitled to all rights, titles, and interests of the Transferor in and to the contracts as if the Transferee were the original party to the contracts. Following the effective date of this Agreement, the term "Contractor," as used in the contracts, shall refer to the Transferee.

(5) Except as expressly provided in this Agreement, nothing in it shall be construed as a waiver of any rights of the Government against the Transferor.

(6) All payments and reimbursements previously made by the Government to the Transferor, and all other previous actions taken by the Government under the contracts, shall be considered to have discharged those parts of the Government's obligations under the contracts. All payments and reimbursements made by the Government after the date of this Agreement in the name of or to the Transferor shah have the same force and effect as if made to the Transferee, and shall constitute a complete discharge of the Government's obligations under the contracts, to the extent of the amounts paid or reimbursed.

(7) The Transferor and the Transferee agree that the Government is not obligated to pay or reimburse either of them for, or otherwise give effect to, any costs, taxes, or other expenses, or any related increases, directly or indirectly arising out of or resulting from the transfer or this Agreement, other than those that the Government in the absence of this transfer or Agreement would have been obligated to pay or reimburse under the terms of the contracts.

(8) The Transferor guarantees payment of all liabilities and the performance of all obligations that the Transferee—

(i) Assumes under this Agreement; or

(ii) May undertake in the future should these contracts be modified under their terms and conditions. The Transferor waives notice of, and consents to, any such future modifications.

(9) The contracts shall remain in full force and effect, except as modified by this Agreement. Each party has executed this Agreement as of the day and year first above written.

UNITED STATES OF AMERICA,

Signed [* * *]

Name and Title [* * *]

AVECIA BIOLOGICS LIMITED,

Signed /s/ Duncan McLellan
Name and Title **Duncan McLellan, Director and Chief Financial Officer**

PHARMATHENE UK LIMITED,

Signed /s/ David P. Wright
Name and Title **David P. Wright - CEO**

CERTIFICATE

I, **Richard Clements**, certify that I am the Company Secretary of AVECIA BIOLOGICS LIMITED, that Duncan McLellan, who signed this Agreement for this corporation, was then a Director and the Chief Financial Officer of this corporation; and that this Agreement was duly signed for and on behalf of this corporation by authority of its governing body and within the scope of its corporate powers. Witness my hand this day of 2nd June 2008.

Signed /s/ Richard Clements

CERTIFICATE

I, **Christopher C. Camut**, certify that I am the Company Secretary of PHARMATHENE UK LIMITED, that David P. Wright, who signed this Agreement for this corporation, was then a Director of this corporation; and that this Agreement was duly signed for and on behalf of this corporation by authority of its governing body and within the scope of its corporate powers. Witness my hand this day of 23 June 2008.

Signed /s/ Christopher C. Camut

Exhibit A

The Contracts

Contract number N01-Al-25492

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Development and Testing of Vaccines Against Anthrax."

Contract number N01-Al-30052

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Production and Testing of Anthrax Recombinant Protective Antigen."

Contract number HHSN266200400034C, N01-Al-40034

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Development, Testing and Evaluation of Candidate Vaccines Against Plague."

List of Affected Contracts

Contract number N01-Al-25492

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NAID), part of the US National Institutes of Health (NIH), for "Development and Testing of Vaccines Against Anthrax."

This contract is substantially complete. As at 15th January 2008, the total contract amount was $10,155,120 and there was an [* * *] which is under discussion between Avecia Biologics Limited and NAID.

Contracting Office: National Institutes of Health
Office of Acquisitions, NIAID
Room 3214
6700-8 Rockledge Dr., MSC 7612
Bethesda, Maryland 20892-7612

Contract number N01-Al-30052

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Production and Testing of Anthrax Recombinant Protective Antigen.'

As at 15th April 2008, the total contract value was $118,036,200 and the total estimated costs remaining to complete were [* * *].

Contracting Office: National Institutes of Health
Office of Acquisitions, NIAID
Room 3214
6700-B Rockledge Dr., MSC 7612
Bethesda, Maryland 20892-7612

Contract number HHSN266200400034C, N01-AI-40034

Contract between Avecia Biologics Limited and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH), for "Development, Testing and Evaluation of Candidate Vaccines Against Plague."

As at 15th April 2008, the total contract value was $50,701,714 and the total estimated costs remaining to complete were [* * *].

Contracting Office: National Institutes of Health
Office of Acquisitions, NIAID
Room 3214
6700-B Rockledge Dr., MSC 7612
Bethesda, Maryland 20892-7612

Exhibit 21

List of Subsidiaries

PharmAthene UK Limited
PharmAthene Canada, Inc.

Exhibit 23

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-146463),
(2) Registration Statement (Form S-3 No. 333-155692),
(3) Registration Statement (Form S-8 No. 333-156371) pertaining to the 2007 Long-Term Incentive Compensation Plan,
(4) Registration Statement (Form S-3 No. 333-156997),
(5) Registration Statement (Form S-3 No. 333-124712),

of PharmAthene, Inc. and in the related Prospectuses of our report dated March 30, 2009, with respect to the consolidated financial statements of PharmAthene, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2008.

/s/ Ernst & Young, LLP
McLean, Virginia
March 30, 2009

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 Annual Report on Form 10-K of PharmAthene, Inc.;

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: March 31, 2009

/s/ David P. Wright
Name: **David P. Wright**
Title: **Principal 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 Annual Report on Form 10-K of PharmAthene, Inc.;

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: March 31, 2009

/s/ Christopher C. Camut
Name: **Christopher C. Camut**
Title: **Principal Financial Officer**

Exhibit 32.1

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

In connection the Annual Report of PharmAthene, Inc. (the "Company") on Form 10-K for the year ended December 31, 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
Principal Executive Officer
March 31, 2009

Exhibit 32.2

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

In connection with the Annual Report of PharmAthene, Inc. (the "Company") on Form 10-K for the year ended December 31, 2008, as filed with the Securities and Exchange Commission (the "Report"), I, Christopher C. Camut, Principal 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
Principal Financial Officer
March 31, 2009