U.S.
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2008

OR

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

For the transition period from ___ to ____

Commission file number: **001-33137**

EMERGENT BIOSOLUTIONS INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
2273 Research Boulevard, Suite 400	
Rockville, Maryland	**20850**
(Address of Principal Executive Offices)	(Zip Code)

(301) 795-1800
(Registrant's Telephone Number, Including Area Code)

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

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 x Accelerated filer o Non-accelerated filer o Smaller reporting company (Do not check if a smaller reporting company)

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

As of October 31, 2008, the registrant had 29,921,107 shares of common stock outstanding.

Emergent BioSolutions Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our ability to obtain new contracts with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, and our performance under those contracts, including the timing of deliveries;
- our plans for future sales of BioThrax;
- our plans to pursue label expansions and improvements for BioThrax;
- our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- the potential benefits of our existing collaboration agreements and our ability to enter into selective additional collaboration arrangements;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this quarterly report, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this quarterly report, including the documents that we have incorporated by reference herein and filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2008	December 31, 2007
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 104,688	$ 105,730
Accounts receivable	14,070	18,817
Inventories	17,516	16,897
Note receivable	10,000	-
Prepaid expenses and other current assets	5,700	2,866
Total current assets	151,974	144,310
Property, plant and equipment, net	120,898	110,218
Deferred tax assets, net	12,598	12,397
Restricted cash	200	5,200
Other assets	1,726	1,383
Total assets	$ 287,396	$ 273,508
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 16,673	$ 20,257
Accrued expenses and other current liabilities	1,463	1,778
Accrued compensation	10,378	9,502
Indebtedness under line of credit	15,000	11,832
Long-term indebtedness, current portion	3,739	3,514
Income taxes payable	2,898	7,665
Deferred tax liabilities, net	597	211
Deferred revenue, current portion	820	902
Total current liabilities	51,568	55,661
Long-term indebtedness, net of current portion	39,651	42,588
Deferred revenue, net of current portion	1,853	2,473
Other liabilities	1,495	1,627
Total liabilities	94,567	102,349
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred Stock $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2008 and December 31, 2007	-	-
Common Stock, $0.001 par value; 100,000,000 shares authorized, 29,850,411 and 29,750,237 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	30	30
Additional paid-in capital	104,288	101,933
Accumulated other comprehensive loss	(1,040)	(1,130)
Retained earnings	89,551	70,326
Total stockholders' equity	192,829	171,159
Total liabilities and stockholders' equity	$ 287,396	$ 273,508

The accompanying notes are an integral part of these consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	**2007**	**2008**	**2007**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Product sales	$ 55,478	$ 41,786	$ 139,308	$ 89,750
Contracts and grants	1,121	1,858	3,496	3,528
Total revenues	56,599	43,644	142,804	93,278
Operating expense:				
Cost of product sales	10,519	11,407	27,211	22,765
Research and development	16,627	12,777	45,308	41,689
Selling, general and administrative	14,115	15,038	41,212	38,889
Income (loss) from operations	15,338	4,422	29,073	(10,065)
Other income (expense):				
Interest income	476	472	1,598	1,945
Interest expense	2	(7)	(4)	(54)
Other income (expense), net	(1)	(14)	183	164
Total other income (expense)	477	451	1,777	2,055
Minority interest in subsidiary	428	-	428	-
Income (loss) before provision for (benefit from) income taxes	16,243	4,873	31,278	(8,010)
Provision for (benefit from) income taxes	5,857	2,028	12,051	(3,205)
Net income (loss)	$ 10,386	$ 2,845	$ 19,227	$ (4,805)
Earnings (loss) per share - basic	$ 0.35	$ 0.10	$ 0.65	$ (0.17)
Earnings (loss) per share - diluted	$ 0.34	$ 0.10	$ 0.64	$ (0.17)
Weighted-average number of shares - basic	29,818,994	29,739,797	29,777,852	28,741,380
Weighted-average number of shares - diluted	30,590,950	29,900,571	30,151,940	28,741,380

The accompanying notes are an integral part of these consolidated financial statements.

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended September 30,	
	2008	**2007**
	(Unaudited)	
Cash flows from operating activities:		
Net income (loss)	$ 19,227	$ (4,805)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation expense	1,733	1,895
Depreciation and amortization	3,547	3,597
Deferred income taxes	185	9,418
Gain on disposal of property and equipment	(182)	-
Excess tax benefits from stock-based compensation	-	(6,708)
Minority interest in subsidiary	(428)	-
Changes in operating assets and liabilities:		
Accounts receivable	4,747	1,318
Inventories	(619)	(901)
Income taxes	(4,767)	(25,820)
Prepaid expenses and other assets	(2,749)	(1,109)
Accounts payable	(1,165)	1,521
Accrued expenses and other liabilities	876	(1,512)
Accrued compensation	(447)	426
Deferred revenue	(702)	(1,015)
Net cash provided by (used in) operating activities	19,256	(23,695)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(16,464)	(36,197)
Issuance of a note receivable	(10,000)	-
Net cash used in investing activities	(26,464)	(36,197)
Cash flows from financing activities:		
Proceeds from borrowings on long term indebtedness and line of credit	45,000	15,333
Issuance of common stock subject to exercise of stock options	620	2,474
Principal payments on long term indebtedness and line of credit	(44,544)	(11,131)
Excess tax benefits from stock-based compensation	-	6,708
Restricted cash release (deposit)	5,000	(5,000)
Net cash provided by financing activities	6,076	8,384
Effect of exchange rate changes on cash and cash equivalents	90	(644)
Net decrease in cash and cash equivalents	(1,042)	(52,152)
Cash and cash equivalents at beginning of period	105,730	76,418
Cash and cash equivalents at end of period	$ 104,688	$ 24,266

The accompanying notes are an integral part of these consolidated financial statements.

1. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying unaudited consolidated financial statements include the accounts of Emergent BioSolutions Inc. (the "Company" or "Emergent") and its wholly-owned and majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

The unaudited consolidated financial statements included herein have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.

In the opinion of the Company's management, any adjustments contained in the accompanying unaudited consolidated financial statements are of a normal recurring nature, and are necessary to present fairly the financial position of the Company as of September 30, 2008, results of operations for the three and nine month periods ended September 30, 2008 and 2007, and cash flows for the nine month periods ended September 30, 2008 and 2007. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

Note receivable

The Company has entered into a loan and security agreement with Protein Sciences Corporation ("PSC") to provide a loan to PSC of up to $10 million in conjunction with an agreement pursuant to which the Company would acquire substantially all of the assets of PSC. The loan is secured by substantially all of PSC's assets, including intellectual property. Under this loan agreement and a related promissory note, PSC had drawn $10 million as of September 30, 2008, and the Company has recorded this as a note receivable. The note bears interest at an annual rate of 8%, and is due and payable on the earlier of December 31, 2008 or when the amount becomes due and payable under the terms of the note. As of September 30, 2008, the Company has recorded accrued interest on the note receivable of $336,000, included in prepaid expenses and other current assets.

On July 9, 2008, the Company initiated a lawsuit against PSC and PSC's senior management, alleging fraudulent conduct by the senior management and breach of the terms of PSC's agreements with the Company. Based on the event of default alleged by the Company, the promissory note has been accelerated and is due and payable immediately. The Company has concluded that, according to the provisions of Statement of Financial Accounting Standards ("SFAS") No. 114, *Accounting by Creditors for Impairment of a Loan*, the $10 million note receivable is not impaired as of September 30, 2008, and has not recorded a reserve against this note.

Capitalized interest

The Company capitalizes interest in accordance with SFAS No. 34, *Capitalization of Interest Cost*, based on the cost of major ongoing capital projects which have not yet been placed in service. For the three month periods ended September 30, 2008 and 2007, the Company incurred interest of $676,000 and $899,000, respectively. Of these amounts, the Company capitalized $674,000 and $890,000, respectively. For the nine months ended September 30, 2008 and 2007, the Company incurred interest of $2.3 million and $2.2 million, respectively. Of these amounts, the Company capitalized $2.2 million in each period.

Earnings per share

Basic net income (loss) per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) by the weighted average number of shares outstanding for the period. Diluted net income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock during the period. The following table presents the calculation of basic and diluted net income (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share data)	**2008**	**2007**	**2008**	**2007**
Numerator:				
Net income (loss)	$ 10,386	$ 2,845	$ 19,227	$ (4,805)
Denominator:				
Weighted-average number of shares—basic	29,818,994	29,739,797	29,777,852	28,741,380
Dilutive securities—stock options	771,956	160,774	374,088	-
Weighted-average number of shares—diluted	30,590,950	29,900,571	30,151,940	28,741,380
Earnings (loss) per share-basic	$ 0.35	$ 0.10	$ 0.65	$ (0.17)
Earnings (loss) per share-diluted	$ 0.34	$ 0.10	$ 0.64	$ (0.17)

Accounting for stock-based compensation

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123(R)"), using the modified prospective method. Under SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate. The Company accounts for equity instruments issued to non-employees in accordance with Emerging Issues Task Force ("EITF") Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services.*

The Company has utilized the Black-Scholes valuation model for estimating the fair value of all stock options granted. The fair value of each option is estimated on the date of grant. Set forth below are the weighted-average assumptions used in valuing the stock options granted and a discussion of the Company's methodology for developing each of the assumptions used:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	**2007**	**2008**	**2007**
Expected dividend yield	0%	0%	0%	0%
Expected volatility	65%	50%	65%	50%
Risk-free interest rate	2.75%	4.01-4.95%	1.78-2.75%	4.01-5.09%
Expected average life of options	3.0 Years	3.0 Years	3.0 Years	3.0 Years

- Expected dividend yield — The Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.
- Expected volatility — Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company analyzed the historical volatility of similar companies at a similar stage of development to estimate volatility. The volatility of these similar companies ranged from 40% to 89%, with an average estimated volatility of 68%. The Company chose a rate of 65%, approximately the mid-point of this range.
- Risk-free interest rate — This is the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option was granted.
- Expected average life of options — This is the period of time that the options granted are expected to remain outstanding. This estimate is based primarily on the Company's expectation of optionee exercise behavior subsequent to vesting of options.

Comprehensive income (loss)

SFAS No. 130, *Reporting Comprehensive Income*, requires the presentation of comprehensive income (loss) and its components as part of the financial statements. Comprehensive income (loss) is comprised of net income (loss) and other changes in equity that are excluded from net income (loss). The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss). Comprehensive income for the three and nine months ended September 30, 2008 was $10.6 million and $19.3 million, respectively. Comprehensive income for the three months ended September 30, 2007 was $2.7 million. Comprehensive loss for the nine months ended September 30, 2007 was $5.4 million.

Reclassifications

Certain amounts classified as accrued expenses and other current liabilities in the consolidated balance sheet as of December 31, 2007 have been reclassified as accounts payable to conform to current period presentation.

Recent accounting pronouncements

In May 2008, the Financial Accounting Standards Board ("FASB") issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ("SFAS No. 162"). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U.S. SFAS No. 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.* The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities—an Amendment of FASB Statement No. 133* ("SFAS No. 161"). SFAS No. 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The provisions of SFAS No. 161 are effective for fiscal years beginning on or after November 15, 2008, with early adoption encouraged. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In February 2008, the FASB issued a one-year deferral for non-financial assets and liabilities to comply with SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157"). The Company adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no material effect upon adoption of this accounting pronouncement on the Company's consolidated results of operations or financial position. The Company does not expect the adoption of SFAS No. 157 as it pertains to non-financial assets and liabilities to have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an Amendment of ARB No. 51* ("SFAS No. 160"). SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements, requires consolidated net income (loss) to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest, establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation, and requires that a parent recognize a gain or loss in net income (loss) when a subsidiary is deconsolidated. The provisions of SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (“SFAS No. 141(R)”). SFAS No. 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values, changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and it may not be applied before that date. The provisions of SFAS No. 141(R) will impact the Company’s financial statements to the extent that the Company is party to a business combination after the pronouncement has been adopted.

In November 2007, the EITF issued EITF No. 07-1, *Accounting for Collaborative Arrangements* (“EITF No. 07-1”). EITF No. 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The provisions of EITF No. 07-1 are effective for fiscal years beginning on or after December 15, 2008 and interim periods within those fiscal years. EITF No. 07-1 shall be applied to all periods presented for all collaborative arrangements existing as of the effective date. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

2. Inventories

Inventories consist of the following:

(in thousands)	September 30, 2008	December 31, 2007
Raw materials and supplies	$ 2,854	$ 2,463
Work-in-process	12,150	11,483
Finished goods	2,512	2,951
Total inventories	$ 17,516	$ 16,897

3. Property, plant and equipment

Property, plant and equipment consist of the following:

(in thousands)	September 30, 2008	December 31, 2007
Land and improvements	$ 4,914	$ 4,974
Buildings and leasehold improvements	28,105	26,410
Furniture and equipment	22,955	19,626
Software	6,297	5,866
Construction-in-progress	78,095	71,129
	140,366	128,005
Less: Accumulated depreciation and amortization	(19,468)	(17,787)
Total property, plant and equipment, net	$ 120,898	$ 110,218

4. Stock options

As of September 30, 2008, the Company has two stock-based employee compensation plans, the Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the “2006 Plan”) and the Emergent BioSolutions Employee Stock Option Plan (the “2004 Plan”) (together, the “Emergent Plans”), under which the Company has granted options to purchase shares of Common Stock. The Emergent Plans have both incentive and non-qualified stock option features.

The 2006 Plan contains an “evergreen provision” that allows for increases in the number of shares authorized for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. As of September 30, 2008, an of 3,424,040 shares of Common Stock are authorized for issuance under the 2006 Plan, and options to purchase a total of 2,575,517 shares of Common Stock under the 2006 Plan are outstanding. Following the closing of the Company’s initial public offering in November 2006, the Company no longer grants options pursuant to the 2004 Plan.

Each option granted under the Emergent Plans becomes exercisable as specified in the relevant option agreement, and no option can be exercised after ten years from the date of grant. The following is a summary of stock option plan activity:

	2006 Plan		2004 Plan		
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2007	1,380,111	$ 9.77	666,519	$ 6.04	
Granted	1,444,140	7.37	-	-	
Exercised	(32,201)	9.85	(67,973)	4.45	
Forfeited	(216,533)	8.60	(19,181)	10.28	
Outstanding at September 30, 2008	2,575,517	$ 8.52	579,365	$ 6.09	$ 15,933,634
Exercisable at September 30, 2008	367,010	$ 10.12	521,826	$ 5.50	$ 5,088,724

5. Income taxes

Significant components of the provision for (benefit from) income taxes attributable to operations consist of the following:

(in thousands)	Three Months Ended September 30, 2008	2007	Nine Months Ended September 30, 2008	2007
Current:				
Federal	$ 5,504	$ 1,931	$ 12,120	$ (6,025)
State	(472)	214	(257)	317
Total current	5,032	2,145	11,863	(5,708)
Deferred:				
Federal	(663)	(114)	(1,560)	2,229
State	1,488	(3)	1,748	274
Total deferred	825	(117)	188	2,503
Total provision for (benefit from) income taxes	$ 5,857	$ 2,028	$ 12,051	$ (3,205)

The estimated effective annual tax rate for the nine months ended September 30, 2008 and 2007 was approximately 39% and 40%, respectively.

The Company’s federal and state income tax returns for the tax years 2007 to 2005 remain open to examination. The Company’s tax returns in the United Kingdom remain open to examination for the tax years 2007 to 2001, and tax returns in Germany remain open indefinitely.

In July 2008, the Company was notified by the Internal Revenue Service that the federal income tax return for the 2006 tax year has been selected for a limited scope audit. A federal income tax audit of the Company's tax return for the 2005 tax year was completed in March 2008. As a result of that audit, the Company paid an assessment of $450,000, including $55,000 of interest.

6. Litigation

On July 9, 2008, the Company filed suit against PSC, Daniel D. Adams ("Adams"), PSC's Chief Executive Officer, and Manon M.J. Cox ("Cox"), PSC's Chief Operating Officer, in the Supreme Court of the State of New York raising claims in connection with the letter of intent, asset purchase agreement and related loan agreement entered into by the Company and PSC. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Adams and Cox. Also on September 12, 2008, the Company filed a first amended complaint against PSC. As amended, the complaint alleges fraud, breach of the asset purchase agreement, loan agreement and related letter of intent, breach of the duty of good faith and fair dealing, unjust enrichment, and unfair business practices. The Company is seeking monetary damages of no less than $13 million, punitive damages, declaratory judgment that the Company has no further funding obligations to PSC, injunctive relief associated with PSC's misappropriation of funds provided by the Company, injunctive relief to protect the collateral for the loan, a declaratory judgment that the asset purchase agreement remains in effect and injunctive relief barring PSC's breach of the no-shop provision, and other appropriate relief. On October 3, 2008, the Company filed a separate suit against Adams and Cox in the U.S. District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages.

On July 29, 2008, PSC announced that it had terminated the asset purchase agreement for alleged breach of the Company's obligation to continue to provide funding and to preserve confidentiality. PSC has since reiterated its position that the asset purchase agreement is terminated in a September 2008 letter to shareholders. Additionally, PSC asserted in an earlier communication to the Company that the Company is liable for a break-up fee of $1.5 million, that this liability reduces the balance of the loan due to the Company from $10 million to $8.5 million and that PSC does not believe that the note is due until December 31, 2008. The Company disputes PSC's position and contends that PSC has defaulted on the loan, breached the contract, has no right to terminate the asset purchase agreement and is required to repay the $10 million loan immediately.

From time to time, the Company is involved in product liability litigation and other lawsuits that arise in the ordinary course of its business. The Company does not believe that any pending proceedings will have a material, adverse effect on the results of its operations. There are currently no pending claims against the Company arising out of the use of BioThrax by the U.S. government. If such cases occur, the Company plans to rely on a combination of contractual indemnification provisions, the government contractor defense, statutory protections and product liability insurance to limit its potential liability.

7. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and commercial. In the biodefense segment, the Company develops, manufactures and commercializes immune related biologics consisting of vaccines and therapeutics for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment relate primarily to the Company's FDA-licensed product, BioThrax. In the commercial segment, the Company develops immune related biologics consisting of vaccines and therapeutics for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Revenues in this segment consist predominantly of milestone payments and development and grant revenues received under collaboration, development contracts and grant arrangements. The "All Other" segment relates to the general operating costs of the Company and includes costs of the centralized services departments, which are not allocated to the other segments, as well as spending on product candidates or activities that are not classified as biodefense or commercial. The assets in this segment consist primarily of cash and fixed assets.

(in thousands)	Reportable Segments Biodefense	Commercial	All Other	Total
		Three Months Ended September 30, 2008		
External revenue	$ 56,132	$ 467	$ -	$ 56,599
Net income (loss)	26,311	(13,423)	(2,502)	10,386
Assets	143,610	23,946	119,840	287,396
		Three Months Ended September 30, 2007		
External revenue	$ 42,679	$ 965	$ -	$ 43,644
Net income (loss)	16,767	(10,591)	(3,331)	2,845
Assets	156,695	19,738	50,318	226,751

(in thousands)	Reportable Segments Biodefense	Commercial	All Other	Total
		Nine Months Ended September 30, 2008		
External revenue	$ 140,615	$ 2,043	$ 146	$ 142,804
Net income (loss)	58,719	(33,148)	(6,344)	19,227
Assets	143,610	23,946	119,840	287,396
		Nine Months Ended September 30, 2007		
External revenue	$ 90,643	$ 2,635	$ -	$ 93,278
Net income (loss)	26,120	(24,124)	(6,801)	(4,805)
Assets	156,695	19,738	50,318	226,751

The accounting policies of the segments are the same as those described in Note 1 — Summary of significant accounting policies. There are no inter-segment transactions.

8. Related party transactions

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide certain legal services to the Company. The Company's Senior Vice President, Legal Affairs and General Counsel is married to a former partner at WilmerHale, who did not participate in providing legal services to the Company. The Company has incurred fees for legal services rendered by WilmerHale of approximately $735,000 and $760,000, respectively, for the nine months ended September 30, 2008 and 2007. Of this amount, approximately $505,000 and $318,000, respectively, remained in accounts payable at September 30, 2008 and 2007.

The Company entered into a marketing arrangement in 2008 with an entity controlled by family members of the Chief Executive Officer to market and sell BioThrax. The contract requires a payment of 17.5% of net sales and reimbursement of certain expenses for certain countries in the Middle East and North Africa, excluding countries to which export is prohibited by the U.S. government. No royalty payments under this agreement have been triggered for the nine months ended September 30, 2008 and 2007. During the nine months ended September 30, 2008, the Company paid the same entity a $70,000 settlement related to a previously terminated agreement.

The Company has entered into the consulting and transportation arrangements outlined in this paragraph with various persons or entities affiliated with a member of the Company’s Board of Directors and the Chief Executive Officer. At September 30, 2008 and 2007, $19,000 and $15,000, respectively, remained in accounts payable for these services. For the nine months ended September 30, 2008 and 2007, the Company paid approximately $137,000 and $155,000, respectively, to an entity affiliated with a member of the Company’s Board of Directors for strategic consultation and project support for the marketing and communications group. For the nine months ended September 30, 2008 and 2007, the Company paid approximately $23,000 and $22,000, respectively, to an entity owned by the Chief Executive Officer for transportation and logistical support.

9. Asset purchase agreement

On May 2, 2008, the Company and VaxGen, Inc. ("VaxGen") entered into an asset purchase agreement in which the Company acquired all assets and rights related to a recombinant protective antigen anthrax vaccine product candidate and related technology from VaxGen, in exchange for consideration of $2 million upon execution of the definitive agreement, up to an additional $8 million in milestone payments, and specified percentages of future net sales. The $2 million was paid to VaxGen in May 2008, and a $1 million milestone payment was paid in August 2008. These amounts have been recorded as research and development expense.

10. Joint venture

In July 2008, the Company entered into a joint venture with the University of Oxford and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium Limited. As part of this arrangement, the Company has entered into a license agreement with the joint venture pursuant to which the Company obtained rights to develop, manufacture and commercialize pharmaceutical compositions intended to prevent or treat *mycobacterium tuberculosis* in humans in developed countries. The Company consolidates the joint venture in accordance with Accounting Research Bulletin No. 51, *Consolidated Financial Statements.* The income/(loss) attributable to the minority interest is recorded as minority interest in subsidiary on the income statement.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, 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 the "Risk Factors" sections of this quarterly 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 biopharmaceutical company focused on the development, manufacture and commercialization of immune related biologics products, consisting of vaccines and therapeutics that assist the body's immune system to prevent or treat disease. We develop vaccines and therapeutics for use against biological agents that are potential weapons of bioterrorism and biowarfare and against infectious diseases that have resulted in significant unmet or underserved public health needs. We manufacture and market BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. We use internally generated cash flows from the sale of BioThrax to substantially fund the development of our product pipeline. We also seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. For financial reporting purposes, we operate in two business segments, biodefense and commercial.

Our biodefense segment focuses on vaccines and therapeutics for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our product candidates in this segment are focused on two specific biological agents: anthrax and botulinum. Within our anthrax product portfolio, in addition to our marketed vaccine, BioThrax, we are developing a recombinant protective antigen anthrax vaccine acquired in May 2008 from VaxGen, Inc., next generation anthrax vaccines, an anthrax immune globulin therapeutic and a recombinant anthrax monoclonal antibody therapeutic. Within our botulinum product portfolio, we are developing a recombinant botulinum vaccine.

Our commercial segment focuses on vaccines and therapeutics for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Our product candidates in this segment include a typhoid vaccine, a tuberculosis vaccine, a hepatitis B therapeutic vaccine, a chlamydia vaccine and a group B streptococcus vaccine.

We continue to negotiate with the non-management members of the board of directors of Protein Sciences Corporation, or PSC, an acquisition of PSC that would add a flu vaccine candidate and technology platform to our portfolio. Based on the proposal currently being negotiated, we do not anticipate completing this acquisition on the terms originally agreed to, and any transaction may be based on a different structure and on substantially different terms from what we announced.

Our biodefense segment has generated net income for each of the last five fiscal years and for the nine months ended September 30, 2008. Our commercial segment has generated revenue through development contracts and grant funding. None of our commercial product candidates have received marketing approval and, therefore, our commercial segment has not generated any product sales revenues. As a result, our commercial segment has incurred a net loss for each of the last five fiscal years and for the nine months ended September 30, 2008.

Product Sales

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. Department of Health and Human Services, or HHS, and U.S. Department of Defense, or DoD, and expect for the foreseeable future to continue to derive substantially all of our product sales revenues from the sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $139.3 million and $89.8 million for the nine months ended September 30, 2008 and 2007, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

Contracts and Grants

We seek to advance development of our product candidates by leveraging external funding. We may slow down development programs or place them on hold during periods that are not covered by external funding. We have received external funding awards for the following development programs:

- post-exposure prophylaxis for BioThrax from HHS;
- anthrax immune globulin therapeutic candidate from National Institute of Allergy and Infectious Diseases, or NIAID;
- recombinant botulinum vaccine candidate from NIAID;
- anthrax monoclonal antibody therapeutic candidate from NIAID and the Biomedical Advanced Research and Development Authority, or BARDA;
- next generation anthrax vaccine candidate from NIAID and BARDA;
- tuberculosis vaccine candidate from the Wellcome Trust and the Aeras Global TB Vaccine Foundation through our collaboration with the University of Oxford; and
- typhoid vaccine candidate from the Wellcome Trust.

We continue to actively pursue additional government sponsored development contracts and grants and to encourage both governmental and non-governmental agencies and philanthropic organizations to provide development funding or to conduct clinical studies of our product candidates.

Manufacturing Infrastructure

We conduct our BioThrax vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed a new 50,000 square foot manufacturing facility on our Lansing campus. We have completed construction of the building and installation of the associated capital equipment, and current spending is related to qualification and validation activities required for regulatory approval and initiation of commercial manufacturing of BioThrax. We expect the facility to cost approximately $75 million when complete, including approximately $55 million for the building and equipment, with the balance related to qualification and validation. We have incurred costs of approximately $72 million for these purposes through September 30, 2008.

This new facility is a large scale manufacturing plant that is intended to be used to produce multiple fermentation-based vaccine products, subject to complying with appropriate change-over procedures. We have made significant progress on qualification and validation activities required for the commercial manufacture of BioThrax, but in connection with the development of our recombinant protective antigen, or rPA, anthrax vaccine product candidate, we are currently evaluating facility requirements for the manufacture of rPA and whether our new Lansing facility would meet those requirements. The plant may ultimately be used for the manufacture of either BioThrax or rPA, or potentially both.

We are currently evaluating alternatives for the manufacture of various product candidates, and may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We may also manufacture some product candidates, such as our hepatitis B product candidate, in China or India. One alternative we continue to evaluate is the utilization of our two buildings in Frederick, Maryland. We have incurred costs of approximately $4 million through September 30, 2008 related to initial engineering design and preliminary utility build out of one of these buildings. Because we are in the preliminary stages of evaluating our alternatives, we cannot reasonably estimate the timing and costs that would be necessary to complete this project. We may also elect to sell or lease all or a substantial portion of one or both of these facilities to third parties.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair value of stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenues from product sales in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition,* or SAB 104. SAB 104 requires recognition of revenues from product sales that require no continuing performance on our part if four basic criteria have been met:

- there is persuasive evidence of an arrangement;
- delivery has occurred or title has passed to our customer based on contract terms;
- the fee is fixed and determinable and no further obligation exists; and
- collectibility is reasonably assured.

We have generated BioThrax sales revenues under U.S. government contracts with the DoD and HHS. Under previous DoD contracts, we invoiced the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We recorded as deferred revenue the full amount of each progress payment invoice that we submitted to the DoD. Title to the product passed to the DoD upon submission of the first invoice. The earnings process was considered complete upon FDA release of the product for sale and distribution. Following FDA release of the product, we segregated the product for later shipment and recognized as period revenue all deferred revenue related to the released product in accordance with the “bill and hold” sale requirements under SAB 104. At that time, we also invoiced the DoD for the final progress payment and recognized the amount of that invoice as period revenue.

Under previous contracts with HHS, we invoiced HHS and recognized the related revenues upon delivery of the product to the government carrier, at which time title to the product passed to HHS. Under our current contracts with HHS, we invoice HHS and recognize the related revenues upon acceptance by the government at the delivery site, at which time title to the product passes to HHS.

Under a collaboration agreement that we entered into with Sanofi Pasteur in May 2006 for our meningitis B vaccine candidate, we received an upfront license fee and are entitled to additional payments for development work under the collaboration. We evaluated the various components of the collaboration in accordance with Emerging Issues Task Force Issue, or EITF, No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several units of accounting in an arrangement. We concluded that under EITF No. 00-21, the license fee and the development work under our agreement with Sanofi Pasteur should be accounted for as a single unit of accounting. We recognize amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. We are recognizing this revenue over the estimated development period under the contract, currently estimated at seven years, as adjusted from time to time for any delays or acceleration in the development of the product candidate. Under the collaboration agreement, we are entitled to payments up to specified levels for development work we perform on behalf of Sanofi Pasteur. We invoice Sanofi Pasteur monthly in arrears, and recognize revenue in the period in which the associated costs are incurred. To date, we have not identified a meningitis B product candidate suitable for commercialization.

From time to time, we are awarded reimbursement contracts for services and development grant contracts with government entities and non-government and philanthropic organizations. Under these contracts, we typically are reimbursed for our costs in connection with specific development activities and may also be entitled to additional fees. We record the reimbursement of our costs and any associated fees as contracts and grants revenue and the associated costs as research and development expense. We issue invoices under these contracts after we incur the reimbursable costs. We recognize revenue upon incurring the reimbursable costs.

Inventories

Inventories are stated at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses and includes the services and products of third party suppliers.

We analyze our inventory levels quarterly and write down in the applicable period inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. We also write off in the applicable period the costs related to expired inventory. We capitalize the costs associated with the manufacture of BioThrax as inventory from the initiation of the manufacturing process through the completion of manufacturing, labeling and packaging.

Income Taxes

We account for income taxes in accordance with Statement of Financial Accounting Standards, or SFAS, No. 109, *Accounting for Income Taxes*, or SFAS No. 109. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A net deferred tax asset or liability is reported on the balance sheet. Our deferred tax assets include the unamortized portion of in-process research and development expenses, the anticipated future benefit of the net operating losses that we have incurred and other timing differences between the financial reporting basis of assets and liabilities.

We have historically incurred net operating losses for income tax purposes in some states, primarily Maryland, and in some foreign jurisdictions, primarily the United Kingdom. The amount of the deferred tax assets on our balance sheet reflects our expectations regarding our ability to use our net operating losses to offset future taxable income. The applicable tax rules in particular jurisdictions limit our ability to use net operating losses as a result of ownership changes. In particular, we believe that these rules will significantly limit our ability to use net operating losses generated by Microscience Limited, or Microscience, and Antex Biologics, Inc., or Antex, prior to our acquisition of Microscience in June 2005 and our acquisition of substantially all of the assets of Antex in May 2003.

We review our deferred tax assets on a quarterly basis to assess our ability to realize the benefit from these deferred tax assets. If we determine that it is more likely than not that the amount of our expected future taxable income will not be sufficient to allow us to fully utilize our deferred tax assets, we increase our valuation allowance against deferred tax assets by recording a provision for income taxes on our income statement, which reduces net income, or increases net loss, for that period and reduces our deferred tax assets on our balance sheet. If we determine that the amount of our expected future taxable income will allow us to utilize net operating losses in excess of our net deferred tax assets, we reduce our valuation allowance by recording a benefit from income taxes on our income statement, which increases net income or reduces net loss, for that period and increases our deferred tax assets on our balance sheet.

We account for uncertainty in income taxes in accordance with Financial Accounting Standards Board, or FASB, Interpretation 48, *Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109, Accounting for Income Taxes*, or FIN 48. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Under FIN 48, we recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

Stock-based Compensation

We adopted SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123(R), on January 1, 2006 using the modified prospective method. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their estimated grant date fair values.

We value our share-based payment transactions using the Black-Scholes valuation model. We measure the amount of compensation cost based on the fair value of the underlying equity award on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

The effect of SFAS No. 123(R) on net income (loss) and net income (loss) per share in any period is not necessarily representative of the effects in future years due to, among other things, the vesting period of the stock options and the fair value of additional stock option grants in future years.

Financial Operations Overview

Revenues

Between May 2005 and February 2007, we supplied 10.0 million doses of BioThrax to HHS for inclusion in the Strategic National Stockpile, or SNS, under a base contract for 5.0 million doses for a fixed price of $123 million and a contract modification for an additional 5.0 million doses for a fixed price of $120 million. We completed delivery of all doses to HHS under the base contract and the contract modification in February 2007.

On September 25, 2007, we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 25, 2007 through September 24, 2010. The first 5.5 million doses delivered under this contract were sold to HHS at a discounted price, as specified in the contract, due to the limited remaining shelf-life for those specific doses. This discounted price does not apply to the final 13.25 million doses under the contract. The firm fixed price for the 18.75 million doses, including the discount, is $400 million in the aggregate. Through September 30, 2008, we have delivered approximately 11 million doses under this contract. If we receive FDA approval of our pending application to extend the expiry dating of BioThrax from three years to four years, HHS has agreed to increase the price per dose under the agreement for 13.25 million doses sold under this contract. In that event, HHS would make a lump sum payment to us reflecting an increase in the price per dose for specified doses delivered prior to such approval and pay an increased price per dose for doses delivered following the date of such approval. The aggregate value of such price adjustment is approximately $34 million. If we do not receive FDA approval of four-year expiry dating during the term of the agreement there will be no adjustment in the price per dose under the agreement.

Under this agreement, we have also agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay approximately $2.2 million. We invoice HHS for each delivery upon acceptance of BioThrax doses delivered into the SNS. The agreement also provides for HHS to pay us up to $11.5 million in milestone payments in connection with us advancing a program to obtain a post-exposure prophylaxis indication for BioThrax. These funds are payable upon achievement of specific program milestones. In October 2007, we achieved the initial milestone and invoiced HHS for $8.8 million. We received this payment from HHS and revenue was recognized in November 2007.

Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied approximately 10 million doses of BioThrax for immunization of military personnel. Our most recent contract with the DoD, as amended in October 2006, provided for the supply of a minimum of approximately 1.5 million doses of BioThrax to the DoD through September 2007. As a result of a further amendment of the DoD contract in June 2007, we completed delivery of all doses to the DoD under this contract prior to June 30, 2007. We are not currently party to a procurement contract with the DoD. As a result of an October 2007 Presidential Directive that outlines the U.S. government’s objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management, in the future the DoD will procure additional doses of BioThrax to satisfy ongoing requirements for its active immunization program directly from the SNS.

On September 30, 2008, we entered into an agreement with HHS to supply up to an additional 14.5 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 30, 2008 through September 30, 2011. Delivery of doses under the agreement is scheduled to commence in September 2009, immediately following the scheduled completion of deliveries under our current 18.75 million dose supply contract with HHS, and continue through September 2011. Funds for the procurement of the first 5.7 million doses of BioThrax have been committed. Procurement of the remaining 8.8 million doses will be funded through the annual appropriations process for the SNS. If the FDA approves our pending supplement to our biologics license application to extend the shelf life of BioThrax from three years to four years, and if four-year dated lots of BioThrax are available at the time of delivery of a particular lot or shipment, we must deliver four-year dated product to the SNS. In the event the FDA has not approved four-year expiry dating at the time of such delivery, we may instead deliver three-year dated product to the SNS. Four-year dated product will be invoiced at a higher price than three-year dated product. The total purchase price for the 14.5 million doses will be between $362.7 million and $402.8 million, depending on product dating. Under the agreement, we have agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay us approximately $1.9 million. We will invoice HHS under the agreement upon completion of each delivery of BioThrax doses to the SNS.

In September 2007, we received a development contract from NIAID, valued at up to $9.5 million, in support of non-clinical and clinical studies of our anthrax immune globulin therapeutic candidate. Under the terms of the development contract, we will use the funds to conduct various studies on this product candidate, including non-clinical efficacy studies and clinical trials. In July 2008, we were awarded two grants from NIAID, totaling over $4.5 million, to support development of our recombinant botulinum vaccine and next generation anthrax vaccine candidates. In September 2008, we received a $24 million development contract from NIAID and BARDA to fund continued development of our anthrax monoclonal antibody therapeutic candidate. Also in September 2008, we signed a development contract with NIAID and BARDA, valued at up to approximately $30 million, to fund development of our next generation anthrax vaccine candidate.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur, which was amended in June 2008, under which we granted Sanofi Pasteur an exclusive, worldwide license under a proprietary technology to develop and commercialize a meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provided for payments for development work under the collaboration. To date, this collaboration has not yielded a product candidate suitable for commercialization. We have deferred recognition of the upfront license fee and development reimbursement payments, and record revenue in accordance with our revenue recognition policies.

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis, primarily because of the timing of our fulfilling orders for BioThrax and work done under new and existing contracts and grants.

Cost of Product Sales

The primary expense that we incur to deliver BioThrax to our customers is manufacturing costs, which are primarily fixed costs. These fixed manufacturing costs consist of attributable facilities, utilities and salaries and personnel-related expenses for indirect manufacturing support staff. Variable manufacturing costs for BioThrax consist primarily of costs for materials, direct labor and contract filling operations.

We determine the cost of product sales for doses sold during a reporting period based on the average manufacturing cost per dose in the period those doses were manufactured. We calculate the average manufacturing cost per dose in the period of manufacture by dividing the actual costs of manufacturing in such period by the number of units produced in that period. In addition to the fixed and variable manufacturing costs described above, the average manufacturing cost per dose depends on the efficiency of the manufacturing process, utilization of available manufacturing capacity and the production yield for the period of production.

Research and Development Expenses

We expense research and development costs as incurred. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel;
- fees to professional service providers for, among other things, preclinical and analytical testing, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services;
- costs of materials used in clinical trials and research and development;
- depreciation of capital assets used to develop our products; and
- operating costs, such as the operating cost of facilities and the legal costs of pursuing patent protection of our intellectual property.

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that development spending for our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow on clinical program that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, on our ability to use or rely on data generated by government agencies, such as the ongoing studies with BioThrax being conducted by the Centers for Disease Control and Prevention, or CDC.

In July 2008, we entered into a joint venture with the University of Oxford and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium Limited. As part of this arrangement, we have entered into a license agreement with the joint venture pursuant to which we obtained rights to develop, manufacture and commercialize pharmaceutical compositions intended to prevent or treat *mycobacterium tuberculosis* in humans in developed countries. We anticipate contributing approximately $21 million to the joint venture over the next three years to support the Phase IIb proof of concept study in humans, primarily in the form of services to be performed by our personnel on behalf of the joint venture, with approximately $4 million in cash being contributed over the three-year period. The Wellcome Trust and the Aeras Global TB Vaccine Foundation are also providing financial support for the Phase IIb clinical trial.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal and accounting services. We currently market and sell BioThrax directly to HHS with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax and if we receive marketing approval for additional products, we expect that we will increase our spending for marketing and sales activities.

Total Other Income (Expense)

Total other income (expense) consists principally of interest income and interest expense. We earn interest income on our cash and cash equivalents, and we incur interest expense on our indebtedness. We capitalize interest expense in accordance with SFAS No. 34, *Capitalization of Interest Cost*, based on the cost of major ongoing projects which have not yet been placed in service, such as our new manufacturing facility. Our total interest cost will increase in future periods as compared to prior periods as a result of the term loan that we entered into in June 2007, as well as any borrowings under our revolving line of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See “Liquidity and Capital Resources — Debt Financing” for additional information.

Results of Operations

Quarter Ended September 30, 2008 Compared to Quarter Ended September 30, 2007

Revenues

Product sales revenues increased by $13.7 million, or 33%, to $55.5 million for the three months ended September 30, 2008 from $41.8 million for the three months ended September 30, 2007. This increase in product sales revenues was primarily due to a 34% increase in the average sales price per dose for BioThrax. In 2007, we provided a discounted price to HHS due to the limited remaining shelf life of doses delivered in September 2007. Product sales revenues for the three months ended September 30, 2008 and 2007 consisted of BioThrax sales to HHS of $55.5 million and $41.8 million, respectively.

Contracts and grants revenues decreased by $737,000, or 40%, to $1.1 million for the three months ended September 30, 2008 from $1.9 million for the three months ended September 30, 2007. Contracts and grants revenues for the three months ended September 30, 2008 consisted of $467,000 from the Sanofi Pasteur collaboration, related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, and $654,000 from NIAID and other governmental agencies. Contracts and grants revenues for the three months ended September 30, 2007 consisted of $538,000 in revenue from the Sanofi Pasteur collaboration, grant revenue from NIAID of $893,000 and grant revenue from the Wellcome Trust of $427,000.

Cost of Product Sales

Cost of product sales decreased by $888,000, or 8%, to $10.5 million for the three months ended September 30, 2008 from $11.4 million for the three months ended September 30, 2007. This decrease was primarily attributable to decreased costs resulting from improved production yield.

Research and Development Expense

Research and development expenses increased by $3.9 million, or 30%, to $16.6 million for the three months ended September 30, 2008 from $12.8 million for the three months ended September 30, 2007. This increase reflects higher contract service costs and asset and technology acquisition costs, and includes increased expenses of $2.1 million on product candidates that are categorized in the biodefense segment, $1.1 million on product candidates categorized in the commercial segment and $601,000 in other research and development expenses, which are in support of technology platforms and central research and development activities.

The increase in spending on biodefense product candidates, detailed in the table below, was attributable to spending on product candidates that we acquired during the year, as well as to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for BioThrax enhancements was related to preparing for and conducting clinical and non-clinical efficacy studies to support applications for marketing approval of these enhancements. The spending for the recombinant protective antigen anthrax vaccine includes a $1 million milestone payment and other development costs related to this product candidate, which was purchased from VaxGen, Inc., or VaxGen, in May 2008. The decrease in spending for the next generation anthrax vaccines program resulted from lower costs related to feasibility studies and formulation development. The increase in spending in our anthrax immune globulin therapeutic was primarily due to the timing of costs related to plasma collection. The increase in spending for our anthrax monoclonal therapeutic is driven by spending for pre-IND filing preparation. The decrease in spending for the botulinum vaccine candidates resulted from advancing this program to the process development stage and the manufacture of clinical trial material in 2007.

The increase in spending on commercial product candidates, detailed in the table below, primarily reflects additional personnel and contracted services. The increase in spending for our typhoid vaccine candidate resulted from conducting a Phase IIb study in the U.S., which commenced in the second quarter of 2008. The decrease in spending for our hepatitis B therapeutic vaccine candidate resulted from the cessation of new patient enrollment for our ongoing Phase II clinical trial in the United Kingdom and Serbia as a result of recruiting difficulties. The decrease in spending for our group B streptococcus vaccine candidate resulted from a decision not to proceed with Phase I clinical trials for two of the protein components of the vaccine candidate. As a result, we expect that spending for our group B streptococcus vaccine candidate will be even further reduced in the future. The spending for our tuberculosis vaccine candidate is related to the formation of our joint venture with the University of Oxford in July 2008. Our chlamydia and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated the development of technology platforms.

We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or other non-governmental and philanthropic organizations in providing funding for further development or procurement.

Our principal research and development expenses for the three months ended September 30, 2008 and 2007 are shown in the following table:

(in thousands)	Three Months Ended September 30, 2008	2007
Biodefense:		
BioThrax enhancements	$ 1,799	$ 995
Recombinant protective antigen anthrax vaccine	2,211	-
Next generation anthrax vaccines	348	702
Anthrax immune globulin therapeutic	1,230	891
Anthrax monoclonal therapeutic	281	-
Botulinum vaccines	659	1,806
Total biodefense	6,528	4,394
Commercial:		
Typhoid vaccine	5,181	3,099
Hepatitis B therapeutic vaccine	810	1,520
Group B streptococcus vaccine	1,537	1,969
Tuberculosis vaccine	873	-
Chlamydia vaccine	264	910
Meningitis B vaccine	309	361
Total commercial	8,974	7,859
Other	1,125	524
Total	$ 16,627	$ 12,777

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $923,000, or 6%, to $14.1 million for the three months ended September 30, 2008 from $15.0 million for the three months ended September 30, 2007. The decrease in selling, general and administrative expenses was driven by lower costs in our headquarters and staff organization and primarily reflects a decrease of approximately $1.0 million resulting from decreased professional services for our headquarters organization, partially offset by an increase of $93,000 in sales and marketing expenses related to the growth of our staff and an increase in our sales and marketing activities. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses decreased by $725,000, or 6%, to $10.8 million for the three months ended September 30, 2008 from $11.5 million for the three months ended September 30, 2007. Selling, general and administrative expenses related to our commercial segment decreased by $197,000, or 6%, to $3.3 million for the three months ended September 30, 2008 from $3.5 million for the three months ended September 30, 2007.

Total Other Income (Expense)

Total other income (expense) increased by $26,000, or 6%, to $477,000 for the three months ended September 30, 2008 from $451,000 for the three months ended September 30, 2007. This increase resulted primarily from a increase in other income (expense) of $13,000, a decrease in interest expense of $9,000, and a increase in interest income of $4,000.

Minority Interest in Subsidiary

In July 2008, we formed a joint venture with the University of Oxford related to our tuberculosis vaccine candidate. The minority interest in subsidiary represents the portion of the net loss realized by our joint venture that is attributable to our partners.

Income Taxes

Provision for income taxes increased by $3.8 million, or 189%, to $5.9 million for the three months ended September 30, 2008 from $2.0 million for the three months ended September 30, 2007. The provision for income taxes for the three months ended September 30, 2008 resulted primarily from our income before provision for income taxes of $16.2 million and an effective tax rate of approximately 36%. The provision for income taxes for the three months ended September 30, 2007 resulted primarily from our income before provision from income taxes of $4.9 million and an effective tax rate of approximately 42%. The decrease in the effective tax rate is due to utilization of foreign operating expenses to reduce tax liabilities. The benefit from income taxes for the three months ended September 30, 2007 also reflects research and development tax credits of $120,000.

Results of Operations

Nine Months Ended September 30, 2008 Compared to Nine Months Ended September 30, 2007

Revenues

Product sales revenues increased by $49.6 million, or 55%, to $139.3 million for the nine months ended September 30, 2008 from $89.8 million for the nine months ended September 30, 2007. This increase in product sales revenues was primarily due to a 36% increase in the number of doses of BioThrax delivered and a 14% increase in the average sales price per dose. Product sales revenues for the nine months ended September 30, 2008 consisted of BioThrax sales to HHS of $138.5 million and aggregate international and other sales of $781,000. Product sales revenues for the nine months ended September 30, 2007 consisted of BioThrax sales to HHS of $63.5 million and sales to the DoD of $26.2 million.

Contracts and grants revenues decreased by $32,000, or 1%, to $3.5 million for the nine months ended September 30, 2008 from $3.5 million for the nine months ended September 30, 2007. Contracts and grants revenues for the nine months ended September 30, 2008 consisted of $2.0 million from the Sanofi Pasteur collaboration, related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, and $1.5 million from NIAID and other governmental agencies. Contracts and grants revenues for the nine months ended September 30, 2007 consisted of $2.2 million in revenue from the Sanofi Pasteur collaboration, grant revenue from NIAID of $893,000 and grant revenue from the Wellcome Trust of $427,000.

Cost of Product Sales

Cost of product sales increased by $4.4 million, or 20%, to $27.2 million for the nine months ended September 30, 2008 from $22.8 million for the nine months ended September 30, 2007. This increase was attributable to a 36% increase in the number of doses of BioThrax delivered, partially offset by decreased costs resulting from improved production yield.

Research and Development Expense

Research and development expenses increased by $3.6 million, or 9%, to $45.3 million for the nine months ended September 30, 2008 from $41.7 million for the nine months ended September 30, 2007. This increase reflects higher contract service costs, and includes increased expenses of $3.4 million on product candidates categorized in the commercial segment and $1.3 million in other research and development expenses, which are in support of technology platforms and central research and development activities, partially offset by decreased expenses of $1.1 million on product candidates that are categorized in the biodefense segment.

The decrease in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials, partially offset by increased spending on product candidates that we acquired during the year. The spending for BioThrax enhancements was related to preparing for and conducting clinical and non-clinical efficacy studies to support applications for marketing approval of these enhancements. The spending for the recombinant protective antigen anthrax vaccine was related primarily to the purchase of this vaccine candidate from VaxGen in May 2008. The increase in spending in our next generation anthrax vaccines program resulted from feasibility studies and formulation development of product candidates. The decrease in spending in our anthrax immune globulin therapeutic candidate was primarily due to the timing of costs related to plasma collection. The spending for the anthrax monoclonal therapeutic candidate was primarily due to the purchase of this vaccine candidate and related technology in March 2008. The decrease in spending for the botulinum vaccine candidates resulted from advancing this program to the process development stage and the manufacture of clinical trial material in 2007.

The increase in spending on commercial product candidates, detailed in the table below, primarily reflects additional personnel and contracted services. The increase in spending for our typhoid vaccine candidate resulted from the manufacture of clinical material and initiating and conducting a Phase IIb study in the U.S., which commenced in the second quarter of 2008. The decrease in spending for our hepatitis B therapeutic vaccine candidate resulted from the cessation of new patient enrollment from our ongoing Phase II clinical trial in the United Kingdom and Serbia as a result of recruiting difficulties. The increase in spending for our group B streptococcus vaccine candidate resulted from preparing for Phase I clinical trials for two of the protein components of the vaccine candidate. We have decided not to proceed with these trials and, as a result, we expect that spending for our group B streptococcus vaccine candidate will be significantly reduced in the future. The spending for our tuberculosis vaccine candidate related to the formation of our joint venture with the University of Oxford in July 2008. Our chlamydia and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated with the development of technology platforms.

We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or other non-governmental and philanthropic organizations in providing funding for further development or procurement.

Our principal research and development expenses for the nine months ended September 30, 2008 and 2007 are shown in the following table:

(in thousands)	Nine Months Ended September 30, 2008	2007
Biodefense:		
BioThrax enhancements	$ 4,883	$ 4,196
Recombinant protective antigen anthrax vaccine	4,847	-
Next generation anthrax vaccine	3,156	1,848
Anthrax immune globulin therapeutic	3,591	6,692
Anthrax monoclonal therapeutic	531	-
Botulinum vaccine	2,609	7,980
Total biodefense	19,617	20,716
Commercial:		
Typhoid vaccine	11,658	7,622
Hepatitis B therapeutic vaccine	2,625	3,988
Group B streptococcus vaccine	5,498	4,549
Tuberculosis vaccine	873	-
Chlamydia vaccine	1,019	2,304
Meningitis B vaccine	1,122	948
Total commercial	22,795	19,411
Other	2,896	1,562
Total	$ 45,308	$ 41,689

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $2.3 million, or 6%, to $41.2 million for the nine months ended September 30, 2008 from $38.9 million for the nine months ended September 30, 2007. The increase in selling, general and administrative expenses was driven by an increase in our headquarters and staff organization to support the overall growth of our business, and primarily reflects an increase of approximately $1.8 million resulting from the addition of personnel and increased legal and other professional services for our headquarters organization and an increase of $494,000 in sales and marketing expenses related to the growth of our staff and an increase in our sales and marketing activities. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $1.6 million, or 5%, to $31.7 million for the nine months ended September 30, 2008 from $30.1 million for the nine months ended September 30, 2007. Selling, general and administrative expenses related to our commercial segment increased by $734,000, or 8%, to $9.5 million for the nine months ended September 30, 2008 from $8.8 million for the nine months ended September 30, 2007.

Total Other Income (Expense)

Total other income decreased by $278,000, or 14%, to $1.8 million for the nine months ended September 30, 2008 from $2.1 million for the nine months ended September 30, 2007. This decrease resulted primarily from a decrease in interest income of $347,000 as a result of lower investment returns related to decreases in interest rates, partially offset by a decrease in interest expense of $50,000.

Minority Interest in Subsidiary

In July 2008, we formed a joint venture with the University of Oxford related to our tuberculosis vaccine candidate. The minority interest in subsidiary represents the portion of the net loss realized by our joint venture that is attributable to our partners.

Income Taxes

Provision for (benefit from) income taxes increased by $15.3 million to a provision for income taxes of $12.1 million for the nine months ended September 30, 2008 from a benefit from income taxes of $3.2 million for the nine months ended September 30, 2007. The provision for income taxes for the nine months ended September 30, 2008 resulted primarily from our income before provision for income taxes of $31.3 million and an effective tax rate of approximately 39%. The benefit from income taxes for the nine months ended September 30, 2007 resulted primarily from our loss before benefit from income taxes of $8.0 million and an effective tax rate of approximately 40%. The benefit from income taxes for the nine months ended September 30, 2007 also reflects research and development tax credits of $635,000.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and principal and interest payments on our debt. We have funded our cash requirements from inception through September 30, 2008 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, development funding from government entities and non-government and philanthropic organizations, the net proceeds from our initial public offering and, to a lesser extent, from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the years in the five year period ended December 31, 2007 and the nine months ended September 30, 2008.

As of September 30, 2008, we had cash and cash equivalents of $104.7 million.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2008 and 2007:

(in thousands)	Nine Months Ended September 30, 2008	2007
Net cash provided by (used in):		
Operating activities(1)	$ 19,346	$ (24,339)
Investing activities	(26,464)	(36,197)
Financing activities	6,076	8,384
Total net cash used	$ (1,042)	$ (52,152)

(1) Includes the effect of exchange rate changes on cash and cash equivalents.

Net cash provided by operating activities of $19.3 million for the nine months ended September 30, 2008 resulted principally from net income of $19.2 million and a decrease in billed but uncollected accounts receivable of $4.7 million for the nine month period, partially offset by a decrease in income taxes payable of $4.8 million primarily due to the timing of payment of our 2007 income tax liability.

Net cash used in operating activities of $24.3 million for the nine months ended September 30, 2007 resulted principally from our net loss of $4.8 million, a decrease in income taxes payable of $13.7 million due to the timing of payment of our 2006 income tax liability and the impact of excess tax benefits related to stock option exercises of $6.7 million.

Net cash used in investing activities for the nine months ended September 30, 2008 and 2007 resulted principally from the purchase of property, plant and equipment and, in 2008, the issuance of a note receivable in the amount of $10.0 million. Capital expenditures of $16.5 million and $36.2 million for the nine months ended September 30, 2008 and 2007, respectively, relate primarily to construction, qualification and validation activities for our new manufacturing facility in Lansing.

Net cash provided by financing activities of $6.1 million for the nine months ended September 30, 2008 resulted primarily from the release of $5.0 million of restricted cash related to our continuing compliance with the debt covenants specified in our HSBC term loan and $620,000 from the exercise of stock options.

Net cash provided by financing activities of $8.4 million for the nine months ended September 30, 2007 resulted primarily from the additional proceeds from a term loan with HSBC of $15.3 million, $2.5 million in proceeds from the exercise of stock options and $6.7 million related to excess tax benefits from the exercise of stock options, partially offset by $11.1 million of principal payments on long-term indebtedness, including the repayment of $8.9 million from our revolving line of credit with Fifth Third Bank, and a $5.0 million restricted cash deposit in accordance with our HSBC term loan.

Debt Financing

As of September 30, 2008, we had $58.4 million principal amount of debt outstanding, comprised primarily of the following:

- $2.5 million outstanding under a forgivable loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase the first facility in Frederick, Maryland;
- $7.9 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for the first Frederick facility;
- $6.5 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for the second facility on the Frederick site;
- $26.5 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan; and
- $15.0 million outstanding under a $15.0 million revolving line of credit with Fifth Third Bank.

Tax Benefits

In connection with our facility expansion in Lansing, the State of Michigan and the City of Lansing have provided us a variety of tax credits and abatements. We estimate that the total value of these tax benefits may be up to $18.5 million over a period of up to 15 years, beginning in 2006. These tax benefits are primarily based on our planned investment in our Lansing facility. In addition, we must maintain a specified number of employees in Lansing to continue to qualify for these tax benefits.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funding. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates.

We may seek to raise additional external debt or equity financing to provide additional financial flexibility and we may from time to time file shelf registration statements to facilitate such financing. Our committed external sources of funds consist of credit that may be available from time to time under our revolving line of credit with Fifth Third Bank and grant and development funding of our anthrax immune globulin therapeutic candidate, anthrax monoclonal antibody therapeutic candidate, next generation anthrax vaccine candidate and recombinant botulinum vaccine candidate. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions.

Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- the timing of, and the costs involved in qualification and validation activities related to our new manufacturing facility in Lansing, Michigan and, if we proceed, the build out of our manufacturing facility in Frederick, Maryland;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to obtain development funding from government entities and non-government and philanthropic organizations; and
- our ability to establish and maintain collaborations.

We may require additional sources of funds for future acquisitions that we may make or, depending on the size of the obligation, to meet balloon payments upon maturity of our current borrowings. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements.

Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Recent Accounting Pronouncements

In May 2008, FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U.S. SFAS No. 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities—an Amendment of FASB Statement No. 133*, or SFAS No. 161. SFAS No. 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations and how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. The provisions of SFAS No. 161 are effective for fiscal years beginning on or after November 15, 2008, with early adoption encouraged. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In February 2008, the FASB issued a one-year deferral for non-financial assets and liabilities to comply with SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. We adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no material effect upon adoption of this accounting pronouncement on our consolidated results of operations or financial position. We do not expect the adoption of SFAS No. 157 as it pertains to non-financial assets and liabilities to have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an Amendment of ARB No. 51*, or SFAS No. 160. SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements, requires consolidated net income (loss) to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest, establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation, and requires that a parent recognize a gain or loss in net income (loss) when a subsidiary is deconsolidated. The provisions of SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, or SFAS No. 141(R). SFAS No. 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values, changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and it may not be applied before that date. The provisions of SFAS No. 141(R) will impact our financial statements to the extent that we are party to a business combination after the pronouncement has been adopted.

In November 2007, the EITF issued EITF No. 07-1, *Accounting for Collaborative Arrangements*, or EITF No. 07-1. EITF No. 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The provisions of EITF No. 07-1 are effective for fiscal years beginning on or after December 15, 2008 and interim periods within those fiscal years. EITF No. 07-1 shall be applied to all periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the impact of the adoption of this statement on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents and restricted cash that have maturities of less than three months. We currently do not hedge interest rate exposure or foreign currency exchange exposure. 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, but would likely increase the interest expense associated with our debt.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2008. The term "disclosure controls and procedures," as defined in Rules 13 a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2008, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the quarter ended September 30, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation against Protein Sciences Corporation. On July 9, 2008, we filed suit against Protein Sciences Corporation, or PSC, Daniel D. Adams, PSC's Chief Executive Officer, and Manon M.J. Cox, PSC's Chief Operating Officer, in the Supreme Court of the State of New York raising claims in connection with the letter of intent, asset purchase agreement and related loan agreement entered into by us and PSC. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Mr. Adams and Ms. Cox. Also on September 12, 2008, we filed a first amended complaint against PSC. As amended, the complaint alleges fraud, breach of the asset purchase agreement, loan agreement and related letter of intent, breach of the duty of good faith and fair dealing, unjust enrichment, and unfair business practices. We are seeking monetary damages of no less than $13 million, punitive damages, declaratory judgment that we have no further funding obligations to PSC, injunctive relief associated with PSC's misappropriation of funds provided by us, injunctive relief to protect the collateral for our loan, a declaratory judgment that the asset purchase agreement remains in effect and injunctive relief barring PSC's breach of the no-shop provision, and other appropriate relief. On October 3, 2008, we filed a separate suit against Mr. Adams and Ms. Cox in the Federal District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages.

On July 29, 2008, PSC announced that it has terminated the asset purchase agreement for alleged breach of the obligation to continue to provide funding and to preserve confidentiality. PSC has since reiterated its position that the asset purchase agreement is terminated in a September 2008 letter to shareholders. Additionally, PSC asserted in an earlier communication to us that we are liable for a break-up fee of $1.5 million, that this liability reduces the balance of the loan due to us from $10 million to $8.5 million, and that PSC does not believe that the note is due until December 31, 2008. We dispute PSC's position and contend that PSC has defaulted on the loan, breached the contract, has no right to terminate the asset purchase agreement and is required to repay the $10 million loan immediately.

PSC has moved to dismiss the first amended complaint in the New York action and a hearing on that motion is currently scheduled for November 2008. PSC has not yet asserted any counterclaims, but it has notified us in writing that it will assert counterclaims for "among other things, breach of contract, intentional misrepresentations, tortious interference with business relations and unfair trade practices." In the Connecticut action, Adams and Cox have yet to respond to the complaint.

BioThrax product liability litigation. Between 2001 and 2003, over 100 individual plaintiffs filed a series of lawsuits in which they claimed damages resulting from personal injuries allegedly caused by vaccination with BioThrax by the DoD. In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four consolidated lawsuits brought by approximately 120 claimants. The District Court's ruling in these consolidated cases was based on two grounds. First, the District Court found that we were entitled to protection under a Michigan state statute that provides immunity for drug manufacturers if the drug was approved by the FDA and its labeling is in compliance with FDA approval, unless the plaintiffs establish that the manufacturer intentionally withheld or misrepresented information to the FDA and the drug would not have been approved, or the FDA would have withdrawn approval, if the information had been accurately submitted. Second, the District Court found that we were entitled to the immunity afforded by the government contractor defense, which, under specified circumstances, extends the sovereign immunity of the U.S. to government contractors who manufacture a product for the government. Specifically, the government contractor defense applies when the government approves reasonably precise specifications, the product conforms to those specifications and the supplier warns the government about known dangers arising from the use of the product. The District Court found that we established each of those factors.

In 2005 and 2006, we were named as a defendant in three federal lawsuits, each filed on behalf of a single plaintiff claiming different injuries caused by DoD's immunization with BioThrax. Each plaintiff sought a different amount of damages. Each of these lawsuits has been dismissed with prejudice and no BioThrax product liability cases remain pending. We believe that we are entitled to indemnification under our prior contract with the DoD for legal fees associated with the BioThrax product liability cases brought by military personnel.

Insurance coverage litigation. On December 26, 2006, we were named as a defendant in a lawsuit brought by Evanston Insurance Company in the U.S. District Court for the Western District of Michigan captioned *Evanston Insurance Company v. BioPort Corporation and Robert C. Myers.* Evanston issued a general liability policy to us in 2000, and we made a claim for coverage under that policy for defense and indemnity costs incurred as a result of the claims asserted in the BioThrax product liability litigation discussed above and the thimerosal litigation discussed below. In its complaint, Evanston asserted a number of purported bases for the court to void or reduce its obligation to defend or indemnify us, including a claim that we failed to disclose on our insurance application our alleged knowledge of "incidents, conditions, circumstances, effects or suspected defects which may result in claims." In October 2008, we resolved this insurance coverage dispute with Evanston and the lawsuit was dismissed with prejudice.

Mil Vax litigation. In 2003, six unidentified plaintiffs filed suit in the U.S. District Court for the District of Columbia against the U.S. government seeking to enjoin the Anthrax Vaccine Immunization Program administered under MilVax under which all military personnel were required to be vaccinated with BioThrax. In October 2004, the District Court enjoined the DoD from administering BioThrax to military personnel on a mandatory basis without their informed consent or a Presidential waiver. This ruling was based in part on the District Court's finding that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded. In December 2005, the FDA issued a final order determining that BioThrax is safe and effective and not misbranded. In February 2006, the U.S. Court of Appeals for the District of Columbia, on appeal of the injunction by the government, ruled that the injunction had dissolved by its own terms as a result of the FDA's final order. The matter remains pending in the District Court, where subsequent proceedings have focused on whether the plaintiffs are entitled to recover attorneys' fees from the government.

In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency DoD civilian personnel and contractors. In December 2006, the same counsel who represented the plaintiffs in the 2003 litigation filed a new lawsuit against the government in the same federal court, on behalf of unnamed service members and the DoD civilian employees or contractors and purportedly on behalf of a class of similarly situated individuals. The suit contends on various grounds that the FDA's 2005 final order should be set aside as substantively and procedurally flawed and that BioThrax is not properly approved for use in the DoD's vaccination program. The plaintiffs seek a declaration that BioThrax is improperly licensed and is not approved for use against inhalation anthrax, an order vacating the FDA's 2005 final order, and an injunction prohibiting the DoD from using BioThrax in a mandatory vaccination program. In February 2008, the federal court in which that case was pending dismissed the action, concluding that FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. On April 24, 2008, plaintiffs filed a notice of appeal of that decision to the U.S. Court of Appeals for the District of Columbia Circuit and the appeal has been assigned docket number 08-5117. Although we are not a party to the lawsuits challenging DoD's mandatory anthrax vaccination program, if the District Court were to enjoin the mandatory use of BioThrax by DoD, the amount of future purchases of BioThrax by the U.S. government could be affected.

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations is a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed in various state and federal courts in the U.S. alleging that thimerosal, a mercury-containing preservative used in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. No specific dollar amount of damages has been claimed.

Emergent BioDefense Operations is currently a named defendant in 40 lawsuits pending in two jurisdictions: three in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines. Because we are not currently and have not historically been in the business of manufacturing or selling pediatric vaccines, we do not believe that we manufactured the pediatric vaccines at issue in the lawsuits. Under a contractual obligation to the State of Michigan, we manufactured one batch of vaccine suitable for pediatric use. However, the contract required the State to use the vaccine solely for Michigan public health purposes. We no longer manufacture any products that contain thimerosal. We have submitted a request for coverage of the defense and indemnity costs incurred as a result of these thimerosal claims to our insurance carriers. The insurance carrier that issued our general liability policies during the relevant years is disputing coverage.

ITEM 1A. RISK FACTORS

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

We have derived substantially all of our revenue from sales of BioThrax under contracts with the DoD or HHS. If DoD and HHS demand for BioThrax is reduced, our business, financial condition and operating results could be materially harmed.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax, our FDA-approved anthrax vaccine and only marketed product. In 2006, 2007, and the nine months ended September 30, 2008, we derived substantially all of our revenue from our BioThrax contracts with the DoD or HHS. We are currently party to two contracts with HHS to supply doses of BioThrax for placement into the SNS. We are not currently party to a procurement contract with the DoD, which currently procures doses of BioThrax directly from the SNS. If the SNS priorities change, or if the DoD dose requirements from the SNS are reduced, our revenues could be substantially reduced.

Our existing and prior contracts with the DoD and HHS do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. HHS has issued a request for proposals for contracts to develop and procure a recombinant protective antigen based anthrax vaccine which we may not win. Additionally, procurement by HHS of a recombinant protective antigen based anthrax vaccine could reduce demand for BioThrax. The success of our business and our operating results for the foreseeable future are substantially dependent on the price per dose, the number of doses and the timing of deliveries for BioThrax sales to the U.S. government.

Our business may be harmed as a result of the government contracting process, which is a competitive bidding process that involves risks not present in the commercial contracting process.

We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, including:

- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the risk that the government will issue a request for proposal to which we would not be eligible to respond;
- the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

The U.S. government may choose to award future contracts for the supply of anthrax vaccines and other biodefense product candidates that we are developing to our competitors instead of to us. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority, or BARDA, has issued a request for proposal for a recombinant protective antigen, or rPA, anthrax vaccine for the SNS. We have submitted a proposal responding to this request for proposal. Our ability to get an award will depend on whether we can persuade BARDA that we have manufacturing facilities that meet the requirements for the manufacture of rPA and the technical merits of our rPA vaccine candidate. The U.S. government may purchase another company's product candidate instead of our rPA vaccine candidate. If we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition, and operating results could be materially adversely affected. Purchases by the U.S. government of an rPA vaccine candidate, whether from us or another company, may reduce demand for BioThrax, perhaps significantly.

Our U.S. government contracts for BioThrax require ongoing funding decisions by the government. The failure to fund these contracts could cause our financial condition and operating results to suffer materially.

Our principal customer for BioThrax is the U.S. government. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to stringent budgetary constraints and political considerations. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer. For example, the sale of most supplied doses under our new contract with HHS is subject to the annual appropriations process.

The success of our business with the U.S. government depends on our compliance with regulations and obligations under our U.S. government contracts and various federal statutes and regulations.

Our business with the U.S. government is subject to specific procurement regulations and a variety of other legal compliance obligations. These laws and rules include those related to:

- procurement integrity;
- export control;
- government security regulations;
- employment practices;
- protection of the environment;
- accuracy of records and the recording of costs; and
- foreign corrupt practices.

In addition, before awarding us any future contracts, the U.S. government could require that we respond satisfactorily to a request to substantiate our commercial viability and industrial capabilities. Compliance with these obligations increases our performance and compliance costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations would have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

Our agreements with HHS to supply doses of BioThrax to HHS for placement into the SNS provide that if we receive FDA approval of an application to extend the expiry dating of BioThrax from three years to four years, HHS will increase the price per dose under the agreements. The regulatory approval process is complex and uncertain, and there is no guarantee that we will receive approval of four-year expiry dating. If we do not receive FDA approval of four-year expiry dating during the term of the agreement, we will not be entitled to receive the increased price per dose.

The pricing under our fixed price government contracts is based on estimates of the time, resources and expenses required to deliver the specified doses of BioThrax. If our estimates are not accurate, we may not be able to earn an adequate return under these contracts.

Our existing and prior contracts for the supply of BioThrax with the DoD and HHS have been fixed price contracts. We expect that our future contracts with the U.S. government for BioThrax as well as biodefense product candidates that we successfully develop also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur and to absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss.

Unfavorable provisions in government contracts may harm our business, financial condition and operating results.

Government contracts customarily contain provisions that give the government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the government to:

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount specified in a contract;
- decline to exercise an option to purchase the maximum amount specified in a contract;
- claim rights to products, including intellectual property, developed under the contract;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our HHS contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination.

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

Ongoing legal proceedings or any future similar lawsuits could limit future purchases of BioThrax by the U.S. government.

The results of future legal proceedings could reduce demand for BioThrax by the U.S. government. For example, in 2003, a group of unnamed military personnel filed a lawsuit seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and, in 2004, a federal court issued the requested injunction. In 2005, the FDA issued an order affirming the BioThrax license, and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved.

In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency DoD civilian personnel and contractors. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 final order should be set aside and that BioThrax is not properly approved for use in the DoD's vaccination program. In February 2008, the federal court in which that case was pending dismissed the action, concluding that FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. In April 2008, the plaintiffs filed a notice of appeal of this decision.

Although we are not a party to any lawsuits challenging the DoD's mandatory use of the vaccine, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax by the U.S. government could be affected. Furthermore, contractual indemnification provisions and statutory liability protections may not fully protect us from all related liabilities, and statutory liability protections could be revoked or amended to reduce the scope of liability protection. In addition, lawsuits brought directly against us by third parties, even if not successful, require us to spend time and money defending the related litigation.

Risks Related to Our Financial Position and Need for Additional Financing

We may not maintain profitability in future periods or on a consistent basis.

We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing in December 2001. Although we were profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on the timing of our fulfilling orders from the U.S. government. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

Our indebtedness may limit cash flow available to invest in the ongoing needs of our business.

As of September 30, 2008, we had $58.4 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. Our leverage could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing the amount of interest that we have to pay on debt with variable interest rates if market rates of interest increase;
- increasing our vulnerability to general adverse economic and industry conditions;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt.

We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. The covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

We expect to require additional funding and may be unable to raise capital when needed, which would harm our business, financial condition and operating results.

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. We also expect our commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for additional products. We also are committed to substantial capital expenditures in connection with our facility expansion in Lansing and may undertake additional facility projects in the future.

As of September 30, 2008, we had $104.7 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- the acquisition of new facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to our new manufacturing facility in Lansing, Michigan and, if we proceed, the build out of our manufacturing facilities in Frederick, Maryland;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to obtain development funding from government entities and non-government and philanthropic organizations; and
- our ability to establish and maintain collaborations.

Our committed external sources of funds consist of the borrowing availability under our revolving line of credit with Fifth Third Bank and grant and development funding of our anthrax immune globulin therapeutic product candidate, anthrax monoclonal antibody therapeutic candidate, and our next generation anthrax vaccine candidate. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, which we may not be able to obtain when needed or on attractive terms, which would force us to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Risks Related to Manufacturing and Manufacturing Facilities

We have initiated a manufacturing facility expansion program. Delays in completing and receiving regulatory approvals for these manufacturing facility projects could limit our potential revenues and growth.

We are currently evaluating alternatives for the manufacture of various product candidates. We may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We are spending significant amounts on our new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which was designed to produce multiple fermentation-based vaccines, subject to complying with appropriate change-over procedures. We also own two buildings in Frederick, Maryland that are available to address our future manufacturing requirements and have initiated initial engineering design and preliminary utility build out for these facilities.

Constructing and preparing a facility for manufacturing is a significant project. For example, constructing the new Lansing facility with the potential for increased manufacturing capacity for BioThrax requires that we scale-up both fermentation and downstream processing compared to the levels employed at our existing production facility for BioThrax. The process for qualifying and validating new facilities for FDA licensure can be costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with the FDA's current Good Manufacturing Practice, or cGMP, regulations, or similar regulatory requirements for sales of our products outside the U.S., may be significant. If BioThrax qualification and validation activities of our new facility in Lansing are delayed, or if we decide to not utilize the Lansing facility for the manufacture of BioThrax, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to the U.S. government and other customers, which would limit our opportunities for growth. Costs associated with constructing, qualifying and validating manufacturing facilities could require us to raise additional funds from external sources. We may not be able to do so on favorable terms or at all.

BioThrax and our immune related biologics product candidates are complex to manufacture, especially on a large scale commercial basis, which could cause us to delay product launches or experience shortages of products.

BioThrax and all our product candidates are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including obtaining materials, seed growth, fermentation, filtration, filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures or manufacturing shut-down, delay in the release of lots, product recalls, spoilage or regulatory action. From time to time we have experienced, and during the quarter experienced, deviations in the manufacturing process that may take significant time and resources to resolve and if unresolved may affect manufacturing output.

FDA approval is required for the release of each lot. We will not be able to sell any lots that fail to satisfy the release testing specifications. We must provide the FDA with the results of potency testing before lots are released for sale. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we have no redundancy. In developing redundancy, we may face significant regulatory hurdles. In the event of a problem with this strain, if we have not developed redundancy, we would not be able to provide the FDA with required potency testing.

In addition, BioThrax must be maintained at a prescribed temperature range during shipping, and variations from that temperature range could result in loss of product and could adversely affect profitability. Delays, lot failures, and shipping deviations or spoilage could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax, which would harm our business, financial condition and operating results.

We currently rely on our manufacturing facilities at a single location in Lansing for the production of BioThrax. Any interruption in manufacturing operations at this location could result in our inability to satisfy the product demands of our customers. A number of factors could cause interruptions, including:

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages or slow downs;
- protests, including by animal rights activists;
- damage to or destruction of the facility;
- regional power shortages; or
- product tampering.

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results.

If the company on whom we rely for filling BioThrax vials is unable to perform these services for us, our business may suffer.

We have outsourced the operation for filling BioThrax into vials to a single company, Hollister-Stier Laboratories LLC. Our contract with Hollister-Stier expires on December 31, 2010. We have not established redundancy for our filling functions. We have identified and contracted with a substitute provider that we believe can handle our filling needs. Before this party may perform filling services for us, it must be qualified and licensed by the FDA. If Hollister-Stier is unable to perform filling services for us, we would need to obtain FDA approval of our potential substitute filler, engage, qualify and license an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to obtain FDA approval for filling BioThrax at its facilities. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant cost and delay. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

Our business may be harmed if we do not adequately forecast customer demand.

The timing and amount of customer demand is difficult to predict. We may not be able to scale-up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, we may not be able to scale-up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never require the production capacity that we expect to have available.

If third parties do not manufacture our product candidates or products in sufficient quantities and at an acceptable cost or in compliance with regulatory requirements and specifications, the development and commercialization of our product candidates could be delayed, prevented or impaired.

We currently rely on third parties to manufacture the supplies of our immune related biologics product candidates that we require for preclinical and clinical development, including our anthrax immune globulin therapeutic, tuberculosis vaccine, typhoid vaccine and hepatitis B therapeutic vaccine candidates. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. Although we recently commissioned a new pilot plant manufacturing facility on our Lansing campus for production of preclinical and clinical supplies of our product candidates, we expect that we will continue to use third parties for these purposes.

In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification for our anthrax immune globulin therapeutic product candidate and contract fill and finish operations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, the success of those products may be jeopardized. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

Third party manufacturers under short-term supply agreements are not obligated to accept any purchase orders we may submit. If any third party terminates its agreement with us, based on its own business priorities, or otherwise fails to fulfill our purchase orders, we would need to rely on alternative sources or develop our own manufacturing capabilities to satisfy our requirements.

If alternative suppliers are not available or are delayed in fulfilling our requirements, or if we are unsuccessful in developing our own manufacturing capabilities, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers would require review and approval from the FDA and the applicable foreign regulatory agencies. This review may be costly and time consuming. There are a limited number of manufacturers that operate under the FDA's cGMP requirements and that are both capable of manufacturing for us and willing to do so.

We currently rely on third parties for regulatory compliance and quality assurance with respect to the supplies of our product candidates that they produce for us. We also will rely for these purposes on any third party that we use for production of commercial supplies of product candidates that we successfully develop. Manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards.

We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the U.S. We do not control compliance by manufacturers with these regulations and standards. If we or these third parties fail to comply with applicable regulations, sanctions could be imposed on us, which could significantly and adversely affect supplies of our product candidates. The sanctions that might be imposed include:

- fines, injunctions and civil penalties;
- refusal by regulatory authorities to grant marketing approval of our product candidates;
- delays, suspension or withdrawal of regulatory approvals, including license revocation;
- seizures or recalls of product candidates or products;
- operating restrictions; and
- criminal prosecutions.

If as a result of regulatory requirements or otherwise we or third parties are unable to manufacture our product candidates at an acceptable cost, our product candidates may not be commercially viable.

Our use of hazardous materials, chemicals, bacteria and viruses requires us to comply with regulatory requirements and exposes us to significant potential liabilities.

Our development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping of these materials. We are also subject to a variety of environmental laws in Michigan regarding underground storage tanks. One such tank on our Lansing campus is leaking. We are in the process of monitoring this leak. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we could spend significant amounts on remediation efforts. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and the Department of Agriculture our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires increased safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel, and establishes a comprehensive national database of registered entities.

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. These laws and regulations may limit the countries in which we may conduct development and manufacturing activities. If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that result, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials. Our general liability and excess insurance policies provide combined limits of $12 million in the annual aggregate. The general liability policy provides coverage of $1 million per occurrence with a $2 million aggregate. The excess liability policy provides for $10 million per occurrence and in the aggregate.

The general liability policy currently does not, with the exception of employee benefits liability, have a deductible. The employee benefits policy deductible is $1,000 per occurrence. Both the general liability and excess liability policies exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials, with the exception of our storage tank liability insurance policy for our Lansing facility. This policy has a $1 million per occurrence and $2 million annual aggregate limit with a $25,000 per claim deductible. The insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury as a result of pollution conditions or other extrodinary or unanticipated events.

Risks Related to Product Development

Our business depends significantly on our success in completing development and commercializing product candidates that are still under development. If we are unable to commercialize these product candidates, or experience significant delays or costs in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our immune related biologics product candidates. In addition to BioThrax product sales, our ability to generate near term revenue is dependent on the success of our development programs, and on the U.S. government’s interest in providing development funding for or procuring our product candidates. The commercial success of our product candidates will depend on many factors, including:

- successful development, formulation and cGMP scale-up of biological manufacturing that meets FDA requirements;
- successful development of animal models by the U.S. government;
- successful completion of non-clinical development, including studies in approved animal models;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- a determination by the Secretary of HHS that our biodefense product candidates should be purchased for the SNS prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements with contract manufacturers at acceptable costs;
- manufacturing stable commercial supplies of product candidates, including materials based on recombinant technology;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

We will not be able to commercialize our product candidates if our preclinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical trials or animal studies do not demonstrate efficacy.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical development, clinical trials to demonstrate the safety of our product candidates and clinical or animal trials to demonstrate the efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results.

We expect to rely on FDA regulations known as the “animal rule” to obtain approval for our biodefense product candidates. The animal rule permits the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval. These regulations are relatively new, and we have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our immune related biologics product candidates in humans. If we are not successful in completing the development and commercialization of our immune related biologics product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

A failure of one or more of our clinical trials or animal efficacy studies can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial or animal efficacy study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials could escalate and become cost prohibitive;
- we may have difficulty finding locations or institutions to conduct animal or human trials;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

For example, the standard of care for the treatment of patients infected with hepatitis B is affecting our ability to recruit participants for our Phase II clinical trial in the United Kingdom and Serbia, causing us to cease enrollment in this trial. In addition, because some of our current and future vaccine candidates contain live attenuated viruses, our testing of these vaccine candidates is subject to additional risk. For example, there have been reports of serious adverse events following administration of live vaccine products in clinical trials conducted by other vaccine developers. Also, for some of our current and future vaccine candidates, we expect to conduct clinical trials in chronic carriers of the disease that our product candidate seeks to prevent. There have been reports of disease flares in chronic carriers following administration of live vaccine products.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing or if the results of these trials or tests are not positive, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not be able to obtain marketing approval; or
- obtain approval for indications that are not as broad as intended.

Our product development costs will also increase if we experience delays in testing, are required to conduct additional testing, or experience delays in product approval. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

Under the Project BioShield Act, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our product candidates may not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates.

Risks Related to Commercialization

If we fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, our opportunities for growth could be harmed.

An element of our business strategy is to establish a market for sales of BioThrax to customers in addition to the U.S. government. These potential customers include foreign governments and state and local governments, which we expect will be interested in BioThrax to protect emergency responders such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals.

The market for sales of BioThrax to customers other than the U.S. government is new and undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have made only modest sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. Foreign governments in the past have requested that we submit an FDA certification of compliance. Until we reach final resolution of the issues raised in the FDA's May 2008 inspection described below under "—Risks related to regulatory approval—Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products," such a certification may be difficult to obtain, potentially limiting our ability to make sales to foreign customers. In 2007 and the nine months ended September 30, 2008, our sales of BioThrax to customers other than the U.S. government represented a small portion of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdiction before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These controls could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD's right under the Defense Production Act to require us to deliver doses that we do not currently anticipate.

Our ability to meet any potential increased demand that develops for sales of BioThrax to customers other than the U.S. government depends on our available production capacity. We use substantially all of our current production capacity at our facility in Lansing to manufacture BioThrax for sale to U.S. government customers. In the event we do not use our new Lansing facility for the manufacture of BioThrax, or if BioThrax qualification and validation activities for this facility are delayed, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to customers other than the U.S. government which could limit our opportunities for growth.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the U.S. States and require us to develop and implement costly compliance programs.

As we continue to expand our operations outside of the U.S., we must comply with numerous laws and regulations relating to international business operations. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or businesses from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the U.S., or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside of the U.S. will require us to dedicate additional resources to compliance with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPAs accounting provisions.

The commercial success of BioThrax and any products that we may develop will depend upon the degree of market acceptance by the government, physicians, patients, healthcare payors and others in the medical community.

Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community. In particular, our biodefense immune related biologics products and product candidates are subject to the product criteria that may be specified by potential U.S. government customers. The product specifications in any government procurement request may prohibit or preclude us from participating in the government program if our products or product candidates do not satisfy the stated criteria.

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the GAO reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the licensed six-dose regimen and annual booster doses, questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences, and uncertainty about the vaccine’s efficacy against inhalational anthrax.

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax include local reactions, such as redness, swelling and limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA with respect to BioThrax. The report of any adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. Serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus and multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

If any products that we develop do not achieve an adequate level of acceptance, we may not generate material revenues with respect to these products. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- the relative convenience and ease of administration;
- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- the strength of marketing and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

Political or social factors, including related litigation, may delay or impair our ability to market BioThrax and our biodefense product candidates and may require us to spend time and money to address these issues.

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 highly charged and unpredictable. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, which would harm our business.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns. For example, between 2001 and 2004, members of the military and various activist groups who opposed mandatory inoculation with BioThrax petitioned the FDA and a federal court to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD prevailed in the challenge to its mandatory vaccination program, the actions of these groups created negative publicity about BioThrax. Lawsuits or publicity campaigns could limit the demand for BioThrax and our biodefense product candidates and harm our future business.

We have a small marketing and sales group. If we are unable to expand our sales and marketing capabilities or enter into sales and marketing agreements with third parties, we may be unable to generate product sales revenue from sales to customers other than the U.S. government.

To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We currently market and sell BioThrax through a small, targeted marketing and sales group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. However, to increase our sales of BioThrax to state and local governments and foreign governments and create an infrastructure for future sales of other biodefense products to these customers, we plan to expand our sales and marketing organization, which will be expensive and time consuming.

We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective marketing and sales force for sales of biodefense product candidates to customers other than the U.S. government or for sales of our commercial product candidates. If we are not successful in our efforts to expand our internal sales and marketing capability, our ability to independently market and sell BioThrax and any other product candidates that we successfully develop will be impaired. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed as a result of FDA requirements or other reasons, we would incur related expenses too early relative to the product launch. This may be costly, and our investment would be lost if we cannot retain our sales and marketing personnel.

We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new immune related biologics products is highly competitive. We face competition with respect to BioThrax, our current product candidates and any products we may seek to develop or commercialize in the future from major pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of immune related biologics are a number of pharmaceutical companies that have vaccine programs, including GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Novartis, as well as smaller more focused companies engaged in immune related biologics development, such as Cangene, Human Genome Sciences, Intercell, Dynport Vaccine Corporation, Elusys, Bavarian Nordic, PharmAthene and Crucell.

Any immune related biologics product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, such as vaccines and therapeutics, including antibiotics, and with other product candidates that are in development for the same indications. In many cases, the currently marketed products have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In addition, we are aware of product candidates of third parties that are in development, which, if approved, would compete against product candidates for which we intend to seek marketing approval.

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the government is funding the development of new products that could compete with BioThrax, and could eventually procure those new products in addition to, or instead of, BioThrax, potentially reducing our BioThrax revenues. We also face competition for our biodefense immune related biologics product candidates. For example, HHS has awarded a development and SNS procurement contract to a competitor for an anthrax immune globulin therapeutic and is assisting this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that it can immunize donors and obtain plasma for its anthrax immune globulin therapeutic product candidate. HHS has awarded another development and SNS procurement contract to another competitor for a monoclonal antibody to anthrax as a post-exposure therapeutic for anthrax infection. Several companies have botulinum vaccines in early clinical or preclinical development. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the U.S. and Europe. The Aeras Global TB Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine candidates in addition to ours, any of which could present competitive risks. Numerous companies have vaccine candidates in development that would compete with any of our commercial immune related biologics product candidates for which we are seeking to obtain marketing approval.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through competing for government funding and through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs or advantageous to our business.

Legislation and contractual provisions limiting or restricting liability of manufacturers may not be adequate to protect us from all liabilities associated with the manufacture, sale and use of our products.

Provisions of our BioThrax contract with HHS and federal legislation enacted to protect manufacturers of biodefense and anti-terrorism countermeasures may limit our potential liability related to the manufacture, sale and use of BioThrax and our biodefense product candidates. However, these contractual provisions and legislation may not fully protect us from all related liabilities.

The Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005, creates general immunity for manufacturers of biodefense countermeasures, including security countermeasures, when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act 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 not entitled to protection under the PREP Act in cases of willful misconduct. Upon a declaration by the Secretary of HHS, a compensation fund is created to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." 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 and thereby expose us to liability.

In October 2008, the Secretary of HHS issued a PREP Act declaration including BioThrax and our anthrax immune globulin therapeutic vaccine candidate as covered countermeasures. We do not know, however, whether the PREP Act will would provide adequate coverage or survive anticipated legal challenges to its validity.

In August 2006, the Department of Homeland Security approved our application under the Support Anti-Terrorism by Fostering Effective Technology Act, or SAFETY Act, enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the SAFETY Act provides a process by which an anti-terrorism technology may be certified as an "approved product" by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. The government contractor defense, under specified circumstances, extends the sovereign immunity of the U.S. to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product. Although we are entitled to the benefits of the SAFETY Act, it may not provide adequate protection from any claims made against us.

In addition, although our prior contracts with DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contracts with HHS do not contain such indemnification, and we may not be able to negotiate similar indemnification provisions in future contracts. Also, the U.S. government may not honor its indemnification obligations. For example, although we have notified the DoD of the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, the DoD has not yet acted on our claim for indemnification for defense costs associated with those claims.

Members of Congress have proposed and may in the future propose legislation that reduces or eliminates the statutory liability protections for manufacturers of biodefense countermeasures

Product liability lawsuits could cause us to incur substantial liabilities and require us to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. For example, we have been a defendant in lawsuits filed on behalf of military personnel who alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in these lawsuits claimed different injuries and sought varying amounts of damages.

Under our prior BioThrax contracts with the DoD and HHS, the U.S. government indemnified us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under such contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbursement from the DoD for uninsured costs incurred in defending these claims. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts.

If we cannot successfully defend ourselves against future claims that our product or product candidates caused injuries and if we are not entitled to indemnity by the U.S. government, or if the U.S. government does not honor its indemnification obligations, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- withdrawal of a product from the market;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently have product liability insurance for coverage up to a $10 million annual aggregate limit with a deductible of $75,000 per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on statutory protections in addition to insurance to mitigate our liability exposure for BioThrax.

If we are unable to obtain adequate reimbursement from governments or third party payors for any products that we may develop or to obtain acceptable prices for those products, our revenues will suffer.

Our revenues and profits from any products that we successfully develop, other than with respect to sales of our biodefense products under government contracts, will depend heavily upon the availability of adequate reimbursement for the use of such products from governmental and other third party payors, both in the U.S. and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining a determination that a product is covered is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain coverage.

Even when a payor determines that a product is covered, the payor may impose limitations that preclude payment for some uses that are approved by the FDA or comparable authorities but are determined by the payor to not be medically reasonable and necessary. Moreover, eligibility for coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that permits the health care provider to cover its costs of using the product.

We expect that the success of some of our commercial vaccine candidates for which we obtain marketing approval will depend on inclusion of those product candidates in government immunization programs. Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the U.S., pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. Foreign governments also commonly fund pediatric vaccination programs through national health programs. In addition, with respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or non-governmental, charitable or philanthropic organizations fund the cost of vaccines.

Federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs and biologics covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product's "average sales price." This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has added an outpatient prescription drug benefit to Medicare, which went into effect in January 2006. These benefits will be provided primarily through private entities, which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

Certain products we may develop may be eligible for reimbursement under Medicaid. If the state-specific Medicaid programs do not provide adequate coverage and reimbursement for any products we may develop, it may have a negative impact on our operations.

The scope of coverage and payment policies varies among third party private payors, including indemnity insurers, employer group health insurance programs and managed care plans. These third party carriers may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. If third party payors do not provide adequate coverage or reimbursement for any products we may develop, it could have a negative effect on our revenues and results of operations.

Foreign governments tend to impose strict price controls, which may adversely affect our revenues.

In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Legislation has been introduced into Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could adversely affect our operating results and our overall financial condition.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to sustain or expand our BioThrax operations or develop or to commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific personnel. We consider Fuad El-Hibri, chief executive officer and chairman of our Board of Directors and Daniel J. Abdun-Nabi, president and chief operating officer to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. Both of these key employees are at will employees and can terminate their employment at any time. We do not maintain “key person” insurance on any of our employees.

In addition, our growth will require us to hire a significant number of qualified scientific and commercial personnel, including clinical development, regulatory, marketing and sales executives and field sales personnel, as well as additional administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

Additional Risks Related to Sales of Biodefense Products to the U.S. Government

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

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

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

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from doing 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 do business with federal, state and local government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations, 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.

In addition, *qui tam* lawsuits have been brought against us in which the plaintiffs argued that we defrauded the U.S. government by distributing non-compliant doses of BioThrax. Although we ultimately prevailed in this litigation, we spent significant time and money defending the litigation. The states, many municipalities and foreign governments typically also have laws and regulations governing contracts with their respective agencies. These domestic and foreign laws and regulations affect how we and our customers can do 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.

We rely on property and equipment owned by the DoD in the manufacturing process for BioThrax.

We have the right to use certain property and equipment owned by the DoD, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We have the option to purchase all or part of existing GFE from the DoD on terms to be negotiated with the DoD. If the DoD modifies the terms under which we use the GFE in a manner that is unfavorable to us, including substantially increasing the usage fee, or we are unable to reach an agreement with the DoD concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing facility.

Risks Related to Regulatory Approvals

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations and consultants to assist us in this process. Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA to establish the product candidate’s safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have significant side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

In the U.S., BioThrax, our biodefense product candidates and our commercial product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market these product candidates, other than biodefense products purchased by HHS for the SNS, we will be required to submit to the FDA a biologics license application, or BLA. Ordinarily, the FDA requires a sponsor to support a BLA application with substantial evidence of the product's safety and effectiveness in treating the targeted indication based on data derived from adequate and well controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. Because humans are rarely exposed to anthrax or botulinum toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing.

We intend to pursue FDA approval using the FDA animal rule, of BioThrax as a post-exposure prophylaxis, our anthrax immune globulin therapeutic candidate, our botulinum vaccine candidate, our recombinant protective antigen anthrax vaccine, our recombinant anthrax monoclonal antibody therapeutic, and a next generation anthrax vaccine. We cannot guarantee that FDA will permit us to proceed with any of our products or product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, 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.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review for a submitted product application, may cause delays in the approval or rejection of an application. For example, the FDA has recently commented on the proposed protocol for our Phase II clinical trial of our typhoid vaccine candidate currently being conducted in the U.S. that will require a protocol revision and Institutional Review Board, or IRB, approval. A delay resulting from the FDA's requirements could result in delays to the clinical program of our typhoid vaccine candidate.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any immune related biologics product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies, including through inspections of our facilities. As an approved product, BioThrax is subject to these requirements and ongoing review.

These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect manufacturing facilities without a warrant or prior notice at reasonable times and in a reasonable manner.

After we acquired BioThrax and related vaccine manufacturing facilities in Lansing in 1998 from the Michigan Biologic Products Institute, we spent significant amounts of time and money renovating those facilities before the FDA approved a supplement to our manufacturing facility license in December 2001. The State of Michigan had initiated renovations after the FDA issued a notice of intent to revoke the FDA license to manufacture BioThrax in 1997. The notice of intent to revoke cited significant deviations by the Michigan Biologic Products Institute from cGMP requirements, including quality control failures. In March 2007, the FDA notified us that our manufacturing facility license is no longer subject to the notice of intent to revoke.

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004 and May 2006. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in substantial compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure compliance with federal standards and regulations.

The FDA conducted a routine, bi-annual inspection of the Lansing facility in March 2008. Following this inspection, the FDA issued inspectional observations on Form FDA 483. Some of the observations noted on the Form FDA 483 were significant. We have filed with the FDA our responses to the inspectional observations relating to the March 2008 inspection, continue to take corrective action, and are engaged in ongoing dialog with the FDA about the observations and corrective actions. If in connection with this inspection or with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in:

- restrictions on the marketing or manufacturing of a product;
- warning letters;
- withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications;
- voluntary or mandatory product recall;
- fines or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals, including license revocation;
- shut down, or substantial limitations of the operations in, manufacturing facilities;
- refusal to permit the import or export of products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

We may not be able to obtain orphan drug exclusivity for any or all our products. If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our products, we may not be able to have competing products approved by the applicable regulatory authorities for a significant period of time.

If one of our competitors obtains orphan drug exclusivity for an indication for a product that competes with one of the indications for one of our product candidates before we obtain orphan drug designation, and if the competitor’s product is the same drug as ours, the FDA would be prohibited from approving our product candidate for the same orphan indication unless we demonstrate that our product is clinically superior or the FDA determines that the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug. None of our products or product candidates has been designated as orphan drugs and there is no guarantee that FDA will grant such designation in the future. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we may have obtained will not block the approval of that competitive product.

The Fast Track designation for BioThrax as a post-exposure prophylaxis for anthrax infection may not actually lead to a faster development or regulatory review or approval process.

We have obtained a Fast Track designation from the FDA for BioThrax as a post-exposure prophylaxis for anthrax infection. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad.

We intend to have some or all of our products marketed outside the U.S. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our product candidates, we expect that a future collaborator will have responsibility to obtain regulatory approvals outside the U.S., and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval.

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market.

Risks Related to Our Dependence on Third Parties

We may not be successful in maintaining and establishing collaborations, which could adversely affect our ability to develop and commercialize our product candidates domestically and internationally.

For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights for ourselves or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or for accessing particular markets.

If we are unable to reach agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, 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 alternative arrangements. The terms of any collaboration or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, whether we are successful in the development of our meningitis B vaccine candidate will depend in large part on whether Sanofi Pasteur selects one or more viable candidates pursuant to the collaboration for development of a product, which has not yet occurred and may not during the balance of the development program.

The risks that we are subject to in our current collaborations, and anticipate being subject to in future collaborations, include the following:

- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability; or
- our collaborators may decide not to continue to work with us in the development of product candidates.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Such terminations or expirations could adversely affect us financially and could harm our business reputation.

If third parties on whom we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business may suffer.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers to conduct the clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates. In addition, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates.

We expect to rely on data from clinical trials conducted by third parties seeking marketing approval for our product candidates. For example, our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses is based on the interim trial report provided to us by the CDC from its ongoing clinical trial. We currently are awaiting the final data from the CDC trial. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts. In prior years, there has been some uncertainty whether Congress would choose to fund the CDC trial. Although the trial has been funded to date, Congress may not continue to fund the completion of all study reports.

Risks Related to Our Intellectual Property

We may fail to protect our intellectual property rights, which would harm our business.

Our success, particularly with respect to our commercial business, will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property covering or incorporated into our technology and products. The patent situation in the field of immune related biologics and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions.

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, patents generally expire, regardless of their date of issue, 20 years from the earliest claimed non-provisional filing date. As a result, the time required to obtain regulatory approval for a product candidate may consume part or all of the patent term. We are not able to accurately predict the remaining length of the applicable patent term following regulatory approval of any of our product candidates.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties.

For example, under our licenses with HPA relating to our botulinum vaccine candidate, HPA is responsible for prosecuting and maintaining patent rights, although we have the right to support the continued prosecution or maintenance of the patent rights if HPA fails to do so. In addition, we have the first right to pursue claims against third parties for infringement of the patent rights and assume the defense of any infringement claims that may arise.

If we are unable to in-license any intellectual property necessary to develop, manufacture or sell any of our product candidates, we will not be successful in developing or commercializing such product candidate.

We expect that we may need to in-license various components or technologies, including, for example, adjuvants and novel delivery systems, for some of our current or future product candidates. We may be unable to obtain the necessary licenses on acceptable terms, or at all. If we are unable to obtain such licenses, we could be prevented or delayed from continuing further development or from commercially launching the applicable product candidate.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements. For example, we consider our license from the Oxford-Emergent Tuberculosis Consortium Limited to our tuberculosis vaccine candidate to be material to our business. We expect to enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for BioThrax or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, other than the BioThrax trademark, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants and third parties.

These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold licenses or other rights. Third parties may own or control these patents and intellectual property rights in the U.S. and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement or other similar suit were brought against us or our collaborators, we or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement or other similar claims, or to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis' manufacture of the modified vaccinia Ankara virus, or MVA, as a smallpox vaccine for biodefense use by the U.S. government. We have a strain of MVA that we are evaluating as a platform technology and a tuberculosis vaccine candidate that is based on another strain of MVA, both of which are distinct from the Acambis strain. Bavarian Nordic claimed that its patents broadly covered the manufacture of MVA-based biological products and that Bavarian Nordic had rights in the biological materials used by Acambis. That litigation was terminated by a settlement and consent order filed by the parties with the U.S. International Trade Commission, or ITC, in August 2007 and subsequently published in the U.S. Federal Register. According to the published terms of the consent order, Acambis agreed not to import or sell within the U.S. its ACAM 3000 vaccine product, and further agreed not to challenge the validity or enforceability of certain Bavarian Nordic patents. Bavarian Nordic also has filed a lawsuit against Oxford BioMedica PLC, Oxford BioMedica Ltd. and Biomedica Inc., collectively Oxford BioMedica, alleging that Oxford BioMedica has infringed certain Bavarian Nordic U.S. patents by making, using, and importing, and inducing others to use, Oxford BioMedica's experimental drug TroVax® which is an MVA-based therapeutic cancer vaccine. Bavarian Nordic also has filed proceedings against the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StMUGV, in which Bavarian Nordic is challenging StMUGV's ownership rights to the MVA in its possession. We have licensed from StMUGV rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based on these rights. Although Bavarian Nordic has not filed infringment claims against us, they have claimed that StMUGV has committed contributory infringment of Bavarian Nordic's patents by providing StMUGV's MVA to us.

Our ability to use our MVA platform technology, or to develop and manufacture MVA-based products such as our tuberculosis product candidate, could be negatively affected by pending or future patent infringement litigation or other legal actions brought by Bavarian Nordic or other parties challenging our rights to use MVA materials or technology. To protect our interests, we have filed oppositions in the European Patent Office against two of Bavarian Nordic's patents covering certain aspects of the MVA technology. We may also become a party to trademark invalidation and interference proceedings in foreign trademark offices. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Acquisition Strategy

Our strategy of generating growth through acquisitions may not be successful.

We have pursued an acquisition strategy since our inception to build our business of developing, manufacturing and commercializing immune related biologics products. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired our pipeline of commercial vaccine candidates through our acquisition of ViVacs in 2006 and Microscience in 2005 and our acquisition of substantially all of the assets of Antex in 2003.

In the future, we may be unable to license or acquire suitable products or product candidates from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical and biological products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the immune related biologics field. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products and product candidates include the following:

- we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on the product;
- companies that perceive us to be their competitor may be unwilling to assign or license their product rights to us; or
- we may be unable to identify suitable products or product candidates within our areas of expertise.

In addition, we expect competition for acquisition candidates in the immune related biologics field to increase, which may mean fewer suitable acquisition opportunities for us as well as higher acquisition prices. If we are unable to successfully obtain rights to suitable products and product candidates, our business, financial condition and prospects for growth could suffer.

If we fail to successfully manage any acquisitions, our ability to develop our product candidates and expand our product candidate pipeline may be harmed.

As part of our business strategy, we intend to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. The failure to adequately address the financial, operational or legal risks of these transactions could harm our business. Financial aspects of these transactions that could alter our financial position, reported operating results or stock price include:

- use of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; and
- amortization expenses related to other intangible assets.

Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

- challenges associated with managing an increasingly diversified business;
- disruption of our ongoing business;
- difficulty and expense in assimilating the operations, products, technology, information systems or personnel of the acquired company;

- diversion of management's time and attention from other business concerns;
- inability to maintain uniform standards, controls, procedures and policies;
- the assumption of known and unknown liabilities of the acquired company, including intellectual property claims; and
- subsequent loss of key personnel.

If we are unable to successfully manage our acquisitions, our ability to develop new products and continue to expand our product pipeline may be limited.

Risks Related to Our Common Stock

Fuad El-Hibri, chief executive officer and chairman of our Board of Directors, has substantial control over us, including through his ability to control the election of the members of our Board of Directors, and could delay or prevent a change of control.

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests and voting arrangements among our significant stockholders. As of October 31, 2008, Mr. El-Hibri was the beneficial owner of approximately 47% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us.

Provisions of our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management.

These provisions include:

- the classification of our directors;
- limitations on changing the number of directors then in office;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- limitations on the removal and appointment of the chairman of our Board of Directors;
- following November 20, 2008, advance notice requirements for stockholder nominations for election of directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval.

Until November 20, 2008, the affirmative vote of holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. Following November 20, 2008, the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. Until November 20, 2008, the affirmative vote of either at least 75% of the directors then in office or holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws. Following November 20, 2008, the affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, Section 203 of the General Corporation Law of Delaware prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

Our stockholder rights plan could prevent a change in control of us in instances in which some stockholders may believe a change in control is in their best interests.

Under a rights agreement that establishes our stockholder rights plan, we issue to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, will entitle its holder to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price of $150 in cash, subject to adjustments.

Our stockholder rights plan is intended to protect stockholders in the event of an unfair or coercive offer to acquire us and to provide our Board of Directors with adequate time to evaluate unsolicited offers. The rights plan may have anti-takeover effects. The rights plan will cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests and those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through October 31, 2008, our common stock has traded as high as $19.20 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors;
- decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;
- regulatory developments in the U.S. and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

We do not anticipate paying any cash dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, to fund the development and growth of our business. Any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 15.1 million shares of our common stock outstanding as of October 31, 2008 have the right to require us to register these shares of common stock under specified circumstances.

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

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds

On November 20, 2006, we completed an initial public offering of 5,000,000 shares of our common stock pursuant to a registration statement on Form S-1 (File No. 333-136622), which was declared effective by the SEC on November 14, 2006. We received net proceeds from the offering of approximately $54.2 million, after deducting underwriting discounts and commissions and other offering expenses.

Through September 30, 2008, we have used approximately $25.3 million of the net proceeds from the offering to fund development of our product candidates, comprised of $3.7 million for label expansions and improvements for BioThrax, $2.2 million for next generation anthrax vaccine candidates, $5.3 million for our anthrax immune globulin therapeutic candidate, $8.2 million for our typhoid vaccine candidate and $5.9 million for our hepatitis B therapeutic vaccine candidate. Through September 30, 2008, we have used approximately $26.5 million of the net proceeds to fund a portion of the construction, installation, qualification and validation activities costs for our new manufacturing facility in Lansing. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours. We have invested the balance of the net proceeds from the offering in short-term, investment grade, interest-bearing instruments. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

On March 31, 2008, we entered into a Second Amendment to Lease Agreement with ARE-QRS Corp. that extended the term of our lease for the first floor of 300 Professional Drive, Gaithersburg, Maryland until November 30, 2009 and provided us with the right to extend the lease for a period of five additional years after the new termination date.

On June 30, 2008, we entered into a Third Amendment to Lease Agreement with ARE-QRS Corp. that extended the term our lease for the second floor of 300 Professional Drive, Gaithersburg, Maryland until November 30, 2009, provided for a 3% increase in the rent, and provided us with the right to extend the lease for both the first and second floors for a period of five additional years after the new termination date.

ITEM 6. EXHIBITS

The exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits hereto.

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

Date: November 6, 2008

By: /s/ Fuad El-Hibri
Fuad El-Hibri
Chief Executive Officer and
Chairman of the Board of Directors (Principal Executive Officer)

Date: November 6, 2008

By: /s/R. Don Elsey
R. Don Elsey
Sr. Vice President Finance, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX Exhibit

Number	Description
10.1	Second Amendment to Lease Agreement between ARE-QRS Corp. and Emergent Product Development Gaithersburg Inc. dated as of March 31, 2008
10.2	Third Amendment to Lease Agreement between ARE-QRS Corp. and Emergent Product Development Gaithersburg Inc. dated as of June 30, 2008
10.3	Amendment to Loan Agreement between Emergent BioDefense Operations Lansing, Inc. and Fifth Third Bank dated August 15, 2008.
10.4	Revolving Credit Note made by Emergent BioDefense Operations Lansing, Inc. in favor of Fifth Third Bank dated August 15, 2008.
10.5*	Exclusive Commercial License of Technology by and among Oxford-Emergent Tuberculosis Consortium Limited, Emergent Product Development UK Limited, Emergent BioSolutions Inc. and Isis Innovation Limited dated July 18, 2008.
10.6*	Contract No. HHS0100200800091C between the Department of Health and Human Services and Emergent BioDefense Operations Lansing Inc. dated September 30, 2008.
31.1	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Confidential treatment requested. Confidential materials omitted and filed separetly with the Securities and Exchange Commission.

EXHIBIT 10.1

SECOND AMENDMENT TO LEASE AGREEMENT

THIS SECOND AMENDMENT TO LEASE AGREEMENT ("**this Second Amendment**") is made as of March 31, 2008, by and between **ARE-QRS CORP.**, a Maryland corporation, having an address at 385 E. Colorado Blvd., Suite 299, Pasadena, California 91101 ("**Landlord**"), and **EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.**, formerly known as Emergent Immunosolutions Inc. and as successor in interest to Antex Biologics, Inc., a Delaware corporation, having an address at Suite 100, 300 Professional Drive, Gaithersburg, Maryland 20879 ("**Tenant**").

RECITALS

A. Landlord and Tenant have entered into that certain Lease ("**Original Lease**") dated as of December 1, 1998, as amended by a First Amendment to Lease dated as of September 30, 2004 ("**First Amendment**"; the Original Lease and the First Amendment are hereinafter collectively referred to as the "**Lease**"), wherein Landlord leased to Tenant certain premises ("**Premises**") located at 300 Professional Drive, Gaithersburg, Maryland 20879, as more particularly described in the Lease.

B. The Lease expires on November 30, 2008. Tenant desires to extend the term of the Lease for a period of 1 year so that it will expire on November 30, 2009, and Landlord is willing to extend the term of the Lease on the terms herein set forth.

AGREEMENT

NOW, THEREFORE, the parties hereto agree that the Lease is amended as follows:

1. **Extension of Term**. Effective as of the date hereof, the definition of Term Expiration Date in Section 2.1.7(c) of the Lease is hereby amended by deleting that definition in its entirety and replacing it with the following new definition:

(c) **Term Expiration Date**: November 30, 2009, subject to extension as set forth in Section 41 or to earlier termination as otherwise provided herein.

2. **Tenant Notices**. Effective as of the date hereof, Section 2.1.11 of the Lease is hereby deleted in its entirety and replaced with the following new Section 2.1.11:

2.1.11 Address for Notices to Tenant:
300 Professional Drive, Suite 100
Gaithersburg, MD 20879
Attention: Terry Boykin

With a copy to:

Emergent BioSolutions Inc.
c/o Denise Esposito
2773 Research Blvd., Suite 400
Rockville, MD 20850

3. **Improvement Rent**. Effective as of the date hereof, Section 5.3 of the Lease is hereby deleted in its entirety.

4. **Rent Credit**. Effective as of the date hereof, Section 5.4 of the Lease is hereby amended by deleting and replacing the reference to "120" therein with "132". All remaining terms of Section 5.4 shall

remain unchanged.

5. **Extension Right**. Effective as of the date hereof, Section 41 the Lease is hereby deleted in its entirety and replaced with the following new Section 41:

41. **Extension Right**. Tenant shall have the right ("**Extension Right**") to extend the term of this Lease for 5 years ("**Extension Term**") on the same terms and conditions as this Lease (other than Basic Annual Rent). Upon the commencement of the Extension Term, Basic Annual Rent shall be an amount equal to the product of $23.75 per rentable square foot multiplied by the rentable square footage of the Premises, and thereafter shall be adjusted on each anniversary of the commencement of the Extension Term by 3%. No Improvement Rent shall be payable by Tenant during the Extension Term.

41.1 Personal Right. The Extension Right is personal to Emergent Immunosolutions, Inc. and is not assignable separate and apart from this Lease.

41.2 Notice. The Extension Right is conditional on Tenant giving Landlord written notice of Tenant's election to exercise the Extension Right at least 9 months prior to the expiration of the initial Term (i.e., the initial Term expires on November 30, 2009).

41.3 Defaults. Notwithstanding anything set forth above to the contrary, the Extension Right shall not be in effect and Tenant may not exercise the Extension Right (a) during any period of time that Tenant is in default under any provision of this Lease that is monetary in nature; or (b) if Tenant has been in default under any provision of this Lease 3 or more times, regardless of whether the defaults are cured, during the 12 month period immediately prior to the date that Tenant intends to exercise the Extension Right.

41.4 Default After Exercise. The Extension Right shall terminate and be of no further force or effect even after Tenant's due and timely exercise of the Extension Right, if, after such exercise, but prior to the commencement date of an Extension Term, (a) Tenant fails to timely cure any default by Tenant under this Lease; or (b) Tenant has defaulted 3 or more times during the period from the date of the exercise of the Extension Right to the date of the commencement of the Extension Term, regardless of whether such defaults are cured.

6. **Miscellaneous**.

6.1 Entire Agreement. This Second Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Second Amendment may be amended only by an agreement in writing, signed by the parties hereto.

6.2 Binding Effect. This Second Amendment is binding on and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

6.3 Counterparts. This Second Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument. The signature page of any counterpart may be detached therefrom without impairing the legal effect of the signature(s) thereon provided such signature page is attached to any other counterpart identical thereto except having additional signature pages executed by other parties to this Second Amendment attached thereto.

6.4 Reaffirmation. Except as amended and/or modified by this Second Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Second Amendment except as necessary to give effect to this Section. In the event of any conflict between the provisions of this Second Amendment and the provisions of the Lease, the provisions of this Second Amendment shall prevail. Regardless of whether specifically amended by this Second Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Second Amendment.

6.5 Broker. Landlord and Tenant each represent and warrant that it has not dealt with any broker, agent, or other person (collectively "**Broker**") in connection with this transaction, and that no Broker brought about this transaction. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

[SIGNATURES APPEAR ON NEXT PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Second Amendment as of the day and year first above written.

TENANT:

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.,
a Delaware corporation

By: /s/Daniel J. Abdun-Nabi
Name: Daniel J. Abdun-Nabi
Title: Secretary

LANDLORD:

ARE-QRS CORP.,
a Maryland corporation

By: /s/Jackie Clem
Name:Jackie Clem
Title:VP RE Legal Affaris

EXHIBIT 10.2

THIRD AMENDMENT TO LEASE AGREEMENT

THIS THIRD AMENDMENT TO LEASE AGREEMENT ("**this Third Amendment**") is made as of June 30, 2008, by and between **ARE-QRS CORP.**, a Maryland corporation, having an address at 385 E. Colorado Blvd., Suite 299, Pasadena, California 91101 ("**Landlord**"), and **EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.**, formerly known as Emergent Immunosolutions Inc. and as successor in interest to Antex Biologics, Inc., a Delaware corporation, having an address at Suite 100, 300 Professional Drive, Gaithersburg, Maryland 20879 ("**Tenant**").

RECITALS

A. Landlord and Tenant have entered into that certain Lease ("**Original Lease**") dated as of December 1, 1998, as amended by a First Amendment to Lease dated as of September 30, 2004 ("**First Amendment**"), and a Second Amendment to Lease dated as of March 31, 2008 ("**Second Amendment**"; the Original Lease, the First Amendment, and the Second Amendment are hereinafter collectively referred to as the "**Lease**"), wherein Landlord leased to Tenant certain premises ("**Premises**") located at 300 Professional Drive, Gaithersburg, Maryland 20879, as more particularly described herein and in the Lease. The Premises contain approximately 24,164 rentable square feet on the 1st floor of the Building ("**First Floor Space**") and approximately 12,252 rentable square feet comprising the Expansion Space located on the 2nd floor of the Building.

B. Landlord and Tenant intended that the Second Amendment apply only to the First Floor Space and not to the Expansion Space. As a result, that portion of the Lease applicable to the Expansion Space expires on November 30, 2008. Tenant now desires to extend the term of the Lease applicable to the Expansion Space for a period of 1 year so that it will expire on November 30, 2009, the expiration date of that portion of the Lease applicable to the First Floor Space. Thus, the expiration date for the entire Premises will be November 30, 2009. Landlord is willing to so extend the term of the Lease applicable to the Expansion Space on the terms herein set forth.

AGREEMENT

NOW, THEREFORE, the parties hereto agree that the Lease is amended as follows:

1. **Extension of Term**. Effective as of the date hereof, the definition of Term Expiration Date in Section 2.1.7(c) of the Lease is hereby amended by deleting that definition in its entirety and replacing it with the following new definition so that the Term Expiration Date for the entire Premises (i.e., the First Floor Space and the Expansion Space) will occur on November 30, 2009:

> (c) **Term Expiration Date**: November 30, 2009, subject to extension as set forth in Section 41.

2. **Increase in Expansion Space Base Rent**. The Expansion Space Base Rent shall increase by the amount set forth in Section 6 of the Lease (i.e., 3%) for the period December 1, 2008 to November 30, 2009.

3. **Extension Right**. Effective as of the date hereof, Section 41 the Lease (as amended by the First Amendment and the Second Amendment) is hereby deleted in its entirety and replaced with the following new Section 41:

> 41. **Extension Right**. Tenant shall have the right ("**Extension Right**") to extend the term of this Lease for 5 years ("**Extension Term**") for the entire Premises only on the

same terms and conditions as this Lease (including, but not limited to, the 3% annual increases in Basic Annual Rent and the Expansion Space Base Rent pursuant to Section 6 of this Lease). No Improvement Rent shall be payable by Tenant during the Extension Term.

41.1 Personal Right. The Extension Right is personal to Emergent Product Development Gaithersburg, Inc. and is not assignable separate and apart from this Lease.

41.2 Notice. The Extension Right is conditional on Tenant giving Landlord written notice of Tenant's election to exercise the Extension Right at least 9 months prior to the expiration of the initial Term (i.e., the initial Term expires on November 30, 2009).

41.3 Defaults. Notwithstanding anything set forth above to the contrary, the Extension Right shall not be in effect and Tenant may not exercise the Extension Right (a) during any period of time that Tenant is in default under any provision of this Lease that is monetary in nature; or (b) if Tenant has been in default under any provision of this Lease 3 or more times, regardless of whether the defaults are cured, during the 12 month period immediately prior to the date that Tenant intends to exercise the Extension Right.

41.4 Default After Exercise. The Extension Right shall terminate and be of no further force or effect even after Tenant's due and timely exercise of the Extension Right, if, after such exercise, but prior to the commencement date of an Extension Term, (a) Tenant fails to timely cure any default by Tenant under this Lease; or (b) Tenant has defaulted 3 or more times during the period from the date of the exercise of the Extension Right to the date of the commencement of the Extension Term, regardless of whether such defaults are cured.

4. **Miscellaneous**.

4.1 Entire Agreement; Capitalized Terms. This Third Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Third Amendment may be amended only by an agreement in writing, signed by the parties hereto. The use of initially capitalized terms in this Third Amendment or terms otherwise defined in the Lease shall have the meaning ascribed to them in the Lease unless the context requires otherwise.

4.2 Binding Effect. This Third Amendment is binding on and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.

4.3 Counterparts. This Third Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument. The signature page of any counterpart may be detached therefrom without impairing the legal effect of the signature(s) thereon provided such signature page is attached to any other counterpart identical thereto except having additional signature pages executed by other parties to this Third Amendment attached thereto.

4.4 Reaffirmation. Except as amended and/or modified by this Third Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Third Amendment except as necessary to give effect to this Section. In the event of any conflict between the provisions of this Third Amendment and the provisions of the Lease, the provisions of this Third Amendment shall prevail. Regardless of whether specifically amended by this Third Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Third Amendment.

4.5 Broker. Landlord and Tenant each represent and warrant that it has not dealt with any broker, agent, or other person (collectively "**Broker**") in connection with this transaction, and that no Broker brought about this transaction. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

[SIGNATURES APPEAR ON NEXT PAGE]

BA3395193.1

IN WITNESS WHEREOF, the parties hereto have executed this Third Amendment as of the day and year first above written.

TENANT:

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG, INC.,
a Delaware corporation

By:/s/R. Don Elsey
Name:R. Don Elsey
Title:Treasurer

LANDLORD:

ARE-QRS CORP.,
a Maryland corporation

By: /s/Jackie Clem
Name:Jackie Clem
Title: VP RE Legal Affairs

BA3395193.1

EXHIBIT 10.3

AMENDMENT TO LOAN AGREEMENT

THIS AMENDMENT TO LOAN AGREEMENT is made as of August 15, 2008, by and between **EMERGENT BIODEFENSE OPERATIONS LANSING INC.**, a Michigan corporation, of Lansing, Michigan ("**Borrower**"), and **FIFTH THIRD BANK**, a Michigan banking corporation, having an office in Grand Rapids, Michigan ("**Lender**").

Borrower and Lender are parties to a Loan Agreement dated June 8, 2007, under which Lender extended to Borrower a revolving line of credit ("**Agreement**"). They want to amend the Agreement.

Borrower and Lender agree as follows:

1. *Section 1* of the Agreement is amended, effectively immediately, by adding to it the following definitions:

"**Credit Termination Date**" means June 1, 2009.

"**Letter of Credit**" has the meaning specified in *Section 3.1* of this Agreement.

"**Letter of Credit Commitment**" means $1,000,000.

2. Effective immediately, *Section 3* of the Agreement is amended in its entirety to read as follows:

SECTION 3. REVOLVING LINE OF CREDIT.

3.1 Subject to satisfaction of the conditions precedent set forth in *Section 10* of this Agreement, and as long as there shall not have occurred a Default or Event of Default, Lender shall extend to Borrower from time to time loans ("**Revolving Credit Loans**") and shall issue Letters of Credit for the account of Borrower ("**Letters of Credit**"), in amounts that shall not at any time in the aggregate, for all Revolving Credit Loans and Letters of Credit outstanding at any time, exceed the Revolving Credit Commitment.

3.2 If the aggregate principal amount of the Revolving Credit Loans and Letters of Credit outstanding at any time exceeds the Revolving Credit Commitment, then Borrower shall immediately take whatever action is required to eliminate the excess.

3.3 If the aggregate principal amount of Letters of Credit outstanding at any time exceeds the Letter of Credit Commitment, then Borrower shall immediately take whatever action is required to eliminate the excess.

3.4 All Revolving Credit Loans shall be evidenced by and payable with interest in accordance with the terms of the promissory note in the form of **Schedule One** ("**Revolving Credit Note**"), which Borrower shall sign and deliver to Lender.

3.5 Each Revolving Credit Loan shall be made upon Borrower's request, subject to the requirements of this *Section 3*.

3.6 Borrower shall have the right to prepay all Revolving Credit Loans, in whole or in part, at any time without penalty. Borrower may reborrow amounts that it prepays, subject to the other provisions of this Agreement.

3.7 Unless it is sooner terminated under *Section 9* of this Agreement or Lender extends it in writing, Lender's obligation to make or to renew Revolving Credit Loans and to issue Letters of Credit shall expire on the Credit Termination Date. If Lender extends it, then Lender's obligation to make or to renew Revolving Credit Loans and to issue Letters of Credit shall expire on the date stated in the extension. If Lender's obligation to make or to renew Revolving Credit Loans and to issue Letters of Credit expires, then the aggregate unpaid principal balance of all outstanding Revolving Credit Loans, together with all interest accrued on them, shall be payable in full on the expiration date.

3.8 Each Letter of Credit shall be issued by Lender only in accordance with, and subject to the limitations set forth in, this *Section 3.8*.

(a) Lender shall not be obligated to issue a Letter of Credit if the sum of the amount of the Letter of Credit, all other outstanding Letters of Credit and all outstanding Revolving Credit Loans would exceed the Revolving Credit Commitment.

(b) Lender shall not be obligated to issue a Letter of Credit if the sum of the amount of the Letter of Credit and the aggregate principal amount of all then-outstanding Revolving Credit Loans and Letters of Credit would exceed the Letter of Credit Commitment.

(c) Lender shall not issue a Letter of Credit that has an expiration date later than 364 days after the Credit Termination Date.

(d) No later than 10:00 a.m. (Grand Rapids, Michigan time) on the third (3^{rd}) business day before the proposed date of issuance of a Letter of Credit, Borrower shall deliver to Lender (1) if the Letter of Credit is to be a standby letter of credit, Lender's standard standby letter of credit application, (2) if the Letter of Credit is to be a commercial letter of credit, Lender's standard commercial letter of credit application and (3) in either case, Lender's standard letter of credit reimbursement agreement ("**Reimbursement Agreement**"), in each case properly completed and signed by Borrower.

(e) As and when required by the applicable Reimbursement Agreement, Borrower shall reimburse to Lender the amount of each drawing made pursuant to a Letter of Credit ("**Reimbursement Payment**"). If Borrower fails at any time to make a Reimbursement Payment, then Borrower shall, without notice, be deemed to have elected to have borrowed a Revolving Credit Loan from Lender in the amount of the Reimbursement Payment, as of the date of the drawing. Each of such Revolving Credit Loans shall bear interest at the rate of interest provided in Revolving Credit Note.

(f) For each Letter of Credit issued, Borrowers shall pay to Lender the fees provided for in the applicable Reimbursement Agreement.

3. Effective immediately, *Section 7* of the Agreement is amended in its entirety to read as follows:

Borrower shall use the proceeds of the Revolving Credit Loans to pay existing indebtedness, to finance Lender's issuance of Letters of Credit on behalf of Borrower and for working capital.

4. Effective immediately, each reference in the Agreement, as amended, to "Revolving Credit Note" shall be considered to refer to the Revolving Credit Note executed and delivered by Borrower on or about the date of this Amendment, in the form attached to this Amendment as **Schedule One**.

5. Simultaneously with the execution and delivery of this Amendment, Borrower shall pay to Lender a fee in the amount of $500.

6. Except as expressly amended by this Amendment, all of the provisions of the Agreement are ratified and confirmed.

Borrower and Lender have signed this Amendment to Loan Agreement as of the date specified above.

EMERGENT BIODEFENSE OPERATIONS LANSING INC.

By: /s/R. Don Elsey

Its Treasurer

FIFTH THIRD BANK

By /s/Leo Tierney

Its Vice President

SCHEDULE ONE

REVOLVING CREDIT NOTE

Lansing, Michigan
$15,000,000 August 15, 2008

FOR VALUE RECEIVED, the undersigned **EMERGENT BIODEFENSE OPERATIONS LANSING INC.**, a Michigan corporation, of Lansing, Michigan ("**Borrower**"), promises to pay to the order of **FIFTH THIRD BANK**, a Michigan banking corporation, ("**Lender**"), at its office in Grand Rapids, Michigan, or at any other place that the holder of this Note designates in writing, the sum of Fifteen Million Dollars ($15,000,000) or any lesser amount that Lender shall have loaned to Borrower under *Section 3* of a certain Loan Agreement dated June 8, 2007, between Borrower and Lender ("**Loan Agreement**"), together with interest (computed on the basis of a three hundred sixty (360) day year for the actual number of days elapsed) on the unpaid balance at an annual rate equal to the LIBOR Index Rate plus 2% (200 basis points) until maturity and after maturity at an annual rate equal to the LIBOR Index Rate plus 4% (400 basis points). Any change in the interest rate on this Note that is occasioned by a change in the LIBOR Index Rate shall be effective on the first day of the month immediately following the month in which the change in the LIBOR Index Rate occurred.

"**LIBOR Index Rate**" means the fluctuating rate per annum that Lender designates from time to time as being its "one Month LIBOR Index Rate." Borrower acknowledges that the LIBOR Index Rate is not necessarily (1) the lowest rate of interest or the only "LIBOR" denominated interest rate then available from Lender or (2) calculated in the same manner as any other "LIBOR" denominated interest rate offered by Lender. Borrower further acknowledges that the LIBOR Index Rate is not necessarily calculated in the same manner as any other "LIBOR" denominated interest rate offered by any other bank or published by any publication. Lender will inform Borrower of the current LIBOR Index Rate upon request. Borrower acknowledges that Lender may make loans based on other indexes or rates as well. Any change in the interest rate on this Note that is occasioned by a change in the LIBOR Index Rate shall be effective on the day of the change in the LIBOR Index Rate.

The interest on this Note shall be payable monthly beginning September 1, 2008, and continuing on the first day of each succeeding month until the principal is paid in full. The principal of this Note shall be payable as provided in *Section 3* of the Loan Agreement.

Borrower authorizes Lender to debit deposit account No. 71654210, which Borrower maintains with Lender, for interest payments that are due to Lender under this Note. If Borrower does not make a payment of interest within ten days after it is due, then Borrower shall immediately pay to Lender a late charge in an amount equal to the greater of Fifty Dollars ($50) or five percent (5%) of the amount of the late payment. This is in addition to Lender's other rights and remedies for default in payment of interest when due.

This Note evidences Borrower's indebtedness to Lender by reason of loans made and to be made from time to time under *Section 3* of the Loan Agreement ("**Loans**"). Lender's records shall be prima facie evidence of all loans and prepayments and of the indebtedness outstanding under this Note at any time. The holder of this Note shall have all of the rights and powers set forth in the Loan Agreement as though they were fully set forth in this Note.

Reference is made to the Loan Agreement for a statement of the conditions under which the principal of this Note and accrued interest may become immediately due and payable without demand.

In this Note, "**maturity**" means the time when the entire remaining unpaid principal balance of this Note is or becomes immediately due and payable.

Except as otherwise provided in the Loan Agreement, the undersigned waives protest, presentment, demand and notice of nonpayment.

ATTEST:

EMERGENT BIODEFENSE OPERATIONS LANSING INC.

/s/Leo Tierney

By: /s/R. Don Elsey

Its Vice President

Its Treasurer

EXHIBIT 10.4

REVOLVING CREDIT NOTE

Lansing, Michigan
$15,000,000 August 15, 2008

FOR VALUE RECEIVED, the undersigned **EMERGENT BIODEFENSE OPERATIONS LANSING INC.**, a Michigan corporation, of Lansing, Michigan ("**Borrower**"), promises to pay to the order of **FIFTH THIRD BANK**, a Michigan banking corporation, ("**Lender**"), at its office in Grand Rapids, Michigan, or at any other place that the holder of this Note designates in writing, the sum of Fifteen Million Dollars ($15,000,000) or any lesser amount that Lender shall have loaned to Borrower under *Section 3* of a certain Loan Agreement dated June 8, 2007, between Borrower and Lender ("**Loan Agreement**"), together with interest (computed on the basis of a three hundred sixty (360) day year for the actual number of days elapsed) on the unpaid balance at an annual rate equal to the LIBOR Index Rate plus 2% (200 basis points) until maturity and after maturity at an annual rate equal to the LIBOR Index Rate plus 4% (400 basis points). Any change in the interest rate on this Note that is occasioned by a change in the LIBOR Index Rate shall be effective on the first day of the month immediately following the month in which the change in the LIBOR Index Rate occurred.

"**LIBOR Index Rate**" means the fluctuating rate per annum that Lender designates from time to time as being its "one Month LIBOR Index Rate." Borrower acknowledges that the LIBOR Index Rate is not necessarily (1) the lowest rate of interest or the only "LIBOR" denominated interest rate then available from Lender or (2) calculated in the same manner as any other "LIBOR" denominated interest rate offered by Lender. Borrower further acknowledges that the LIBOR Index Rate is not necessarily calculated in the same manner as any other "LIBOR" denominated interest rate offered by any other bank or published by any publication. Lender will inform Borrower of the current LIBOR Index Rate upon request. Borrower acknowledges that Lender may make loans based on other indexes or rates as well. Any change in the interest rate on this Note that is occasioned by a change in the LIBOR Index Rate shall be effective on the day of the change in the LIBOR Index Rate.

The interest on this Note shall be payable monthly beginning September 1, 2008, and continuing on the first day of each succeeding month until the principal is paid in full. The principal of this Note shall be payable as provided in *Section 3* of the Loan Agreement.

Borrower authorizes Lender to debit deposit account No. 71654210, which Borrower maintains with Lender, for interest payments that are due to Lender under this Note. If Borrower does not make a payment of interest within ten days after it is due, then Borrower shall immediately pay to Lender a late charge in an amount equal to the greater of

Fifty Dollars ($50) or five percent (5%) of the amount of the late payment. This is in addition to Lender's other rights and remedies for default in payment of interest when due.

This Note evidences Borrower's indebtedness to Lender by reason of loans made and to be made from time to time under *Section 3* of the Loan Agreement ("**Loans**"). Lender's records shall be prima facie evidence of all loans and prepayments and of the indebtedness outstanding under this Note at any time. The holder of this Note shall have all of the rights and powers set forth in the Loan Agreement as though they were fully set forth in this Note.

Reference is made to the Loan Agreement for a statement of the conditions under which the principal of this Note and accrued interest may become immediately due and payable without demand.

In this Note, "**maturity**" means the time when the entire remaining unpaid principal balance of this Note is or becomes immediately due and payable.

Except as otherwise provided in the Loan Agreement, the undersigned waives protest, presentment, demand and notice of nonpayment.

ATTEST:	**EMERGENT BIODEFENSE OPERATIONS LANSING INC.**
/s/Leo Tierney	By /s/R. Don Elsey
Its Vice President	Its Treasurer

EXHIBIT 10.5

Confidential Materials omitted and filed with the
Securities and Exchange Commission. Asterisks denote omissions.

DATED July 18, 2008

(1) BADHUL LIMITED
to be renamed
OXFORD-EMERGENT TUBERCULOSIS CONSORTIUM LIMITED

And

(2) EMERGENT PRODUCT DEVELOPMENT UK LIMITED

And

(3) EMERGENT BIOSOLUTIONS INC.

And

(4) ISIS INNOVATION LIMITED

EXCLUSIVE COMMERCIAL LICENCE OF TECHNOLOGY

(ISIS PROJECT No. 2382)

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THIS AGREEMENT is made on 2008 (the "**Effective Date**")

BETWEEN:

(1) **BADHUL LIMITED** to be renamed **OXFORD-EMERGENT TUBERCULOSIS CONSORTIUM LIMITED (Company No. 6631227)** whose registered office is at 9400 Garsington Road, Oxford Business Park, Oxford OX4 2HN **(the " Company ")**;

(2) **EMERGENT PRODUCT DEVELOPMENT UK LIMITED** (Company No. 032070465) whose registered office is at 545 Eskdale Road, Winnersh, Wokingham, Berkshire RG41 5TU, England, United Kingdom ("**Emergent**");

(3) **EMERGENT BIOSOLUTIONS INC.**, a Delaware corporation with a place of business at 2273 Research Boulevard, Suite 400, Rockville, MD 20850, United States of America ("**Emergent Parent**"); and

(4) **ISIS INNOVATION LIMITED** (Company No. 2199542) whose registered office is at University Offices, Wellington Square, Oxford OX1 2JD, England ("**Isis**").

BACKGROUND:

A. Emergent and the University have established the Company as a joint venture company pursuant to a subscription and shareholders' agreement of even date herewith (the "**SSA**") for the purpose of developing and commercialising one or more vaccines incorporating MVA85A (or any improvements thereto) against *Mycobacterium tuberculosis* disease in humans, whether or not in combination with one or more other vaccines, against other diseases in humans.

B. Isis is a wholly owned subsidiary of the University and the University has assigned its rights in certain technology and data to Isis.

C. Isis has granted the Company a licence to certain technology and data pursuant to the Isis Licence Agreement and has given its consent to the Company to grant a sub-licence under such technology and data to Emergent.

D. The Company wishes to license the Licensed Technology and the Company Data and Emergent wishes to acquire a licence to the Licensed Technology and the Company Data, on the terms of this agreement.

E. Emergent Parent is the holding company of Emergent and joins this agreement solely for the purpose of agreeing to the payment obligation set forth in clause 17.

F. Isis joins this agreement solely for the purposes of agreeing to the obligations in, and receiving the benefit from, clauses 2.3, 13 and 19.6.

AGREEMENT:

1 Interpretation

1.1 Words and expressions used in this agreement have the meanings set out in schedule 1.

1.2 The provisions relating to interpretation set out in schedule 1 shall apply to this agreement.

1.3 Unless the context otherwise requires, any reference in this agreement to the Licensed Product is to each and every Licensed Product independently of each other.

1.4 If there is any inconsistency between the main body of this agreement and any schedule, the main body of this agreement shall prevail.

2 Grant of Licence

2.1 The Company grants to Emergent a licence under the Licensed Technology to:

2.1.1 undertake research with a view to Developing Licensed Products and Combination Products for use in the Field;

2.1.2 Develop and have Developed Licensed Products and Combination Products for use in the Field;

2.1.3 apply for, obtain and maintain Regulatory Approvals (other than Marketing Authorisations) for Licensed Products and Combination Products for use in the Field;

2.1.4 Manufacture, have Manufactured and otherwise make and have made, use and have used Licensed Products and Combination Products for use in the Field;

2.1.5 apply for, obtain and maintain Marketing Authorisations for Licensed Products and Combination Products in the Field in the Territory; and

2.1.6 Market Licensed Products and Combination Products in the Field in the Territory.

The licences in clauses 2.1.1, 2.1.2 and 2.1.3 are co-exclusive with the Company and the licences in clauses 2.1.4, 2.1.5 and 2.1.6 are, subject to clauses 2.9 and 2.11, exclusive.

2.2 In addition to the rights granted pursuant to clause 2.1, the Company grants to Emergent a royalty-free, non-exclusive perpetual, irrevocable, worldwide licence (with the right to grant sub-licences without consent of, or accounting to, the Company) to use the Emergent ODP Technology and Company Manufacturing Technology in any field for any purpose and to access, reference and otherwise use and reproduce any Company New Data generated by any Emergent Company jointly with others, for any purpose.

2.3 The Company grants to Emergent a licence to access, reference and otherwise use and reproduce the Company Data and the Company Regulatory Documents for the purposes set out in clause 2.1. Subject to clauses 2.9 and 2.11, the licence in this clause 2.3 is co-exclusive with the Company for the purposes set out in clauses 2.1.1, 2.1.2 and 2.1.3, and exclusive for the purposes set out in clauses 2.1.4, 2.1.5 and 2.1.6, in each case other than in respect of the data detailed in schedule 4, part B, which is licensed on a non-exclusive basis. Isis will use its Efforts to obtain Control of the data, protocols, standard operating procedures and written documentation relating to trial TB012 (the "**TB012 Data**") and trial GM920 (the "**GM920 Data**") such that such data, protocols, standard operating procedures and written documentation may be licensed to the Company and, through the Company, to Emergent as Company Existing Data. The Company shall notify Emergent when it obtains such Control and such notice shall include details of whether TB012 Data and the GM920 Data should be included in part A or part B of schedule 4 and such schedule shall be deemed to be updated accordingly.

2.4 The Parties anticipate collaborating with each other and with Aeras to establish Correlates. If either Party establishes a Correlate whether solely or jointly with the other Party or Third Parties, then whether or not patentable:

2.4.1 that Party will provide the other Party with details of, and a perpetual, non-exclusive right to use and to permit others to use, any rights it has in, any Correlate; and

2.4.2 where the Correlate was established by the collaboration of the Parties with each other or with Aeras the Parties will, and will use their Efforts to procure that Aeras (and their or its sub contractors) will, comply with the provisions of clause 3.7 on publication.

2.5 As soon as is reasonably possible after the Effective Date and in any event within thirty (30) days of the Effective Date (or, with respect to the Documents, sixty (60) days of the Effective Date), the Company will:

2.5.1 at the Company's cost, supply Emergent with the Documents and the Existing Data;

2.5.2 transfer or cause to be transferred to Emergent or its designee the reports from IDT to the University regarding process development forming part of the Company Manufacturing Technology; and

2.5.3 use Efforts, at Emergent's cost, to commence the process to transfer the OMP Designation to Emergent.

2.6 Emergent may grant sub-licences under clauses 2.1 and 2.3 in accordance with this agreement through multiple tiers with the Company's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed; provided that, subject to clause 5.14, Emergent may, without the prior consent of the Company, grant sub-licences under clauses 2.1 and 2.3 to (i) sub-contractors appointed to undertake activities under the Overall Development Plan if and to the extent that such sub-licence is required to enable the sub-contractor to provide such services and does not include any right to Market any Licensed Product or Combination Product on its own account; and (ii) other Emergent Companies. Emergent may grant sub-licences under clause 2.2 through multiple tiers without the Company's prior written consent. Emergent shall be entitled to perform any of its obligations under this agreement through Emergent Companies, sub-licensees and sub-contractors.

2.7 Subject only to termination by the Company in accordance with clauses 19.2 (Emergent's insolvency) or 19.4 (Emergent's breach) or by Emergent in accordance with clauses 19.3.1 (termination without cause), 19.3.3 (unsuccessful clinical trial) or 19.3.4 (safety concerns), the Licence is perpetual and irrevocable. The licence granted under clause 2.2 shall survive expiration or termination of this agreement for any reason with respect to Company Manufacturing Technology, Emergent ODP Technology and Company New Data conceived, discovered, developed or otherwise made prior to the Termination Date.

2.8 To the extent not previously disclosed to Emergent, within fifteen (15) Business Days of it being disclosed to the Company, the Company shall disclose and supply to Emergent all Company New Data, Licensed Technology and Company Regulatory Documents arising or generated after the Effective Date.

2.9 During the Term, the Company undertakes that it shall not except as expressly permitted by this agreement, grant or agree to grant any rights in the Licensed Technology, the Company Data or the Company Regulatory Documents in the Field; or assign, mortgage, charge or otherwise encumber or transfer any of the same; or disclose any Confidential Information contained therein; provided that the Company retains the right to:

2.9.1 use and sub-license Third Parties (with Emergent's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed), to use the Licensed Technology, the Company Data and the Company Regulatory Documents to develop the Manufacturing Process;

2.9.2 sub-license Isis (and through Isis, the University) to use the Licensed Technology, the Company Data and the Company Regulatory Documents for Non-Commercial Use in accordance with the Isis Licence Agreement;

2.9.3 enter into the Aeras Agreement; and

2.9.4 grant, if Emergent is unable or unwilling to supply Licensed Product or Licensor Combination Product to the University for use in Phase I Clinical Trials to be conducted by the University and notified to Emergent in accordance with clause 6.7, a non-exclusive, royalty-free licence under the Company Manufacturing Technology to a Third Party approved by Emergent (such approval not to be unreasonably withheld, conditional or delayed) to the extent necessary to enable that Third Party to Manufacture the required supplies of such Licensed Product or Licensor Combination Product for such Phase I Clinical Trial; provided that the Company shall procure that such Third Party shall keep the Company Manufacturing Technology confidential and shall not use it for any other purpose.

2.10 The Parties acknowledge that additional licences from Third Parties may be necessary to Exploit Licensed Products and Combination Products and, except as otherwise agreed, the Company shall be responsible for obtaining such licences. For the avoidance of doubt, if Emergent obtains any licence from a Third Party that is necessary to Exploit Licensed Products and Combination Products (if, and in the form, Developed or being Developed under the Overall Development Plan), in the Field, Emergent shall grant the Company a sub-licence for such purpose, subject to reimbursement of any royalties or other fees that Emergent is required to pay to such Third Party pursuant to such sub-licence.

2.11 If the Company requests Emergent to Manufacture Licensor Combination Product and such Manufacture requires access to or use of Manufacturing Technology or other Intellectual Property Rights Controlled by the University, Isis or the Company, the Company shall procure that Emergent is granted such access and licence for the sole purpose of Manufacturing such Licensor Combination Product for supply to the University or Company.

2.12 In the event that the Company determines that Emergent is not using Efforts to Market the Licensed Product within a specific country or countries in the Developed World (other than the public markets in China and India) in accordance with the Marketing Plan, the Company shall provide Emergent with written notice of such failure and a suggested corrective plan to enable Emergent to correct the asserted lack of diligence. Upon receipt of such notice and suggested corrective plan, Emergent

shall have ninety (90) days to cure such failure, or otherwise to demonstrate to the Company to the Company's reasonable satisfaction that Emergent's efforts in such country or countries constitute Efforts in accordance with the Marketing Plan. In the event that Emergent is unable to cure such failure or make such demonstration within such ninety (90) day period, the Company and Emergent shall offer Aeras the opportunity to add such country or countries to the Developing World definition under the Aeras Agreement. If Aeras does not accept any such offer within ninety (90) days of receipt of the offer, Emergent's rights to distribute the Licensed Product in the applicable country or countries shall become non-exclusive. The public markets in China and India are subject to clause 6.4.

3 Emergent Licence and Publication

3.1 Emergent grants to the Company a royalty-free licence to use the Emergent Manufacturing Technology, to:

3.1.1 develop the Manufacturing Process;

3.1.2 apply for, obtain and maintain Regulatory Approvals (other than Marketing Authorisations) for Licensed Products and Company Combination Products for use in the Field; and

3.1.3 apply for, obtain and maintain Marketing Authorisations for Licensed Products and Company Combination Products for use in the Field outside the Territory.

The licences in this clause 3.1 are non-exclusive.

3.2 Emergent grants to the Company a royalty-free licence to access, reference and otherwise use and reproduce the Emergent Data and the Emergent Regulatory Documents, to:

3.2.1 undertake research with a view to Developing Licensed Products and Company Combination Products for use in the Field;

3.2.2 Develop and have Developed Licensed Products and Company Combination Products for use in the Field;

3.2.3 apply for, obtain and maintain Regulatory Approvals (other than Marketing Authorisations) for Licensed Products and Company Combination Products for use in the Field;

3.2.4 apply for, obtain and maintain Marketing Authorisations for Licensed Products and Company Combination Products for use in the Field outside the Territory; and

3.2.5 Market Licensed Products and Company Combination Products in the Field outside the Territory.

The licences in this clause 3.2 are non-exclusive.

3.3 Except as set out in clause 3.5, the Company may not grant sub-licences under clause 3.1 or 3.2 without Emergent's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. The Parties acknowledge that Emergent has given its consent to the appointment by the Company of Aeras as a sub-licensee on the terms of the Aeras Agreement and to the performance of activities under the Overall Development Plan by the University.

3.4 As soon as reasonably practicable after it becomes available to Emergent, Emergent shall disclose and supply to the Company, all Emergent Data and Emergent Regulatory Documents arising or generated after the Effective Date.

3.5 The Company may grant:

3.5.1 to Isis and the University a non-exclusive, royalty-free licence for the University, University Personnel and University Collaborators to use and have used and, subject to prior review by Emergent, publish Emergent Data, in each case for Non-Commercial Use for so long and to the extent that the Company grants to Isis and the University an equivalent licence to use the Company Data; and

3.5.2 if the Company is unable or unwilling to supply Licensed Product or Licensor Combination Product to the University for use in Phase I Clinical Trials to be conducted by the University and notified to Emergent in accordance with clause 6.7, a non-exclusive, royalty-free licence under the Emergent Manufacturing Technology to a Third Party approved by Emergent (such approval not to be unreasonably withheld, conditional or delayed) to the extent necessary to enable that Third Party to Manufacture the required supplies of such Licensed Product or Licensor Combination Product for such Phase I Clinical Trial; provided that the Company shall procure that such Third Party shall keep the Emergent Manufacturing Technology confidential and shall not use it for any other purpose.

3.6 The Company will provide Emergent with a list of University Collaborators who have been granted access to or provided with MVA85A within sixty (60) days of the Effective Date. On Emergent's written request within sixty (60) days of the end of each Licence Year, or at such other times as Emergent may reasonably request in writing, the Company shall update such schedule to include any other University Personnel or University Collaborators who have been granted access to or provided with MVA85A after the Effective Date.

3.7 Each Party (the "**Publishing Party**") shall give to the other Party for review and approval all proposed academic, scientific and medical publications and public presentations, including audio visual presentations and posters, relating to activities conducted under the Overall Development Plan or otherwise generated using any Emergent Data, or Company Data, intended for publication no less than ten (10) Business Days before submission for publication or, if an abstract or materials for an oral presentation, five (5) Business Days before submission of the abstract or materials. The other Party may require any of its Confidential Information to be redacted from any such materials and may request that publication (through any media) be delayed for a period not exceeding three (3) months from the date of notification if such delay is necessary in order to protect Intellectual Property Rights in Emergent Data or Company Data. If the Publishing Party has not received any request for delay within ten (10) Business Days or, if an abstract or materials for an oral presentation, five (5) Business Days of the date of notification, the Publishing Party will be free to assume that the other Party has no objection to the proposed publication. Each Party shall comply with standard academic practice regarding authorship of scientific publications and recognition of the contribution of the other Party (and its sub-licensees and sub-contractors) in any publications and presentations.

3.8 The Company acknowledges that the Exploitation of Licensed Products and Company Combination Products and Licensor Combination Products by the Company or its permitted sub-licensees pursuant to clause 3 may require a licence under additional Intellectual Property Rights, including Intellectual Property Rights Controlled by Third Parties, and acknowledges that:

3.8.1 Emergent does not grant and shall not grant to the Company any rights with respect to any Licensed Product, Company Combination Product or Licensor Combination Product except as set out in clauses 3.1 and 3.2 and then only to the extent that the relevant Intellectual Property Rights are Controlled by Emergent;

3.8.2 any licence that may be granted to the Company pursuant to this agreement shall be subject to the rights (if any) that any Third Party may have in the relevant Licensed Product, Company Combination Product or Licensor Combination Product; and

3.8.3 Emergent does not make any warranties of any kind with respect to Emergent Data, Emergent ODP Technology or Emergent Manufacturing Technology or the Exploitation of Licensed Products or Combination Products including warranties with respect to quality, suitability or non-infringement.

4 Materials

4.1 The Master Seed Stock is and will remain the property of Isis.

4.2 As between the Parties, the Company Seed Stock will belong to the Company.

4.3 Emergent may use and have used the Master Seed Stock and the Company Seed Stock within the scope of the Licence and will not use or permit them to be used for any other purpose.

4.4 During the Term and for so long as Emergent has the right to manufacture Licensed Products or Combination Products, Emergent will have access to the Master Seed Stock and the Company Seed Stock as reasonably required in connection with the Exploitation of Licensed Products and Combination Products. In addition, Emergent will be entitled to exercise such Control over the Master Seed Stock (or a reasonable portion of it) and the Company Seed Stock as may be reasonably required by Emergent in connection with obtaining or maintaining any Regulatory Approval and the Company shall not unreasonably refuse to take, at Emergent's cost, any action reasonably required by Emergent to protect the continuing availability and integrity of the Master Seed Stock and the Company Seed Stock as reasonably required for the Exploitation of Licensed Products and Combination Products. The Company will have access to the Master Seed Stock and the Company Seed Stock on reasonable notice and as reasonably required in connection with the exercise of the Company's rights pursuant to clause 3; provided that the Company shall not exercise such rights of access in any manner that might adversely affect obtaining or maintaining any Regulatory Approval.

4.5 At the Effective Date the progenitor seed stock is held by the University and the remainder of the Master Seed Stock is held by IDT. If during the Term or while Emergent has the right to manufacture Licensed Products or Combination Products, IDT ceases to manufacture the Licensed Product or an additional manufacturer is

appointed to manufacture Licensed Products or Combination Products, Emergent may deliver, or if requested by Emergent, the Company will procure the delivery, at Emergent's cost, of, a quantity of the Master Seed Stock and the Company Seed Stock sufficient for the manufacture of Licensed Products and Combination Products to any replacement or additional manufacturer appointed by Emergent or its permitted sub-licensees. In addition, Emergent may deliver, or if requested by Emergent, the Company will procure the delivery, at Emergent's cost, of, a quantity of the Master Seed Stock and the Company Seed Stock sufficient for emergency back-up purposes to one or more additional Third Parties appointed by Emergent, its permitted sub-licensees or the Company.

4.6 As between the Parties, Emergent Seed Stock will belong to Emergent.

4.7 Subject to clause 3.8, the Company and the University may use and have used the Master Seed Stock, the Company Seed Stock and the Emergent Seed Stock to the extent necessary to make, or have made, Licensed Product or Company Combination Products for use in their research in accordance with clause 3; provided that at all times there remains sufficient stock of Master Seed Stock, Company Seed Stock and Emergent Seed Stock to complete all activities planned under the Overall Development Plan.

5 Overall Development Plan

5.1 The Parties acknowledge that the Development of Licensed Products and Combination Products will be governed by the Overall Development Plan. The Overall Development Plan will identify all activities to be conducted by or on behalf of the Parties relating to the Development of any Licensed Product or Combination Product and will include the anticipated timelines for such activities; provided that if the Company does not wish to include the Development of an Emergent Combination Product in the Overall Development Plan, Emergent shall be entitled to Develop such Emergent Combination Product outside the Overall Development Plan. The Parties acknowledge that they will each be responsible for conducting certain activities under the Overall Development Plan and will cooperate in the performance of their respective activities under the Overall Development Plan.

5.2 Unless Emergent terminates this agreement pursuant to clause 19.3.6, or otherwise terminates this agreement prior to the commencement of the Infant Phase III Study, Emergent shall be responsible for obtaining funds for and undertaking the Infant Phase III Study in accordance with clause 7.1. The Parties will cooperate in preparing a draft protocol for the Infant Phase III Study at least six (6) months prior to the proposed commencement of the Infant Phase III Study and the Company shall provide such draft protocol to Aeras for review and comment in accordance with the Aeras Agreement. Emergent shall be responsible for finalising the draft protocol, provided that all comments provided by Aeras to the Company within the time permitted by the Aeras Agreement will be reasonably considered by Emergent. Emergent shall, not less than six (6) weeks prior to submission of such draft protocol to the relevant Regulatory Authorities and Ethics Committees, submit to the Company the final draft protocol together with the plan and budget for the Infant Phase III Study and the Overall Development Plan shall be updated in accordance with the Company's procedures for adopting changes to the Overall Development Plan. If a relevant Regulatory Authority or Ethics Committee requires an amendment to the protocol, or Emergent otherwise chooses to amend the protocol, plan or budget for the Infant

Phase III Study after submission of the final draft protocol to the Company in accordance with this clause 5.2, Emergent shall promptly submit to the Company a copy of such amended protocol, plan or budget and the Overall Development Plan shall be updated in accordance with the Company's procedures for adopting changes to the Overall Development Plan.

5.3 For so long as any ongoing activities are being conducted by either Party under the Overall Development Plan:

5.3.1 Emergent shall have the right to appoint at least one (1) director to the Board;

5.3.2 the Company shall establish a steering committee to oversee the conduct of the Overall Development Plan and Budget and, acting by consensus, make recommendations to the Board;

5.3.3 Emergent shall have the right to appoint at least two (2) members to the Steering Committee; and

5.3.4 Emergent shall have the right to appoint at least one (1) representative on any steering committee established by Aeras, Isis, Emergent and Wellcome Trust in accordance with the Aeras Agreement;

and the Company shall take such actions as reasonably necessary to give Emergent the benefit of such rights.

5.4 The Company shall procure that the Steering Committee shall from time to time, and at least once in each Licence Year, review the Overall Development Plan and the Budget and recommend to the Board any changes, updates or amendments to the Overall Development Plan and/or the Budget it considers necessary. The Company shall procure that whenever the Steering Committee recommends to the Board any changes, updates or amendments to the Overall Development Plan and/or the Budget, the Steering Committee will provide a copy of such changes, amendments or updates to Emergent and the Company will specify the date on which it intends to adopt such updated Overall Development Plan and/or the Budget as the Overall Development Plan and/or the Budget (as the case may be).

5.5 Except with respect to the incorporation of Emergent's protocol, plan and budget for the Infant Phase III Study and any amendments thereto submitted by Emergent to the Company in accordance with clause 5.2, any proposed change, update or amendment to the Overall Development Plan and the Budget, as the case may be, shall constitute a "**Material Change**" if such change, update or amendment would, if implemented:

5.5.1 result in Emergent being obliged to commit to the Company material additional finances or resources;

5.5.2 be reasonably likely to result in a delay (as against the then current timelines shown in the Overall Development Plan) of six (6) months or more in obtaining any Marketing Authorisation for a Licensed Product or any Combination Product (other than an Emergent Combination Product being Developed outside the Overall Development Plan) in the Territory and such delay:

5.5.2.1 is not commercially reasonable taking into account the resources then available to the Company; or

5.5.2.2 does not arise as a consequence or result of a delay to the completion of another activity under the Overall Development Plan where such original delay was beyond the reasonable control of the Company; or

5.5.3 result in a net reduction in the financial and other resources being committed to the Company and such reduction in resources would have a material adverse effect on the prospects of the Company obtaining Marketing Authorisation for a Licensed Product or Combination Product for any Indication.

5.6 No Material Change to the Overall Development Plan and/or the Budget of the type described in clause 5.5.1 may be adopted by the Company without the prior approval of Emergent to such change.

5.7 No Material Change to the Overall Development Plan and/or the Budget of the types described in clause 5.5.2 or clause 5.5.3 may be adopted by the Company without the prior approval of Emergent to such change (such approval not to be unreasonably withheld, delayed or conditioned).

5.8 Emergent will notify the Company in writing within twenty (20) Business Days of receipt of the draft revised Overall Development Plan and/or Budget, if it considers that any proposed change, update or amendment constitutes a Material Change. Such notice shall also indicate whether Emergent is granting or withholding its approval. If it is withholding its approval, such notice shall also include its reasons for withholding its approval. If no notification of approval or objection is sent to the Company within such twenty (20) Business Day period and at least one (1) reminder has been sent to Emergent during such twenty (20) Business Day period, Emergent shall have been deemed to have given its approval to the Material Change.

5.9 If Emergent approves the Material Change or it is deemed approved pursuant to clause 5.8, the Company shall be entitled to adopt the proposed Overall Development Plan and/or Budget incorporating such Material Change.

5.10 If Emergent does not approve a Material Change, the Company shall not implement such proposed Material Change.

5.11 If the Parties cannot, after using their respective reasonable endeavours, agree whether a proposed change, update or amendment to the Overall Development Plan and/or the Budget constitutes a Material Change, then the Company may and on Emergent's requests shall, on not less than two (2) Business Days' notice, procure that a meeting of the Steering Committee is convened to attempt to resolve the matter.

5.12 If following such meeting, the matter has not been resolved to the satisfaction of the Parties, either Party shall, within twenty (20) Business Days of such Steering Committee meeting, be entitled to refer the matter for determination by an Expert.

5.13 If the Expert Opinion determines that a proposed change, update or amendment to the Overall Development Plan and/or Budget constitutes a Material Change, then Emergent's approval of such change shall be required in accordance with clauses 5.6 and 5.7. If the Expert Opinion determines that a proposed change, update or amendment to the Overall Development Plan and/or Budget does not constitute a Material Change, then the Company may adopt any such proposed change, update or amendment as the Overall Development Plan and/or the Budget for the purposes of

this agreement and shall, following adoption, notify Emergent of the date of such adoption.

5.14 Each Party may sub-contract performance of its obligations under this agreement provided that:

5.14.1 the sub-contract protects the Licensed Technology, the Emergent Manufacturing Technology, the Data and the Regulatory Documents to no less extent than this agreement does;

5.14.2 the sub-contract imposes obligations of confidentiality equivalent to those contained in clause 15 and compliance with all relevant Regulatory Approvals and Applicable Law;

5.14.3 the sub-contracting Party uses its Efforts to obtain all rights arising under such sub-contract and which are necessary for the Exploitation of Licensed Product and Combination Products (if and in the form Developed or being Developed under the Overall Development Plan) in the Field; and

5.14.4 the sub-contracting Party uses its Efforts to procure that the sub-contract is assignable without consent to the other Party on termination of this agreement.

6 Isis Licence Agreement and Aeras Agreement

6.1 The Parties acknowledge that this agreement is a sub-licence to the Isis Licence Agreement and that the Aeras Agreement is also a sub-licence to the Isis Licence Agreement. The Company will not terminate either the Isis Licence Agreement or the Aeras Agreement (other than for the breach or insolvency of respectively Isis or Aeras) without Emergent's prior written consent.

6.2 The Company will use its Efforts to enforce its rights and perform its obligations under the Isis Licence Agreement and the Aeras Agreement. Without prejudice to the generality of the foregoing, the Company will enforce its rights under the Isis Licence Agreement to procure that:

6.2.1 if requested by Emergent, the University shall remove Emergent's Confidential Information from proposed publications and delay publication to protect any Intellectual Property Rights in Emergent Data;

6.2.2 the University shall handle, use and store any Samples, to which it has been granted access, in accordance with Applicable Law and the relevant Study Subject's consent;

6.2.3 for any clinical trial involving a Licensed product or Combination Product conducted by the University, the University shall obtain the required consent from each Study Subject;

6.2.4 Isis and the University shall take such actions as Emergent may require in connection with securing Patent Extensions;

6.2.5 Isis and the University shall, if requested by Emergent, join as a party in legal actions against any misappropriation or infringement of any rights included in the Licensed Technology in the Field in the Territory; and

6.2.6 if requested by Emergent, the Isis License Agreement shall be terminated if Isis commits a material breach of that agreement and fails to remedy such breach within the applicable cure periods.

6.3 The Company will not amend, vary or terminate the Isis Licence Agreement or the Aeras Agreement without Emergent's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). The Company will not enter into, or amend, vary or terminate, any further agreements with Aeras or any agreements with Third Parties relating to the supply or distribution of Licensed Products or Combination Products, without Emergent's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). The Company shall not grant consent for Aeras to grant sub-licences in accordance with the Aeras Agreement, or to sub-contract the performance of Aeras's Development activities under the Overall Development Plan, in each case without Emergent's consent (such consent not to be unreasonably withheld, conditioned or delayed).

6.4 Emergent and the Company will explore avenues to supply Licensed Product to the public markets in China and India in consultation with Aeras. The Company will put forward Emergent's proposal regarding such supply and if such proposal demonstrates to the reasonable satisfaction of Aeras that Emergent, acting with the Company, has a strategy for and the capability (including through partnering with Third Parties) to supply Licensed Products or Combination Products to the public markets in China and/or India in accordance with the principles set out in clause 8.2.1, then the public markets in China and/or India as appropriate will be deleted from the definition of the Developing World for this agreement and the Aeras Agreement with effect from the date on which such capability was demonstrated. Following such change to the definition of Developing World, Emergent shall, on reasonable notice and during reasonable business hours, permit the Company (and through it, Aeras) to audit Emergent's supply of Licensed Products and Combination Products to the public markets in China and/or India. If the Company receives notice from Aeras that Emergent is materially failing to supply Licensed Products and Combination Products to the public markets in China and/or India in accordance with the principles set out in clause 8.2.1, the Company shall promptly forward such notice to Emergent. If, six (6) months after the date of such notice received by the Company from Aeras, Emergent is still materially failing to supply Licensed Products and Combination Products to the public markets in China and/or India in accordance with the principles set out in clause 8.2.1, the relevant public markets will be added back to the definition of the Developing World with effect from the end of such six (6) month period.

6.5 Other than in accordance with clauses 6.6 and 6.7, the Company will not permit Aeras to conduct any clinical trials on a Licensed Product or a Combination Product (other than the Infant Phase IIb Study), which are reasonably necessary or useful for Aeras to obtain a Regulatory Approval in the Developing World, without Emergent's prior written approval of the protocol and study plans for such clinical trial (such consent not to be unreasonably withheld, conditioned or delayed), and the Company will not permit Aeras to conduct any other clinical trials on a Licensed Product or a Combination Product (other than the Infant Phase IIb Study) without Emergent's prior written consent.

6.6 The Company will not permit the University to conduct any clinical work (other than a Phase I Clinical Trial notified to Emergent in accordance with clause 6.7) on a Licensed Product or a Combination Product outside the Overall Development Plan without

Emergent's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed). The Parties agree that if the proposed [**] it will be treated as a Phase I Clinical Trial for the purposes of this agreement and it will be subject to clause 6.7.

6.7 If the Company receives a request from the University to conduct a Phase I Clinical Trial, outside the Overall Development Plan, of a Licensed Product or a Licensor Combination Product, the Company shall, promptly upon receiving the draft protocol for such Phase I Clinical Trial from the University, provide a copy of such draft protocol to Emergent and shall notify Emergent of the deadline for the Company to provide comments to the University. The Company shall consider any and all comments received from Emergent before such deadline and, if requested by Emergent, shall provide such comments to the University.

7 Infant Phase III Study

7.1 Without prejudice to the generality of clause 5.1, and subject to clause 19.3.6, the availability of suitable trial sites, sufficient quantities of Licensed Product appropriate for the applicable clinical trial use being available and the relevant Regulatory Approvals having been obtained, Emergent will, if the Trial Success Criteria of the Bridging Study, the De-escalation Study and the Infant Phase IIb Study are achieved:

7.1.1 meet all the costs and expenses of a Phase III Clinical Trial for the Infant Indication (the "**Infant Phase III Study**");

7.1.2 unless otherwise agreed by the Parties, act as sponsor of the Infant Phase III Study; and

7.1.3 use its Efforts to enrol the first subject in the Infant Phase III Study within twelve (12) months of the later of:

7.1.3.1 the date on which Regulatory Approval for the Infant Phase III Study is granted; and

7.1.3.2 the Successful Completion Date of the Bridging Study, the De-escalation Study, and the Infant Phase IIb Study.

7.2 If (i) the Trial Success Criteria for the Infant Phase IIb Study are not achieved; (ii) Emergent does not exercise its right to terminate this agreement pursuant to clause 19.3.6; and (iii) an Emergent Company subsequently commences the Infant Phase III Study pursuant to clause 7.1, the Trial Success Criteria for the Infant Phase IIb Study shall be deemed to have been achieved on the date the first Study Subject is dosed in the Infant Phase III Study and the Milestone Fee that would have been due upon the Successful Completion Date of the Infant Phase IIb Study shall become due on the date of such dosing and shall be payable in accordance with clause 16.3.

7.3 Emergent will, and will use its Efforts to ensure that its sub-contractors will, comply in all material respects with all relevant Regulatory Approvals and Applicable Law whilst conducting the Infant Phase III Study.

7.4 If, after completion of the Infant Phase III Study and production of the final clinical trial report, any Samples collected by or on behalf of Emergent during the Infant Phase III Study remain and are not required to be retained by the protocol, Emergent shall permit the Company or, at its direction, the University to access and use for Non-Commercial Use such excess Samples, subject to Applicable Law and the relevant

Study Subject's consent. Emergent shall use its Efforts to ensure that the informed consent forms used for Study Subjects participating in the Infant Phase III Study would permit such use. The Company shall handle, use and store the Samples in accordance with Applicable Law and the relevant Study Subject's consent. The Company (i) shall immediately return to Emergent or its designee or destroy each Sample if requested by Emergent following a request by the relevant Study Subject and (ii) shall, to the extent that any Samples remain upon completion of the permitted use of such Samples by the Company or the University, return all remaining Samples to Emergent or its designee or, if requested or permitted by Emergent, destroy any remaining Samples.

8 Manufacturing

8.1 The Parties will, through the Steering Committee, cooperate to develop the Manufacturing Process. It is anticipated that the Company will appoint one or more mutually acceptable Third Party manufacturers with appropriate expertise to undertake process development activities. Without prejudice to clause 5.14, if a Party appoints a Third Party to undertake any activities in connection with the Development of the Manufacturing Process, that Party will procure that the Company is licensed or otherwise granted access to any Intellectual Property Rights underlying such process development which do not vest in that Party. The Parties acknowledge that certain activities relating to the development of such manufacturing process will be funded by the Wellcome Grant.

8.2 Emergent will, working with the Company in accordance with clause 8.1, use its Efforts to develop a manufacturing process for a Licensed Product which:

8.2.1 is capable of producing [**] doses of Licensed Product in each year of manufacture within a specified number of years from the date on which the Infant Marketing Approval is granted (such number to be determined when the Aeras supply agreement is entered into) with the objective of being able to make, at the end of that number of years, at least [**] doses per year of the Licensed Product available to Humanitarian Organisations at an affordable level for use in the Developing World and on such development to supply Aeras or other Humanitarian Organisations such quantities of Licensed Product; provided that if and to the extent that Emergent or its sub-licensee is supplying the public markets in China and/or India at affordable prices, the number of doses to be made available to Humanitarian Organisations shall be reduced by the number of doses made available by Emergent or such sub-licensee at such prices to such markets.

8.2.2 with respect to Manufacture in or for EEA countries, fulfils the requirements of EMEA for the grant of Marketing Authorisation for the Licensed Product in the EEA.

8.3 Each of the Parties will, and will use its Efforts to ensure that its sub-contractors will, comply in all material respects with all relevant Applicable Law whilst conducting the manufacturing process development set out in clause 8.2.

8.4 Each of the Parties will, and will use its Efforts to ensure that its sub-contractors will, use its Efforts to ensure that all Regulatory Approvals required to undertake the work set out in clause 8.2 and any Manufacture of Licensed Product are obtained.

8.5 Each of the Parties will, and will use its Efforts to ensure that its sub-contractors will, provide to the other Party all chemistry, manufacturing and controls data (or a drug master file containing the same) relating to the Manufacture of Licensed Products or Combination Products and shall grant to the other Party a right of reference to such data and drug master files for the purpose of obtaining and maintaining Regulatory Approvals relating to the Exploitation of such Licensed Products or Combination Products.

8.6 Subject to clauses 2.9.1 and 8.1, the Company acknowledges that Emergent has the sole right to Manufacture and have Manufactured Licensed Products and Combination Products and that it is anticipated that Emergent may enter into agreements with one or more Third Parties to fulfil its obligations pursuant to clause 8.2. The Company will provide Emergent with all information relating to the anticipated demand for Licensed Product in the Developing World within ten (10) Business Days of receiving the same from Aeras or any other Developing World Distributor.

9 Regulatory Matters

9.1 Provided that the OMP Designation has been transferred to Emergent in accordance with clause 2.5.3 Emergent will use its Efforts to maintain the OMP Designation.

9.2 Each Party shall communicate to the other Party in writing any data relating to a Licensed Product or Combination Product of which it becomes aware which discloses a serious adverse event, promptly (and in any event within forty-eight (48) hours) and where that serious adverse event is a SUSAR, immediately. The Parties will (and where appropriate will use their Efforts to procure that their respective sub-licensees and sub-contractors will) enter into such further data safety exchange agreements as reasonably necessary to enable the Parties to comply with their reporting obligations under Applicable Law from time to time.

9.3 Neither Party will use in any capacity, in connection with the conduct of any activities involving any Licensed Product or Combination Product, the services of any party who has been debarred pursuant to Section 306 of the Federal Food, Drug, and Cosmetic Act, as amended, or who is the subject of a conviction described in such section.

9.4 Each Party will inform the other Party in writing immediately if it becomes aware that it, or any party who conducts any activities involving any Licensed Product or Combination Product, is debarred or is the subject of a conviction described in Section 306 of the Federal Food, Drug, and Cosmetic Act, as amended, or that any action, suit, claim, investigation or legal or administrative proceeding is pending or is threatened, relating to the debarment or conviction of it, or any party who conducts any activities pursuant to or authorised by this agreement.

9.5 Unless otherwise agreed by the Parties, Emergent shall be responsible for seeking, obtaining and maintaining all Regulatory Approvals necessary or reasonably useful for the conduct of all clinical trials conducted under the Overall Development Plan (other than the Infant Phase IIb Study and any clinical trial ongoing at the Effective Date) and shall be responsible for all communications with Regulatory Authorities or Ethics Committees concerning any such trial; provided that the Parties acknowledge that:

9.5.1 Aeras, the University and the Company shall be responsible for seeking, obtaining and maintaining all Regulatory Approvals necessary or reasonably useful for the conduct of the Infant Phase IIb Study and shall

be responsible for all communications with Regulatory Authorities or Ethics Committees concerning the Infant Phase IIb Study;

9.5.2 the University shall be responsible for seeking, obtaining and maintaining all Regulatory Approvals necessary or reasonably useful for the conduct of any clinical trial ongoing at the Effective Date and any Phase I Clinical Trial notified to Emergent in accordance with clause 6.7 and shall be responsible for all communications with Regulatory Authorities or Ethics Committees concerning any such trials; and

9.5.3 subject to clause 6.5 and 9.10, Aeras shall be responsible for seeking, obtaining and maintaining all Regulatory Approvals necessary or reasonably useful for the conduct of any other clinical trials reasonably necessary or useful to secure Regulatory Approvals in the Developing World and shall be responsible for all communications with Regulatory Authorities or Ethics Committees concerning any such trials.

The Company shall not apply for any Regulatory Approval for any other clinical trial involving a Licensed Product or a Combination Product in the Field, whether inside or outside the Territory, without Emergent's prior written consent.

9.6 Subject to clauses 9.5 and 9.10, and unless otherwise agreed by the Parties, Emergent and its permitted sub-licensees shall be responsible for seeking, obtaining and maintaining all Regulatory Approvals relating to the Exploitation of Licensed Products and Combination Products in the Territory and the Company and its permitted sub-licensees (including Aeras) shall be responsible for seeking, obtaining and maintaining all Regulatory Approvals relating to the Exploitation of Licensed Products and Company Combination Products outside the Territory, provided that Emergent and its permitted sub-licensees shall have the exclusive right to seek, obtain and maintain all Marketing Authorisations in the Territory.

9.7 Prior to making any submission to a Regulatory Authority, including any application or document in support of a Marketing Authorisation or other Regulatory Approval (other than with respect to a Combination Product Developed or being Developed outside the Overall Development Plan in accordance with clause 5.1), the Parties shall, and the Company shall procure that the University and Aeras shall, through the Steering Committee and, where appropriate any committee established under the Aeras Agreement, consult and cooperate in preparing such filings. Each Party shall have the right to review and comment on all such submissions to Regulatory Authorities in accordance with specific timelines or other arrangements agreed on by the Steering Committee; provided that, unless otherwise agreed in writing by the Parties, each Party shall allow the other Party at least thirty (30) days to review and comment on any such submissions to Regulatory Authorities and shall reasonably consider any and all timely comments received from the other Party with respect to such submissions.

9.8 Subject to clauses 9.5 and 9.10, and unless otherwise agreed by the Parties, Emergent shall be responsible for responding to all communications relating to a Licensed Product or Combination Product received from a Regulatory Authority or Ethics Committee in the Territory and the Company shall be responsible for responding to all communications relating to a Licensed Product or Company Combination Product received from a Regulatory Authority or Ethics Committee outside the Territory.

9.9 Each Party will, and the Company will use its Efforts to procure that the University and Aeras, promptly notify the other Party of (i) any communication received by it from any Regulatory Authority or Ethics Committee relating to a Licensed Product or Combination Product and (ii) any proceedings initiated by any Regulatory Authority relating to a Licensed Product or Combination Product. To the extent practicable, the Party responsible for responding to such communication pursuant to clauses 9.5, 9.8 or 9.10 will allow the other Party a reasonable opportunity to review and comment upon, prior to submission to any Regulatory Authority or Ethics Committee, any response that Party proposes to submit to the relevant Regulatory Authority or Ethics Committee in response to such communication. Each Party will notify the other Party of any meeting or teleconference to be held with any Regulatory Authority relating to a Licensed Product or Combination Product and, to the extent permissible, will allow the other Party or its designee to attend and participate in such meeting or teleconference.

9.10 Emergent shall have the first right to seek, obtain and maintain all Regulatory Approvals reasonably useful or necessary for the Exploitation of Licensed Products and Combination Products in China and India. If Emergent declines to submit, within four (4) years of the date on which the first Marketing Authorisation for any Licensed Product or Combination Product in the Territory is granted, any application for, or other document in support of, a Regulatory Approval, that is reasonably necessary or useful for the Exploitation of Licensed Products and Combination Products in China or India, the Company (or, at its discretion, Aeras) shall be responsible for seeking, obtaining and maintaining such Regulatory Approval in such country. If the Company (or Aeras) seeks any Regulatory Approval in China or India in accordance with this clause 9.10, Emergent shall reimburse the Company (or Aeras) for half of the out-of-pocket expenses incurred by the Company (or Aeras) in connection with the preparation and submission of any application for such Regulatory Approval. Whichever Party is responsible for seeking, obtaining and maintaining Regulatory Approvals in China or India pursuant to this clause 9.10 shall also be responsible for all communications with Regulatory Authorities and Ethics Committees in such country in connection with the Development or Exploitation of Licensed Products or Combination Products in such Country.

9.11 In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with a Licensed Product or Combination Product, or in the event either Party (or any of its sub-licensees) determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of a Licensed Product or Combination Product, the Party notified of or desiring such recall or similar action shall, within twenty four (24) hours, advise the other Party thereof by telephone or facsimile. Following notification of a recall (i) with respect to Licensed Products or Combination Products in the Developing World or in China or India, when the Company (or Aeras) is responsible for obtaining Regulatory Approvals in such country pursuant to clause 9.10, as between the Parties, the Company shall decide in its sole discretion whether to conduct a recall (except in the case of a government mandated recall) and the manner in which any such recall shall be conducted, and (ii) with respect to Licensed Products or Combination Products in the Territory or in China or India, when Emergent is responsible for obtaining Regulatory Approvals in such country pursuant to clause 9.10, Emergent shall decide in its sole discretion whether to conduct a recall (except in the case of a government mandated recall) and the manner in which any such recall shall be conducted. Unless

otherwise agreed by the Parties, the costs of any such recall shall be borne by the Party incurring them.

10 Exploitation

10.1 Emergent shall use its Efforts to Market a Licensed Product (or, if Developed, a Combination Product) in the Field in the Territory.

10.2 Within six (6) months of the Successful Completion Date of the Infant Phase IIb Study, Emergent will deliver to the Company a marketing plan, which will describe Emergent's planned activities to Market Licensed Products in the Territory.

10.3 Emergent will review and, where appropriate, update the Marketing Plan at least once every Licence Year and will deliver to the Company, not less than one (1) month prior to the commencement date of the revised Marketing Plan, the revised Marketing Plan together with an update on the implementation of the Marketing Plan including what has and has not been achieved since the last written update on the implementation of the Marketing Plan.

10.4 Emergent will use its Efforts to apply for, as promptly as possible, and if the application is accepted use its Efforts to obtain, the Infant Marketing Approval within two (2) years of the Successful Completion Date of the final Phase III Clinical Trial for the Infant Indication. If the Infant Marketing Approval is granted, Emergent will use its Efforts to Market such approved Licensed Product for the Infant Indication in the Field in the Territory.

10.5 If the Infant Marketing Approval is granted, Emergent will, unless otherwise agreed as part of an Approved Alternative Strategy, use its Efforts to apply for, as promptly as possible, and if the application is accepted use its Efforts to obtain, the Adolescent Marketing Approval within two (2) years of the Successful Completion Date of the final Phase III Clinical Trial for the Adolescent Indication. If the Adolescent Marketing Approval is granted, Emergent will use its Efforts to Market such approved Licensed Product for the Adolescent Indication in the Field in the Territory.

10.6 If the Adolescent Marketing Approval is granted, Emergent will, unless otherwise agreed as part of an Approved Alternative Strategy, use its Efforts to apply for, as promptly as possible, and if the application is accepted use its Efforts to obtain, the HIV Marketing Approval within two (2) years of the Successful Completion Date of the final Phase IIb Clinical Trial for the HIV Indication or, if necessary for Marketing Authorisation, the final Phase III Clinical Trial for the HIV Indication. If the HIV Marketing Approval is granted, Emergent will use its Efforts to Market such Licensed Product for the HIV Indication in the Field in the Territory.

10.7 Emergent will use its Efforts to prepare marketing materials and train its own and/or its sub-licensees' sales staff in good time before the grant of Marketing Authorisation for a Licensed Product in the Territory as reasonably necessary to achieve the Overriding Aims.

10.8 Following commercial launch of the first Licensed Product in the Territory, Emergent shall use its Efforts to increase sales of Licensed Product in the Territory to [**] doses per year.

10.9 The Parties acknowledge that the provisions of clauses 10.5 and 10.6 reflect (i) the current Overall Development Plan, (ii) the Parties' expectations regarding the Development of the Licensed Product (and in particular the order in which Indications

will be Developed), and (iii) the proposed strategy for obtaining Marketing Authorisation for a Licensed Product and achieving the Overriding Aims. The Parties further acknowledge that in the course of Developing a Licensed Product it may be necessary or potentially beneficial to amend such strategy and the Overall Development Plan. If Emergent wishes to change the order of proposed Development activities or otherwise have the Overall Development Plan amended in a manner potentially inconsistent with the Parties expectations for Development as set out in clauses 10.5 and 10.6, Emergent shall submit to the Company its reasoned proposal, including details of the extent to which such proposal would replace or amend the obligations set out in such clauses, and the Parties shall discuss such proposed alternative strategy in good faith. If an alternative strategy proposed by Emergent as amended in the course of such discussions, is approved in writing by the Company and Isis (the "Approved Alternative Strategy"), Emergent shall not be in breach of those obligations set out in clauses 10.5 and 10.6 identified in the Approved Alternative Strategy as having been replaced or amended; provided that it is using its Efforts to implement the Approved Alternative Strategy.

10.10 Emergent shall have the sole right to select the Trademarks for the marketing and sale of the Licensed Products in the Territory. Emergent shall own such Trademarks and all rights and goodwill with respect thereto.

11 Data

11.1 The Company will communicate all Company New Data to Emergent in writing promptly in accordance with an agreed timetable or failing such agreement as reasonably required by Emergent. The Company will procure that the Company New Data are complete and include, with respect to each clinical trial from which Company New Data are obtained, all completed case report forms and all other clinical trial documentation required to be in the possession of a clinical trial sponsor by Article 15(5) of Directive 2001/20/EC, Article 16 of Directive 2005/28/EC or other relevant Applicable Law and any other clinical trial documentation that is otherwise reasonably requested by Emergent.

11.2 Emergent acknowledges and agrees that, as between the Parties, the Company New Data belong to the Company.

11.3 Emergent will communicate in writing to the Company within a reasonable time all Emergent Data reasonably requested by the Company.

11.4 The Company acknowledges and agrees that, as between the Parties, Emergent Data belong to Emergent.

11.5 Each Party acknowledges that even if Study Subjects are not explicitly identified by name, clinical trial data may not be exempt from applicable data protection rules. The Parties will in relation to any clinical trial involving a Licensed Product or a Combination Product, comply fully with the requirements of Applicable Law relating to the collection and transfer of Study Subject data and implement appropriate quality control and quality assurance procedures having regard to the purpose for which the data are being obtained and further processed, including by obtaining appropriate Study Subject consent.

11.6 Each Party will obtain from each Study Subject, prior to enrolment into, and as a condition of that Study Subject's participation in, any clinical trial involving a Licensed Product or a Combination Product, his or her consent to:

11.6.1 direct access to his or her medical records;

11.6.2 the processing of data relating to him or her and to the movement of that data to other countries, including countries outside of the EEA; and

11.6.3 the transfer of such data to Emergent, the Company and Isis, and in each case their permitted sub-licensees, and the use of those data in obtaining Regulatory Approvals.

The Parties acknowledge that the informed consent form for use with Study Subjects participating in the Infant Phase IIb Study has been submitted to the Medicines Control Council in South Africa for approval as part of the trial protocol and that, except to the extent already provided for in such informed consent form, this clause 11.6 shall not apply to the Infant Phase IIb Study.

12 Know-how, Improvements and Inventions

12.1 To the extent not previously disclosed, the Company will communicate all Company Know-how and Company Manufacturing Technology in writing to Emergent within a reasonable time of the date on which such Company Know-how or Company Manufacturing Technology was first documented or reported to the Company. Emergent acknowledges and agrees that, as between the Parties, the Company Know-how belongs to the Company; provided that any Know-how conceived, discovered, developed or otherwise made solely by the Company under the Wellcome Grant shall vest in the University and shall be licensed to the Company pursuant to the Isis Licence Agreement.

12.2 Emergent will communicate Emergent ODP Technology and Emergent Manufacturing Technology to the Company as reasonably required in connection with the activities to be performed under the Overall Development Plan or as otherwise reasonably requested by the Company. The Company and Emergent acknowledge and agree that, as between the Parties:

12.2.1 the Emergent Manufacturing Technology belongs to Emergent; and

12.2.2 the Emergent ODP Technology: (i) that is conceived, discovered or otherwise made under the Wellcome Grant shall vest in the University; provided that such rights are licensed to the Company and Emergent pursuant to the Isis Licence Agreement; and (ii) otherwise shall be owned by the Company and licensed to Emergent pursuant to clauses 2.1 and 2.2.

12.3 The Parties agree that as between themselves all Intellectual Property Rights in any Invention conceived, discovered, developed or otherwise made jointly by the Company and an Emergent Company (or their respective sub-contractors) which relates to or is reasonably useful for the Exploitation of a Licensed Product or Combination Product in the Field:

12.3.1 that is made under the Wellcome Grant, shall vest in the University, provided that such rights are licensed to the Company pursuant to the Isis Licence Agreement and to Emergent pursuant to clauses 2.1 and 2.2; and

12.3.2 other than an Invention conceived, discovered, developed or otherwise made under the Wellcome Grant, shall vest in the Company.

12.4 The Parties agree that as between themselves all Intellectual Property Rights in any Invention conceived, discovered, developed or otherwise made jointly by the Company or an Emergent Company (or their respective sub-contractors) which does not relate to or is not reasonably useful for the Exploitation of a Licensed Product or Combination Product in the Field:

12.4.1 that is conceived, discovered, developed or otherwise made under the Wellcome Grant, shall vest in the University provided that such rights are licensed to the Company pursuant to the Isis Licence Agreement and to Emergent as Licensed Technology pursuant to clause 2;

12.4.2 other than an Invention conceived, discovered, developed or otherwise made under the Wellcome Grant, shall vest in the Party better placed to exploit such Invention; provided that if neither Party is better placed to exploit such Invention, all the Intellectual Property Rights in such Invention shall be owned by the Company.

12.5 The Party in whom the Intellectual Property Rights in an Invention vest pursuant to clause 12.3.2 or 12.4.2 shall grant or Emergent shall procure that the relevant Emergent Company shall grant to the assigning Party (or, where the relevant Emergent Company is not Emergent, to Emergent) a non-exclusive, perpetual, royalty-free licence to use all Intellectual Property Rights in the Invention, in the case of any such licence in favour of the Company, to Exploit Licensed Products and Company Combination Products in the Field and in the case of any such licence in favour of Emergent, for any purpose; and on assignment in accordance with clause 12.10 the Parties shall enter into a revenue sharing agreement that reflects the relative inventive contributions of each Party to such Invention.

12.6 Subject to clause 12.7, but notwithstanding any other provision in this clause 12, the Parties agree as between themselves that any Manufacturing Technology conceived, discovered, developed or otherwise made jointly by the Company and an Emergent Company in the performance of activities under the Overall Development Plan:

12.6.1 that are conceived, discovered, developed or otherwise made under the Wellcome Grant, shall vest in the University, provided that such rights are licensed to the Company pursuant to the Isis Licence Agreement and to Emergent pursuant to clauses 2.1 and 2.2; and

12.6.2 other than Manufacturing Technology conceived, discovered, developed or otherwise made under the Wellcome Grant, shall, subject to clause 12.7, vest in the Company.

12.7 Where any Manufacturing Technology is the subject of a patent or patent application Controlled by Emergent (a "**Manufacturing Patent**") the Parties agree that, as between themselves, any development of the Manufacturing Technology made by the Company, an Emergent Company, or an Emergent Company jointly with the Company, in the performance of the Overall Development Plan which would, if commercially practised, infringe and/or be dominated by or rendered unpatentable by that Manufacturing Patent, shall:

12.7.1 if made under The Wellcome Grant, vest in the University provided that such rights are licensed to the Company pursuant to the Isis Licence Agreement and Emergent pursuant to clauses 2.1 and 2.2; and

12.7.2 if not made under the Wellcome Grant, vest in Emergent (an "**Emergent Improvement**").

12.8 Unless otherwise agreed by the Parties, any data, protocols, standard operating procedures and written documentation prepared jointly by the Company and an Emergent Company in the performance of activities under the Overall Development Plan:

12.8.1 that is made under the Wellcome Grant, shall vest in the University, provided that such rights are licensed to the Company pursuant to the Isis Licence Agreement and to Emergent pursuant to clause 2.1; and

12.8.2 other than works made under the Wellcome Grant, shall vest in the Company; provided that such data, protocols, standard operating procedures and written documentation shall constitute Company New Data and in addition to the rights granted pursuant to clause 2.3, Emergent shall have a royalty free, non-exclusive, worldwide perpetual, irrevocable licence (with the right to sub-license through multiple tiers) to access, reference and otherwise use and reproduce such Company New Data for any purpose.

12.9 If and to the extent that any Intellectual Property Rights (including Manufacturing Technology) conceived, discovered, developed or otherwise made (i) solely by Emergent or (ii) jointly by the Company and one or more Emergent Companies, vest in the Company pursuant to this clause 12, Emergent shall have a non-exclusive, perpetual, irrevocable, worldwide, royalty-free licence (with the right to grant sub-licences without the consent of or accounting to the Company) to practice, access, reference, reproduce and otherwise use such Intellectual Property Rights for any purpose.

12.10 Each of the Parties shall, and does hereby, assign and shall cause its employees, affiliates, sub-contractors and sub-licensees (and their respective employees) to assign to the other, such right, title and interest in and to any Intellectual Property Rights, as is necessary to fully effect the ownership provisions set out in this clause 12. If and to the extent that such Intellectual Property Rights are Know-How, the transferring Party shall treat such Know-How as if it were the Confidential Information of the other Party and shall not use or disclose such Know-How except as permitted by this agreement.

12.11 As between the Parties, for the purpose of allocating ownership of Intellectual Property Rights in accordance with this Agreement, the determination of whether Intellectual Property Rights are conceived, discovered, developed or otherwise made by a Party shall be made in accordance with English law.

13 Patent Filing and Maintenance

13.1 Emergent will pay the Company the Past Patent Costs, representing Emergent's sole contribution to the patent costs incurred by the Company prior to the Parties entering into this agreement, within thirty (30) days of the later of receipt of an invoice for the same from the Company and the Effective Date.

13.2 Subject to the remainder of this clause 13, the Company will, at Emergent's cost, prosecute, defend, maintain and renew the Company Patent Rights in the countries in

the Territory listed in schedule 5, part B, as may be amended from time to time by the Parties, until, with respect to Company Patent Rights in a particular country or region:

13.2.1 the Company Patent Rights can no longer be renewed;

13.2.2 the Company is advised by patent counsel that there is no further principled argument to be advanced in favour of patentability;

13.2.3 there is no reasonable prospect of obtaining a Marketing Authorisation for any Licensed Product for any Indication in the relevant country;

13.2.4 Emergent and, in the case of any Isis Application, Isis consent, such consent not to be unreasonably withheld, conditioned or delayed, that the Company may discontinue pursuit of the Company Patent Rights; or

13.2.5 Emergent and the Company and, in the case of any Isis Application, Isis agree to discontinue pursuit of the Company Patent Rights;

provided that Emergent acknowledges that the Company may not, without Isis's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed, narrow the scope of the claims of an Isis Application other than as required to establish patentability or take any other action which could reasonably be expected to have a material adverse impact on Isis's ability to license the Isis Applications to a Third Party outside the Field applicable to Licensed Products.

13.3 In relation to the prosecution, defence, maintenance and renewal of the Company Patent Rights, the Company will:

13.3.1 use patent professionals reasonably acceptable to Emergent;

13.3.2 keep Emergent fully informed of all material developments, consult fully with Emergent in relation to all material matters of tactics and strategy and will in good faith take account of any comments of the Company, in particular before taking any material patenting decisions, and will give Emergent adequate advance notice of its intention to file any Company Patent Rights, to designate any country in Company Patent Rights, or to take any material decision in relation to Company Patent Rights (before or after grant), and will provide copies of all relevant documents to Emergent;

13.3.3 as reasonably necessary to allow Emergent to exercise its rights pursuant to clause 13.3.2, allow representatives from Emergent and any professional advisors of Emergent to attend any meetings with the Company's patent professionals in person or by telephone and will arrange additional meetings with Emergent's patent professionals as and when reasonably requested by Emergent, at the expense of Emergent;

13.3.4 provide Emergent with adequate notice of any formal hearings or other proceedings which the Company is entitled to attend and will permit representatives of Emergent to attend as well;

13.3.5 disclose to the United States Patent and Trademark Office (and where required by Applicable Law, its equivalent in any jurisdiction) any information considered material for patentability as required by 37 C.F.R. § 1.56 (or the equivalent in any jurisdiction) and, if Emergent has any

such information, it shall promptly report such information to the Company to enable the Company to make such disclosure; and

13.3.6 provide (or procure that its patent professionals will provide) copies of all official correspondence to and from patent offices relating to the Licensed Technology to Emergent (including renewal notices) within fourteen (14) days of dispatch or receipt;

provided that, without limiting the foregoing, Emergent will have the right to review the text of all patent specifications, claims and any other documents filed at any stage of Company Patent Rights or of any opposition, re-examination, interference or other similar procedure relating to a granted or pending Company Patent Rights.

13.4 If, with respect to the Company Patent Rights, the Company intends not to (i) pursue in any country the filing, prosecution (including any interferences, re-issue proceedings and re-examination) or maintenance (including the defence of oppositions) of an Isis Application, or (ii) take any other action with respect to Company Patent Rights in a country that is necessary or useful to establish or preserve rights thereto, in either case as permitted by clause 13.2, then the Company shall so notify Emergent and, if related to the Isis Application, Isis, promptly in writing to enable Emergent, subject to, with respect to an Isis Application, Isis's prior written consent (such consent not to be unreasonably withheld, delayed or conditioned) to meet any deadline by which an action must be taken to establish or preserve any rights in the Patent Rights, as applicable, in such country; provided, however, that any such notification shall be made at least thirty (30) days prior to such deadline. Emergent shall, subject to, with respect to an Isis Application, Isis's prior written consent (such consent not to be unreasonably withheld, delayed or conditioned), have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such Company Patent Rights in such country through patent attorneys or agents of its choice. If Emergent elects to pursue such filing or registration, as the case may be, or continue such support, then Emergent shall notify the Company of such election.

13.5 If, at any time, the Company is unwilling to prosecute or maintain Company Patent Rights as required pursuant to clause 13.2, Emergent will consider in good faith the Company's reasons for wishing to allow such Patent Rights to lapse in the country in question. If there is a dispute as to whether the Company is permitted to allow any Patent Rights to lapse pursuant to clause 13.2, such dispute shall be determined by an Expert. If the dispute involves an Isis Application, Isis shall participate in such determination. If the expert determines that the Company is not entitled to allow an Isis Application to lapse, Emergent shall be entitled, and Isis and the Company shall permit Emergent to assume responsibility for such prosecution and maintenance in that country.

13.6 The Parties acknowledge that if Isis or the University grants a Third Party a licence under the Isis Application in all or part of the Territory which includes exclusive rights to commercialise a product (that is not a Licensed Product), with effect from the date of such licence, the Company shall only be required to pay for half of the external legal costs and expenses reasonably incurred in the prosecution, defence or maintenance of any Isis Application in the territory in which the Third Party is granted a licence which claim such product and the Licensed Product. In such circumstances, the amount payable by Emergent in respect of patent costs pursuant to clause 13.2 shall be

reduced accordingly and shall not in any event exceed the costs suffered or incurred by the Company in prosecuting and maintaining the Company Patent Rights in the Territory having taking into account any payments received from Isis. If at any time the Company receives a contribution for past patent costs relating to the Isis Applications in the Territory, the Company shall pay such amount to Emergent.

13.7 The Parties and Isis shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents relating to the Company Patent Rights ("**Patent Extensions**"). In the event that elections with respect to obtaining such Patent Extensions are to be made, Emergent shall have the right to make the election and the Company and Isis agree to abide by such election and take such actions as Emergent may require in connection with securing such Patent Extensions. Neither the Company nor Isis shall seek to obtain any other Patent Extension for the Company Patent Rights with respect to a Licensed Product or any other product without Emergent's prior consent.

13.8 Where reasonably necessary under the law of any country, Emergent will use its Efforts to register its interest in the Licensed Technology with the relevant patent office (or equivalent) in that country. The Company will, at the Licensee's request and expense, take all actions (including using its reasonable endeavours to procure any necessary Third Party's consent) and execute all deeds and documents that may be reasonably necessary in connection with such registration.

14 Enforcement and Defence

14.1 Each Party will notify the other in writing of any misappropriation or infringement of any Intellectual Property Rights in the Licensed Technology of which it becomes aware.

14.2 The Company has the first right (at its cost and expense) to, and shall at Emergent's request (and at Emergent's cost and expense), take legal action against any misappropriation or infringement of any rights included in the Licensed Technology in the Field in the Territory. The Company must discuss any proposed legal action, other than emergency actions, with Emergent prior to the legal action being commenced and the Parties shall consider in good faith what action is appropriate in all the circumstances. Emergent may, in its sole discretion (at its cost and expense), and shall at the Company's request (at the Company's cost and expense), join the action as a party; provided that Emergent shall not be required to join any such action unless:

14.2.1 the Company has a bona fide legal action against a third party for misappropriation or infringement of any rights included in the Licensed Technology; and

14.2.2 on balance, with due regard for all relevant circumstances, including Applicable Law, the Company has a more than fifty (50%) percent chance of success in such action (and if the parties do not agree on the likely chance of success either may refer the dispute to an expert in accordance with clause 22.14; provided that in such circumstances the expert shall be an independent lawyer of at least ten (10) years' standing in contentious patent matters);

14.2.3 the Company cannot achieve the same result by bringing the legal action under a different law or in a different jurisdiction; and

14.2.4 in order to bring the action, as a matter of law, Emergent is required to be a party.

14.3 With respect to any action pursuant to clause 14.2, the Company will:

14.3.1 keep Emergent fully informed and consult with Emergent at each stage of the legal action;

14.3.2 use legal counsel reasonably acceptable to Emergent;

14.3.3 save with the prior written consent of Emergent, such consent not to be unreasonably withheld, conditioned or delayed, not settle any action taken under clause 14.2 or any counterclaim for invalidity which is made in response to a legal action taken by the Company if such settlement would have an adverse affect on the scope of the Company Patent Rights or Emergent's rights; and

14.3.4 not settle any action or counterclaim referred to in clause 14.3.3 without the prior written consent of Emergent if such settlement would involve an admission of fault by Emergent or impose any payment or other obligation on Emergent.

14.4 If legal action is taken pursuant to clause 14.2 or 14.5, any award of damages (including punitive damages) or other settlement, shall, after payment of all costs and expenses incurred by the Company and Emergent in making such recovery, be paid to Emergent and deemed to be Net Sales for the purposes of clause 16. The Company will indemnify and hold Emergent harmless against all costs (including lawyers' and patent agents' fees and expenses reasonably incurred), claims, demands and liabilities arising out of or consequent upon (i) Emergent joining or instigating any action at the Company's request; or (ii) the Company pursuing any action that discloses no reasonable grounds for bringing or defending a claim, or is an abuse of the court's process, and will settle any reasonable invoice received from Emergent in respect of such costs, claims, demands and liabilities within thirty (30) days of receipt.

14.5 If the Company has notified Emergent in writing that it does not intend to take any action in relation to the misappropriation or infringement or the Company has not taken any such action within 120 days of the notification or request under clause 14.1, or earlier if the claim for damages would be prejudiced by such delay, Emergent may take such legal action at Emergent's cost; and if required by Emergent, the Company shall join the action as a party.

14.6 Each Party shall immediately give notice to the other of any certification which it receives or of which it becomes aware that a Third Party makes under the United States Drug Price Competition and Patent Term Restoration Act of 1984 claiming that any patent rights covering the Licensed Product or Combination Product are invalid or that infringement will not arise from the manufacture, use or sale of the Licensed Product or Combination Product by such Third Party. The Company's and Emergent's rights and obligations with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as set out in clauses 14.2 to 14.5.

14.7 If a Third Party institutes an infringement suit against either Party or any of its permitted sub-licensees or sub-contractors, alleging that the Exploitation of the Licensed Technology, Data or Emergent Manufacturing Technology, infringes such

Third Party's Intellectual Property Rights (an "**Infringement Suit**"), then that Party (the "**Defending Party**") shall have the first right (at its cost and expense), but not the obligation, to assume direction and control of the defence of claims arising therefrom (including the right to settle such claims at its sole discretion). If the Defending Party determines not to assume such direction and control directly or through its designee, then the Defending Party shall so notify the other Party and that other Party may, at its cost and expense, defend against such claims; provided, however, that the other Party shall obtain the written consent of the Defending Party prior to ceasing to defend, settling or otherwise disposing of such claims, such consent not to be unreasonably withheld, conditioned or delayed. For the avoidance of doubt, neither Party shall be required to consent to any such settlement if it would involve an admission of fault by it or its permitted sub-licensees or impose any payment or other obligation on it or its permitted sub-licensees or have a material adverse affect on its rights. Any proceeds in connection with any such litigation (or the settlement thereof) shall be used to reimburse each of the Parties for their reasonable costs and expenses (including any amount paid to the other Party pursuant to this clause 14) and any damage awards or other payments or penalties incurred by them (or if such proceeds are insufficient to reimburse such costs, expenses and other payments in full, a pro-rata share of such costs, expenses and other payments) and the excess (if any) shall be shared equally between Emergent and the Company.

14.8 If either Party brings or defends an action in accordance with this clause 14, the Party that did not instigate the action or is not controlling the defence shall use all reasonable efforts to assist and cooperate with the other Party in bringing or defending such action. Such assistance shall include the execution of such documents as may be reasonably required in connection with any such action. Except as otherwise provided for in this clause 14, the Party that instigates such action shall reimburse all external costs and expenses (including lawyers' and patent agents' fees and expenses reasonably incurred) incurred by the other Party arising out of or consequent upon such assistance, and will settle any reasonable invoice received from such other Party in respect of such costs and expenses within thirty (30) days of receipt.

14.9 Nothing in this clause 14 shall prevent either Party, at its own expense, from obtaining any licence or other rights from Third Parties it deems appropriate in order to permit the full and unhindered exercise of its rights under this agreement.

15 Confidentiality

15.1 Except as permitted by this clause 15, each Party (which for the purpose of this clause shall include Isis) (being a receiving or disclosing Party as the case may be) will keep confidential the Confidential Information of another Party and will not disclose or supply the Confidential Information of another Party to any Third Party or use it for any purpose, except in accordance with the terms of this agreement.

15.2 The Company may disclose:

15.2.1 the Licensed Technology to prospective licensees of the Licensed Technology outside the Territory; and

15.2.2 details of this agreement and the progress of the Licensed Technology to Isis, the University and the Wellcome Trust;

provided that in each case the Company shall ensure that such prospective licensee, Isis, the University or the Wellcome Trust, as the case may be, accepts appropriate

obligations of confidentiality and non-use which shall be no less restrictive than those set out in this clause 15 before it makes any disclosure of Confidential Information.

15.3 Subject to the terms and conditions of the SSA, the Company may disclose details of this agreement and the progress of the Licensed Technology to:

15.3.1 a prospective Public Funder provided that the disclosing Party shall ensure that the prospective Public Funder accepts a continuing obligation of confidentiality in the same terms as this clause before it makes any disclosure of the Confidential Information; and

15.3.2 in accordance with any grant agreement with a Public Funder entered into in accordance with the SSA.

15.4 Emergent may, and may permit other Emergent Companies to, disclose the existence and terms of this agreement and the progress of the Licensed Technology to the extent it deems necessary to comply with the rules or regulations of a relevant stock exchange or similar governing body (including the U.S. Securities and Exchange Commission).

15.5 Emergent may, and may permit its permitted sub-licensees to, disclose to a permitted sub-licensee of the Licensed Technology such of the Company's Confidential Information as is necessary for the exercise of any rights sub-licensed to such sub-licensee provided that the disclosing party shall ensure that such sub-licensees accept a continuing obligation of confidentiality and non-use in the same terms as this clause 15 and as otherwise consistent with this agreement before it makes any disclosure of the Company's Confidential Information.

15.6 Emergent may, and may permit its sub-licensees to, disclose the Licensed Technology and the Company Data:

15.6.1 to any Regulatory Authority or government agency or authority to the extent such disclosure is useful or reasonably necessary to obtain any Regulatory Approval, patents or to achieve the purposes of this agreement; and

15.6.2 to Third Parties as may be necessary or reasonably useful in connection with the Exploitation of any Licensed Product or Combination Product in accordance with this agreement.

15.7 Emergent and other Emergent Companies may disclose Emergent ODP Licensed Technology and Company Manufacturing Technology as reasonably required in the conduct of their businesses outside the Field applicable to Licensed Products; provided that, for such purpose, Emergent shall and shall procure that each other Emergent Company shall treat Emergent ODP Technology and Company Manufacturing Technology as if they were its own Confidential Information.

15.8 Each of Emergent and the Company may disclose the Confidential Information of another Party to existing or potential acquirers or merger candidates, existing or potential pharmaceutical collaborators, investment bankers, existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; provided that the disclosing Party shall ensure that the intended recipient of such Confidential Information accepts a continuing obligation of confidentiality in the same terms as this clause before that Party makes any disclosure of that Confidential Information.

15.9 Notwithstanding any other provisions of this agreement, information or Know-how of a Party shall not be deemed to be Confidential Information with respect to a receiving Party for the purposes of this agreement if the receiving Party can demonstrate such information or Know-how:

15.9.1 was already known to, or otherwise in the lawful possession of, the receiving Party or any of its affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to, or, with respect to Know-how discovered or developed by the receiving Party, but deemed the Confidential Information of the disclosing Party, at the time of discovery or development by, such receiving Party;

15.9.2 was, at the time of disclosure by the disclosing Party, or, with respect to Know-how discovered or developed by the receiving Party, but deemed the Confidential Information of the disclosing Party, at the time of discovery or development by the receiving Party, or thereafter becomes publicly known or available through no fault or negligence of the receiving Party or any of its affiliates or sub-licensees;

15.9.3 is obtained by the receiving Party from a Third Party in circumstances where the receiving Party has no reason to believe that there has been a breach of an obligation of confidentiality or non-use owed to the disclosing Party relative to such information or Know-how; or

15.9.4 except with respect to Know-how discovered or developed by the receiving Party but deemed the Confidential Information of the disclosing Party, was substantially and independently developed by officers or employees of the receiving Party who had no knowledge and made no use of the disclosing Party's Confidential Information.

15.10 Clause 15.1 will not prevent disclosure of Confidential Information if and to the extent that:

15.10.1 such disclosure is approved for release in writing by an authorised representative of the original disclosing Party; or

15.10.2 the receiving Party is required to disclose the Confidential Information:

15.10.2.1 by law or regulation or for the purpose of any judicial proceedings (provided that (i) in the case of a disclosure under the Freedom of Information Act 2000, clause 15.11 will apply, and (ii) in any other case and where reasonably practicable, the disclosing Party shall provide the other Parties with reasonable advance notice of and an opportunity to comment on any such required disclosure, seek confidential treatment with respect to any such disclosure to the extent available and requested by another Party and use good faith endeavours to incorporate any comments of the other Parties in any such disclosure or request for confidential treatment); or

15.10.2.2 for the purposes of arbitration or determination by an Expert or an IP Expert, in each case pursuant to clause 22.

15.11 If any Party receives a request under the Freedom of Information Act 2000 to disclose any information that, under this agreement, is Confidential Information, it will notify

and consult with the other Parties. The other Parties will use their commercially reasonable efforts to respond within five (5) Business Days after receiving notice if that notice requests it to provide information to assist in determining whether or not an exemption to the Freedom of Information Act 2000 applies to the information requested under that Act.

16 Payments

16.1 Emergent will pay the Signing Fee to the Company within five (5) Business Days of the later of the Effective Date and receipt by Emergent of an invoice for the amount payable.

16.2 Subject as set out in clauses 16.5, 16.6, 16.8, 16.9, 16.11, and 16.12, Emergent will pay to the Company:

16.2.1 on Net Sales in any country in the Territory (other than the public markets in China and India) (i) which would but for the Licence infringe a Valid Claim of any Isis Application or (ii) where the Company or Emergent have allowed an Isis Application to lapse, in breach of clause 13.2 and as a result of such breach there is no Valid Claim of an Isis Application that would be infringed by the sale of a Licensed Product or Combination Product in such country, a royalty equal to the Royalty Rate; and

16.2.2 on Net Sales in all other countries in the Territory (other than the public markets in China and India), a royalty equal to [**].

16.3 Subject to clauses 16.7, 16.8, 16.9, 16.11, and 16.12, if, and for such period as the public markets in China and/or India form part of the Developed World, the Licensee will during the Term pay to the Licensor a royalty equal to [**] percent ([**]%) of Net Sales in such market, if and to the extent that such royalty is recovered through the price for the Licensed Product or Combination Product charged by Emergent (or a sub-licensee appointed by Emergent) in such markets after deduction of cost of goods.

16.4 Each Party will promptly notify the other Party of the date on which it (or, in the case of Emergent, an Emergent Company or any sub-licensee) achieves (or is deemed to have achieved) a Milestone; provided that where such Milestone is achieved by the Company, the Company shall include with such notice evidence reasonably acceptable to Emergent that such Milestone has been achieved. On giving such notice, or upon receipt of such notification (as the case may be), the Company will issue Emergent with an invoice for the Milestone Fee pertaining to such Milestone and Emergent will pay to the Company that Milestone Fee within twenty (20) Business Days of receipt of such invoice.

16.5 All sums due to the Company pursuant to clause 16.2 will be due in respect of the relevant Licensed Product or Combination Product in each country until the later of:

16.5.1 the expiry of the period of ten (10) years from the first commercial sale of a Licensed Product or Combination Product in that country; and

16.5.2 the expiration date of the last to expire Valid Claim of the Isis Application in such country;

(the "**Royalty Term**"). Upon expiry of the Royalty Term the Licence will convert into (to the extent not already) a fully paid-up, non-exclusive, perpetual licence with the

right to sub-license through multiple tiers (without the consent of, or subject to clause 16.3, accounting to, the Company).

16.6 If Emergent pays royalties, directly or indirectly through the Company, to any Enabling Third Parties, then Emergent will be entitled to [**] to the Company under [**] directly or indirectly to such Enabling Third Parties [**] (other than the public markets in China and India), [**] under [**] in a particular Quarter.

16.7 If, and for such period as the public markets in China and/or India form part of the Developed World and Emergent pays royalties to any of the Enabling Third Parties with respect to sales in such markets, then Emergent will, if and to the extent that [**] charged by Emergent (or a sub-licensee appointed by Emergent) in such markets [**], be entitled to [**] to the Company under [**] directly or indirectly to the Enabling Third Parties [**] in China and/or India (as the case may be), [**] under [**] in a particular Quarter. In assessing whether [**], the [**] to Enabling Third Parties will be [**] whether the [**] to the Company are [**].

16.8 If the product on which royalties are payable under this agreement is a Multivalent TB Product or a Combination Product and the Company does not Control all the Intellectual Property Rights in that Multivalent TB Product or the Combination Product then the Net Sales of that Multivalent Product or Combination Product will be adjusted in accordance with schedule 6.

16.9 The Parties anticipate that the execution and performance of [**] will [**]. If this proves to be incorrect, the royalties otherwise due with respect to the relevant country will be adjusted in an equitable manner as agreed between the Parties or, if the Parties fail to agree within six (6) months of receipt of [**], as determined by an Expert to be appointed by Emergent.

16.10 The Signing Fee and the Milestone Fees are non-refundable and will not be considered as an advance payment on royalties payable under clause 16.2 or 16.3.

16.11 Emergent will make all payments in pounds sterling or any currency replacing pounds sterling in its entirety. Any change of currency will be determined on the last business day of each complete Quarter, using the average of the daily buying and selling rates quoted by Barclays Bank plc during that Quarter. Where Emergent has to withhold tax by Applicable Law, Emergent will deduct the tax and pay it to the relevant taxing authority. Emergent will use reasonable endeavours to obtain a certificate of tax deduction from the relevant tax authority as soon as reasonably practicable and will supply the Company with such certificate of tax deduction within ten (10) Business Days of its receipt by Emergent.

16.12 In the event that full payment of any amount due from Emergent to the Company under this agreement less any amount withheld in accordance with clause 16.11 is not made by the date stipulated for such payment, Emergent shall be liable to pay interest on the amount unpaid at the rate of four percent (4%) over the base rate for the time being of Barclays Bank plc, from the date when payment was due until the date of actual payment.

17 Emergent Parent Payment Obligation

17.1 In consideration of the Company entering into this agreement, from and after the Effective Date, in the event that Emergent fails to make any payment under this

agreement when due, Emergent Parent shall make such payment on a timely basis, in accordance with the terms hereof.

17.2 If Emergent fails to make any payment under this agreement for more than ten (10) Business Days following the due date for payment of any amount payable to the Company under this agreement, then provided that written notice of such failure has been notified to Emergent Parent, Emergent Parent shall, within twenty (20) Business Days of a written demand from the Company, pay that amount to the Company in the manner set out in the written demand.

18 Royalty Reports and Audit

18.1 Following the grant of the first Marketing Authorisation in the Territory, Emergent will provide the Company with a royalty report within thirty (30) days after the close of each Quarter during the Royalty Term (and if, and for such period as the public markets in China and/or India form part of the Developed World, with respect to royalties, if any, due pursuant to clause 16.3, throughout the Term) in which the Licensed Product or Combination Product is Marketed by an Emergent Company. Each Royalty Report will for the Territory:

18.1.1 set out the Net Sales of any Licensed Product and Combination Product by product and country;

18.1.2 set out all sales by Emergent Companies on which royalties are payable pursuant to clause 16.2 or 16.3;

18.1.3 set out any royalties paid to Enabling Third Parties pursuant to clause 16.6 or 16.7; and

18.1.4 provide a calculation of the royalties due.

On receipt of the Royalty Report, the Company shall issue an invoice for the royalties due. Emergent must pay the Company all sums due in respect of each Quarter within thirty (30) days of receipt of the relevant invoice.

18.2 Emergent Companies must keep complete and accurate records of all commercial uses made of the Licensed Technology in the Territory during the Royalty Term (and during the Term with respect to public markets in China and/or India if and for such period as such markets form part of the Developed World) including accounts of all Licensed Product and Combination Product used and Marketed by an Emergent Company in each Licence Year by product and country for at least six (6) years after the end of the relevant Licence Year. The Company may, through an independent certified accountant, audit all such records (including accounts) during normal business hours on at least thirty (30) days' written notice no more than once in any Licence Year for the purpose of determining whether sums are due to the Company under this agreement and the accuracy of the Royalty Reports and payments. Emergent Companies will:

18.2.1 co-operate with the Company and the independent accountant; and

18.2.2 promptly provide them with all information and records which they may reasonably request for the purposes of this clause 18.2 during normal business hours;

provided that all books and financial records made available to such accountant shall be deemed to be Confidential Information and the accountant shall disclose whether or

not the Royalty Reports are accurate and the specific details regarding any inaccuracies but no other information.

18.3 If the actual figure determined by the accountant is one hundred and five percent (105%) or more of that disclosed by Emergent's Royalty Reports for the same period then Emergent will bear the accountant's costs. In all other cases the Company will bear the accountant's costs.

19 Duration and Termination

19.1 This agreement will take effect on the Effective Date, as stated on the first page of this agreement and, unless terminated earlier as provided herein, shall continue in effect until the expiry of the period of twenty (20) years from the grant of the first Marketing Authorisation for a Licensed Product or until the expiration date of the last to expire Valid Claim of the Isis Application, whichever is later. Notwithstanding expiration of the Royalty Term, Emergent shall continue to have access to and be entitled to use the Master Seed Stock and the Company Seed Stock and any master seed stock arising or manufactured by or on behalf of Emergent after expiry of the Royalty Term shall belong to Emergent.

19.2 Either Party may terminate this agreement, in its entirety, immediately on written notice, if the other Party has a petition presented for its winding-up, or passes a resolution for voluntary winding-up otherwise than for the purposes of a bona fide amalgamation or reconstruction, or compounds with its creditors, or has an administrator, receiver or administrative receiver appointed of all or any part of its assets, or enters into any arrangements with creditors, or takes or suffers any similar action in consequence of debts.

19.3 Emergent may terminate this agreement:

19.3.1 on not less than thirty (30) days' written notice (i) if the approvals of the relevant Regulatory Authorities and Ethics Committees required to commence the Infant Phase IIb Study have not been obtained by 1 December 2009; or (ii) if, for any reason, no Study Subject in such trial has been dosed by 31 May 2010;

19.3.2 for any or no reason on no less than twelve (12) months' written notice served after the expiration of the Phase IIb Period; provided that in the event that any clinical trial sponsored by an Emergent Company and being conducted as part of the Overall Development Plan is ongoing at the Termination Date, Emergent shall, unless otherwise agreed with the Company and subject to Applicable Law, complete such ongoing clinical trial; and further provided that, notwithstanding anything to the contrary in this agreement or the SSA, Emergent shall not be obliged to commence any clinical trials after the date on which such notice was served;

19.3.3 on not less than ninety (90) days' notice if a clinical trial for the Infant Indication within the Overall Development Plan does not meet its Trial Success Criteria; provided that to be effective such notice must be given within the period of ninety (90) days commencing on the date on which Emergent receives the final results of such clinical trial;

19.3.4 on not less than sixty (60) days' notice if a clinical trial of the Licensed Product, within or outside the Overall Development Plan, is suspended or

terminated for safety reasons; provided that to be effective such notice must be given within the period of ninety (90) days commencing on the date on which Emergent receives notice of such suspension or termination;

19.3.5 subject to clause 19.5, on written notice, if the Company commits a material breach of this agreement, and the breach is not remedied (where remediable) within ninety (90) days of the notice given by Emergent in writing calling on the Company to effect such remedy or, if the relevant default cannot be cured within ninety (90) days, such longer period as may reasonably be required for the Company, acting diligently, to cure such breach; provided that the Company shall not be considered to be in breach of this agreement if any failure to satisfy an obligation in this agreement is a result of any act or omission of Emergent;

19.3.6 for any or no reason on thirty (30) days' written notice, provided that to be effective such notice must be given within the period of six (6) months commencing on the date on which Emergent receives the final report of the Infant Phase IIb Study, the Bridging Study and the De-escalation Study, whichever is the later; provided that notwithstanding such termination Emergent shall, if the Trial Success Criteria for the Infant Phase IIb Study have been achieved, pay to the Company the Milestone Fee payable on the Successful Completion Date of the Infant Phase IIb Study, but shall be under no further obligations to the Company other than those in clauses 19.7 and 19.8, and those which are expressed to survive termination of this agreement pursuant to clauses 19.10 and 19.11. For the avoidance of doubt, (i) if the Trial Success Criteria for the Infant Phase IIb Study are not achieved and (ii) Emergent terminates this agreement pursuant to this clause 19.3.6, Emergent shall not be required to pay the Milestone due on Successful Completion Date of the Infant Phase IIb Study even if the Company or any Thirty Party commences a Phase III Clinical Trial for a Licensed Product; or

19.3.7 on no less than thirty (30) days' written notice if the Company terminates the Isis Licence Agreement for a material breach of that agreement by Isis.

19.4 The Company may terminate this agreement:

19.4.1 subject to clauses 2.12, 6.4 and 19.5, on written notice, if Emergent commits a material breach of this agreement, and the breach is not remedied (where remediable) within the period allowed by notice given by the Company in writing calling on Emergent to effect such remedy such period being not less than ninety (90) or, if the relevant default cannot be cured within ninety (90) days, such longer period as may reasonably be required for Emergent, acting diligently, to cure such breach; provided however that without limitation, Emergent's breach of any obligation in clauses 7.1.1, 10.1 and 10.8 will be a material breach; or

19.4.2 without prejudice to clause 19.4.1, if Emergent applies for a declaration of invalidity or files oppositions or applications for revocation or re-examination, with respect to any Isis Application or conducts any measure equivalent to any of the foregoing actions in any jurisdiction; provided however that nothing in this agreement shall prevent Emergent or any of

its sub-licensees from raising any defence available to it or required to be raised in any action for infringement of the Isis Applications brought by the Company or any of its sub-licensees and the Company shall not be entitled to terminate this agreement pursuant to this clause 19.4.2 in such circumstances.

19.5 If the Parties disagree whether there has been a breach giving rise to the right to terminate under clauses 19.3.5 (Company's breach) or 19.4.1 (Emergent's breach) or if, on the expiry of any remedy period provided for in the relevant clause, the Parties disagree whether the breach has been remedied, they will initiate the dispute resolution procedure in clause 22.17 and this agreement will continue in full force and effect pending resolution of the dispute. On a decision pursuant to 22.17 that there has been a breach, the Party in breach will remedy such breach and on a decision that a breach has not been remedied, the Party in breach will be given the opportunity to remedy such breach (unless there has been a prior decision finding that the breaching Party has failed to remedy the same breach), in each case within the cure period provided for in 19.3.5 or 19.4.1 (as appropriate); provided that such remedy period shall commence on the date of such decision.

19.6 On termination of this agreement by Emergent pursuant to clause 19.2 (Company's insolvency) or clause 19.3.5 (Company's breach) Isis and Emergent shall, unless the Isis Licence Agreement has been terminated for breach by, or the insolvency of, Isis such that the Company's licence under such agreement converts into a fully paid up, perpetual licence, negotiate in good faith a licence agreement pursuant to which Isis grants Emergent rights, subject to obligations, in each case substantially similar to those granted to, and accepted by, Emergent pursuant to this agreement, failing which, or if the Isis License Agreement has been so terminated:

19.6.1 the Licence shall convert into a fully paid up, exclusive (save as set out in clause 2.3) perpetual licence with the right to grant sub-licences through multiple tiers provided that the license granted pursuant to clause 2.3 shall continue as set out in clause 2.7;

19.6.2 notwithstanding such termination, Emergent shall continue to have access to and be entitled to use the Master Seed Stock and the Company Seed Stock for the purpose of exercising its rights pursuant to clause 19.6.1, the Company shall, at the Company's cost, deliver to Emergent, or its nominee, such Master Seed Stock or Company Seed Stock within thirty (30) days of the Termination Date and any master seed stock arising or manufactured by or on behalf of Emergent after such termination shall belong to Emergent;

19.6.3 the Company will, at the Company's cost, (i) provide Emergent with such assistance as is reasonably necessary to effectuate a smooth and orderly transition to Emergent (or as it may direct), of any Development activities then being conducted by or on behalf of the Company pursuant to the Overall Development Plan; and (ii) use its Efforts to transfer to Emergent (or its nominee) any Regulatory Approvals, applications and regulatory documentation relating to activities conducted for any Licensed Product or a Company Combination Product which the Company Controls at the Termination Date;

19.6.4 provided that the Developing World Distributor is not in breach of any agreement it may have with the Company, the Emergent Licence shall continue solely to the extent necessary to enable any Developing World Distributor to Develop and Market Licensed Products and, if at that time the Developing World Distributor has been granted rights with respect to the same, Company Combination Products, in each case in the Field outside the Territory unless, at Emergent's option, Emergent enters into a direct licence with such Developing World Distributor;

19.6.5 the Emergent Licence shall continue solely to the extent necessary to enable the University, University Personnel and University Collaborators to continue to use Emergent Data disclosed to such persons prior to the Termination Date for Non-Commercial Use;

19.6.6 subject as set out in clauses 19.6.4 and 19.6.5, all licences and rights granted to the Company with respect to Emergent Manufacturing Technology and Emergent Data or otherwise in connection with the Exploitation of Licensed Products or Combination Products shall terminate on the Termination Date;

19.6.7 the Company will provide Emergent with copies of all agreements and arrangements to which it is a party (but Emergent is not) which relate solely to the Development of one or more Licensed Products or Combination Products, within thirty (30) days of the Termination Date;

19.6.8 provided that the termination of this agreement was not caused directly or indirectly by the other party to the Contract and that the other party is not then in breach of such Contract, use its Efforts to deal with each Contract, at Emergent's reasonable request, in one of the following ways: (i) assign the benefit (subject to the assumption of the burden) of the Contract to Emergent or its nominee and, where consent of a Third Party is required, seek to obtain such consent; (ii) novate the Contract to Emergent or its nominee; or (iii) terminate the Contract in accordance with its terms at the Company's cost;

19.6.9 if any agreements or arrangements relating to a Licensed Product or a Combination Product also relate to other products, use its reasonable endeavours to provide Emergent with a copy of such agreement redacted to remove the confidential information of any Third Party;

19.6.10 if Emergent notifies the Company that the assignment or novation of a Contract to Emergent in accordance with clause 19.6.8 is required to enable Emergent to continue the Exploitation of a Licensed Product or a Combination Product, use its Efforts, until such assignment or novation takes effect or, if the Company is unable to assign or novate such Contract, for a maximum period of six (6) months, to perform its obligations under such Contract, and Emergent shall reimburse the Company for all costs incurred in performing the Contract in accordance with Emergent's instructions after the Termination Date, provided that, if it is permissible under such Contract, Emergent shall perform such obligations on behalf of the Company (but at Emergent's expense); and

19.6.11 without prejudice to clauses 19.10 and 19.11, clauses 2.9 (other than clause 2.9.1), 3.7, 6, 9.2, 13.4, 13.7, 14.5, 19.6 and 21.1 will survive such termination indefinitely.

19.7 On termination of this agreement, other than by Emergent pursuant to clause 19.2 (Company's insolvency) or clause 19.3.5 (Company's breach) (in which event clause 19.6 shall apply), Emergent will:

19.7.1 subject to clauses 19.7.2 and 19.12, on the Termination Date cease to use the Licensed Technology for any purpose and cease to Exploit any Licensed Product or any Combination Product anywhere in the Territory;

19.7.2 have the right to exhaust supplies of Licensed Products and any Combination Products then in inventory;

19.7.3 use its Efforts to promptly transfer to the Company (or its nominee), at Emergent's cost, the OMP Designation and any Regulatory Approvals relating solely to a Licensed Product or a Company Combination Product;

19.7.4 to the extent held by or on behalf of Emergent on the Termination Date ship to the Company (or its nominee) the Company's Seed Stock within thirty (30) days of the Company requesting such materials;

19.7.5 grant the Company a perpetual, non-exclusive licence under the Emergent Manufacturing Technology, to the extent necessary to enable the Company to continue Exploitation of the Licensed Product or Company Combination Product in the Field in the form and as conducted by the Company immediately prior to the Termination Date;

19.7.6 grant the Company a non-exclusive licence in the Territory to access, reference and otherwise use the Emergent Data and the Emergent Regulatory Documents, in each case to the extent necessary to enable the Company to continue Exploitation of the Licensed Product or Company Combination Product in the Field in the form and as conducted by Emergent immediately prior to the Termination Date;

19.7.7 grant the Company a non-exclusive licence to access and use the Emergent Seed Stock and Emergent shall deliver to the Company, or its nominee, such Emergent Seed Stock within thirty (30) days of the Termination Date;

19.7.8 provide the Company with copies of all sub-licences, contract manufacturing agreements and other agreements and arrangements to which it is a party (but the Company is not) which relate solely to the Exploitation of one or more Licensed Product or a Company Combination Product, within thirty (30) days of the Termination Date;

19.7.9 provided that the termination of this agreement was not caused directly or indirectly by the sub-licensee or other party to the Contract and that sub-licensee or other party is not then in breach of such Contract, use its Efforts to deal with each Contract, at the Company's reasonable request, in one of the following ways: (i) assign the benefit (subject to the assumption of the burden) of the Contract to the Company or its nominee and, where consent of a Third Party is required, seek to obtain such

consent; (ii) novate the Contract to the Company or its nominee; or (iii) terminate the Contract in accordance with its terms at Emergent's cost;

19.7.10 if any sub-licences, contract manufacturing agreements or other agreements or arrangements relating to a Licensed Product or a Company Combination Product also relate to other products, use its reasonable endeavours to provide the Company with a copy of such agreement redacted to remove the confidential information of any Third Party;

19.7.11 if the Company notifies Emergent that the assignment or novation of a Contract to the Company in accordance with clause 19.7.9 is required to enable the Company to continue the Exploitation of a Licensed Product or a Company Combination Product, use its Efforts, until such assignment or novation takes effect or, if Emergent is unable to assign or novate such Contract, for a maximum period of six (6) months or, in relation to the supply of the Licensed Product or a Company Combination Product two (2) years, to perform its obligations under such Contract, and the Company shall reimburse Emergent for all costs incurred in performing the Contract in accordance with the Company's instructions after the Termination Date, provided that, if it is permissible under such Contract, the Company shall perform such obligations on behalf of Emergent (but at the Company's expense), and further provided that in no event shall Emergent be under any obligation to develop or acquire any manufacturing methods or other technologies in addition to what has been developed at the Termination Date;

19.7.12 prior to or within thirty (30) days of the Termination Date provide the Company with one copy of each piece of marketing literature for the Licensed Product or a Company Combination Product (if any) and destroy all other copies of such marketing literature after the sale of inventory in accordance with clause 19.7.2;

19.7.13 use its Efforts to promptly transfer to the Company (or its nominee), at Emergent's cost, all Regulatory Approvals and applications for Regulatory Approvals for any Licensed Product or a Company Combination Product which Emergent Controls at the Termination Date; and

19.7.14 without prejudice to clauses 19.10 and 19.11, clauses 19.7 and 21.2 will survive such termination indefinitely;

provided that, if this agreement is terminated by Emergent pursuant to clause 19.3.4 because of the suspension or termination of a clinical trial (whether inside or outside the Overall Development Plan) as a direct result of adverse safety data arising from a Phase I Clinical Trial conducted by the University outside the Overall Development Plan, all actions described in clause 19.7 shall be undertaken at the Company's cost and the licences granted pursuant to clauses 19.7.5, 19.7.6 and 19.7.7 shall be subject to payment of such reasonable royalties as may be agreed by the Parties (or, in the absence of agreement within three (3) months of the Termination Date, as determined by an Expert. All licences in this clause 19.7 shall otherwise be free of charge, provided that, if and to the extent that the Company requires access to any Intellectual Property Rights Controlled by a Third Party, the Company shall be responsible for all royalty and other payments due to such Third Party and shall reimburse Emergent for any amounts due to such Third Party in connection with the

Exploitation of Licensed Products and Company Combination Products. Without prejudice to the provisions of this clause 19.7 each of the Parties shall co-operate fully with the other to ensure a smooth and uninterrupted transition of any Development activities relating to any Licensed Product or Combination Product and the supply of any Licensed Product or a Company Combination Product following the Termination Date.

19.8 On expiration or termination of this agreement for any reason, each Party shall promptly return or, at the other Party's request or, with its consent (such consent not to be unreasonably withheld, conditioned or delayed), destroy, all Confidential Information of the other Party that is not subject to a licence grant hereunder that survives such expiration or termination; provided that each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations under this agreement.

19.9 For the avoidance of doubt any rights granted by Emergent with respect to the Exploitation of Licensed Products or Combination Products by the Company following the Termination Date are subject to clause 3.8.

19.10 Clauses 2.2 (with respect to Emergent ODP Technology and Company Manufacturing Technology conceived, discovered, developed or otherwise made prior to the Termination Date or date of expiration), 2.4 (with respect to Correlates established prior to the Termination Date or date of expiration), 3.5.1 (to the extent necessary to enable the University, University Personnel and University Collaborators to continue to use Emergent Data disclosed to such persons prior to the Termination Date or date of expiration, for Non-Commercial Use), 4.4, 4.5, 7.4 (with respect to Samples provided to the Company prior to the Termination Date or date of expiration), 9.2, 14.4, 19.9, 21.1 to 21.7, 22.2 and 22.14 to 22.20 and any other provisions expressed to survive termination or expiration of this agreement, will survive the termination or expiration of this agreement, for whatever reason, indefinitely.

19.11 Clauses 15 and 19.8 will survive the termination or expiration of this agreement, for whatever reason, for a period of six (6) years.

19.12 Notwithstanding any other provisions of this agreement, the licences granted to Emergent pursuant to clauses 2.2 and 12 shall survive expiration of this agreement or its termination for any reason.

19.13 If the Company terminates this agreement pursuant to clause 19.2 (Emergent's insolvency) or clause 19.4.1 (Emergent's breach) and at such time Emergent has Control of any Trademark used in connection with the Exploitation of Licensed Products or Company Combination Products in the Territory at the Termination Date (other than any corporate name or logo), Emergent will assign such Trademark to the Company.

20 Warranties

20.1 Each Party hereby warrants to the other Party that:

20.1.1 it is duly organised and validly existing under the laws of England and Wales;

20.1.2 the execution and performance by it of its obligations under this agreement will not:

20.1.2.1 result in a breach of any provision of its Memorandum of Association or Articles of Association; or

20.1.2.2 result in a breach of or constitute a default under any agreement, instrument or arrangement to which it is a party, or any order, judgement or decree of any court or governmental agency to which it is bound; and

20.1.3 it has taken all corporate action necessary for the authorisation, execution and delivery of this agreement.

20.2 The Company hereby warrants to Emergent that as at the Effective Date to the best of its knowledge and belief (which knowledge and belief shall be the knowledge and belief of the Inventors, [**]):

20.2.1 Isis is the applicant for the Isis Applications;

20.2.2 the Inventors have executed such assignments as have been required by the relevant patent offices to pass all of their right, title and interest in and to the Isis Applications in each country where the Isis Applications are active, to the Company;

20.2.3 each existing application and all prior applications to which a priority claim is made under the Patent Applications have been properly filed and all applicable fees with respect to any such application have been paid on or before the due date for payment;

20.2.4 the Inventors were employed by the University at the time of their inventive contribution to the invention claimed in the Isis Applications and throughout its reduction to practice;

20.2.5 to the extent that any work giving rise to the Licensed Technology was funded by a Third Party, the terms of such funding provided for any arising Intellectual Property Rights to vest in the University;

20.2.6 the University has assigned all of its right, title and interest in and to the Isis Applications to Isis;

20.2.7 neither it nor Isis nor the University, has received any notice that a person other than an Inventor has asserted or is asserting any claim to be an inventor of the invention claimed in the Isis Applications;

20.2.8 neither it nor Isis nor the University has granted any ongoing right in or to the Isis Applications, the Master Seed Stock, the Company Manufacturing Technology or the Existing Data to a Third Party other than (i) in respect of the data detailed in schedule 4, part B, and (ii) rights to use MVA85A for non-commercial academic purposes granted to the institutions listed in schedule 10 under material transfer agreements; nor has it or the University entered into any covenant not to sue with respect to the Licensed Technology;

20.2.9 neither it nor Isis nor the University has received any report, pursuant to a material transfer agreement referred to in clause 20.2.8, of an Improvement with respect to MVA85A;

20.2.10 save for the opposition filed in Ecuador by the Association of Pharmaceutical Laboratories of Ecuador, neither Isis nor the University has received any notice (i) that the Licensed Technology existing as of the Effective Date is invalid or unenforceable, in whole or in part; or (ii) alleging that the Isis Applications are invalid or unenforceable;

20.2.11 there is no actual infringement or threatened infringement or misappropriation of the Licensed Technology by any Third Party;

20.2.12 the University was the sponsor of all clinical trials from which the Existing Data have been obtained;

20.2.13 the only MVA858A used in any clinical trial involving a Licensed Product sponsored by the University was from lots 010402 and 010507 manufactured by IDT;

20.2.14 Isis has disclosed all adverse information with respect to the safety and efficacy of MVA85A; and

20.2.15 Isis has disclosed, with respect to all clinical trials of which the University is the Sponsor involving a Licensed Product, (i) all material communications with Regulatory Authorities; (ii) any ethics committee refusal to grant approval for the clinical trial or refusal to approve an amendment to the protocol for the clinical trial; (iii) any suspension of the clinical trial, whether initiated by the sponsor, an ethics committee, a Regulatory Authority or an investigator; (iv) any action or recommendation of a data safety monitoring board to suspend the clinical trial; and (v) all findings of any audit of the clinical trial for compliance with cGCP; in each case which the Company or the University received or became aware of after 1 September 2007.

20.3 The Company hereby warrants to Emergent that neither the Company nor Isis nor the University, nor any officer, employee, or to the knowledge of the Company, Isis or the University, contractor or agent of the Company, Isis or the University, in each case involved with the generation of the Existing Data, has been debarred or is subject to debarment under Section 306 of the Federal Food, Drug, and Cosmetic Act, as amended.

20.4 Neither Party shall be liable to the other for damages for a breach of a warranty in this clause 20. The only remedy which the Parties may exercise for a breach of a warranty in this clause 20 is, in circumstances where such breach is material, to terminate this agreement pursuant to clause 19.3.5, in the case of Emergent, and clause 19.4.1, in the case of the Company.

20.5 Except as expressly provided in this agreement, and to the fullest extent permissible by law, the Company does not make any warranties of any kind including warranties with respect to:

20.5.1 the quality of the Licensed Technology;

20.5.2 the suitability of the Licensed Technology for any particular use;

20.5.3 whether use of the Licensed Technology will infringe third-party rights; or

20.5.4 whether the Isis Application will be granted or the validity of any patents that issue in response to the Isis Application.

21 Liability and Indemnities

21.1 Subject to clause 21.5, Emergent agrees to indemnify the Company and hold the Company harmless from and against any and all claims, damages and liabilities asserted by Third Parties (including claims for negligence) ("**Third Party Claims**") which arise directly or indirectly from the use of the Licensed Technology or the Marketing of any Licensed Product or Combination Product by Emergent or its permitted sub-licensees and/or sub-contractors (other than the Company, the University or any University Personnel) unless if and to the extent such claim is a result of the supply of defective Licensed Product or Combination Product by or on behalf of the Company; except for Third Party Claims (i) relating to or arising in connection with Intellectual Property Rights, including any allegation that Exploitation of the Licensed Technology, Data or Emergent Manufacturing Technology infringes the rights of any Third Party; or (ii) if and to the extent the Company has an obligation to indemnify Emergent and its permitted sub-licensees pursuant to clause 21.2.

21.2 Subject to clause 21.6, the Company agrees to indemnify Emergent and its permitted sub-licensees harmless from and against any and all Third Party Claims which arise directly or indirectly from the use of the Licensed Technology or the Marketing of any Licensed Product or Combination Product by the Company, the University, University Personnel or University Collaborators or their respective sub-licensees and/or sub-contractors (other than by Emergent and its permitted sub-licensees and/or subcontractors) unless if and to the extent such claim is a result of the supply of defective Licensed Product or Combination Product by or on behalf of Emergent except for Third Party Claims (a) relating to or arising in connection with Intellectual Property Rights, including any allegation that Exploitation of the Licensed Technology or Data by Emergent or its permitted sub-licensees and/or sub-contractors infringes the rights of any Third Party; or (b) if and to the extent Emergent has an obligation to indemnify the Company pursuant to clause 21.1.

21.3 Each of the Parties will, and Emergent shall procure that its permitted sub-licensees will, use reasonable endeavours to avoid, dispute, resist, appeal, compromise or defend any Third Party Claim brought against it and to minimise its losses, claims, liabilities, costs, charges and expenses. The indemnified party shall give the indemnifying Party prompt written notice of any Third Party Claim for which it requires indemnification under this clause 21 together with copies of all relevant papers and official documents. The Parties shall confer on how to respond to the Third Party Claim and how to handle the Third Party Claim in an efficient manner. In the event that a party is seeking indemnification under this clause 21 it shall permit the indemnifying Party (at the indemnifying Party's option) to assume direction and control of the defence of the Third Party Claim (including the right to settle the claim solely for monetary consideration), and shall co-operate as requested (at the expense of the indemnifying Party) in the defence of the Third Party Claim. The indemnified party will not (except as required by Applicable Law) take any material action (including any admission, compromise, settlement or discharge of any claim) in respect of any Third Party Claim without the consent of the indemnifying Party (which will not be unreasonably withheld, conditioned or delayed).

21.4 The liability of either Party for any breach of this agreement, or arising in any other way out of the subject-matter of this agreement, will not extend to incidental or consequential damages or to any indirect loss of profits.

21.5 The Company's sole remedy for breach of any provision of this agreement by Emergent shall be either specific performance or to terminate the agreement where the breach gives rise to a termination right under clause 19.4.1. The Company may recover under the indemnity set out in clause 21.1 up to a maximum of seven million five hundred thousand pounds (£7,500,000) per claim or series of related claims.

21.6 Emergent's sole remedy for breach of any provision of this agreement by the Company shall be either specific performance or to terminate the agreement where the breach gives rise to a termination right under clause 19.3.5. Emergent may recover under the indemnity set out in clause 21.2 up to a maximum of seven million five hundred thousand pounds (£7,500,000) per claim or series of related claims.

21.7 Nothing in this clause 21 will limit either Party's liability for fraud or intentional misconduct, or death or personal injury arising as a result of that Party's negligence.

21.8 The Company will (itself or through an Emergent Company) obtain and continuously maintain the following insurance with an insurance company of a credit rating of A or better or self-insure:

21.8.1 during the period covered by the Overall Development Plan, clinical trials insurance of at least seven million five hundred thousand pounds (£7,500,000) per claim including non-negligence cover in accordance with the conditions of the Associated British Pharmaceutical Industry agreed wording;

21.8.2 from the date of first Marketing Authorisation, product liability insurance of at least seven million five hundred thousand pounds (£7,500,000) per occurrence; and

21.8.3 during the Term and for at least two (2) years afterwards, general commercial liability insurance (public liability for bodily injury and property damage), including contractual liability, of at least seven million five hundred thousand pounds (£7,500,000) per occurrence.

21.9 Emergent will (itself or through an Emergent Company) obtain and continuously maintain the following insurances with an insurance company of a credit rating of A or better:

21.9.1 during the period covered by the Overall Development Plan, clinical trials insurance of at least seven million five hundred thousand pounds (£7,500,000) per claim including non-negligence cover in accordance with the conditions of the Associated British Pharmaceutical Industry agreed wording;

21.9.2 from the date of first Marketing Authorisation, product liability insurance of at least seven million five hundred thousand pounds (£7,500,000) per occurrence; and

21.9.3 during the Term and for at least the duration of any applicable statutory period of limitation afterwards, general commercial liability insurance (public liability for bodily injury and property damage), including contractual liability, of at least seven million five hundred thousand pounds (£7,500,000) per occurrence.

21.10 Each Party will:

21.10.1 provide the other with a copy of each such insurance policy and certificate and annually on renewal; provided that each Party may redact from each such policy and certificate any information that is not relevant to the insurance requirements under this agreement;

21.10.2 notify the other of any claims made under these policies relating to Licensed Products or Combination Products or the subject matter of this agreement during the Term and for at least the duration of any applicable statutory period of limitation afterwards; and

21.10.3 comply with the terms of these insurance policies during the Term and for at least the duration of any applicable statutory period of limitation afterwards.

22 General

22.1 **Further Assurance** – Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to implement or give effect to this Agreement.

22.2 **Advertising** – Emergent must not use the name of the Company, the University or the Inventor in any advertising, promotional or sales literature, without the Company's prior written approval.

22.3 **Packaging** – Emergent will ensure that any Licensed Product and Combination Product and the packaging associated with them are marked suitably with any relevant patent or patent application numbers to satisfy the laws of each of the countries in which such products are sold or supplied and in which they are covered by the claims of any patent or patent application, to the intent that the Company shall not suffer any loss or any loss of damages in an infringement action.

22.4 **Taxes** – Where Emergent has to make a payment to the Company under this agreement which attracts value-added, sales, use, excise or other similar taxes or duties, Emergent will be responsible for paying those taxes and duties against issue by the Company of a valid invoice in the prescribed form. All invoices shall be in a form reasonably acceptable to Emergent.

22.5 **Notices** – All notices, requests, demands and other communications required or permitted to be given pursuant to this agreement shall be in writing and should be sent, by courier, post or facsimile (but not e-mail) unless agreed otherwise in writing, provided the Parties may communicate by e-mail, and reference to "writing" will be deemed to include communications by e-mail (i) in connection with the day to day operation of this agreement (including the submission of Marketing Plans, Royalty Reports and revisions to the overall Development Plan), (ii) for the transmission of technical data and (iii) as otherwise agreed by the Parties. Any such communication will be deemed to have been given (a) when delivered, if personally delivered or sent by facsimile on a Business Day (so long as promptly confirmed by post), and (b) on the second Business Day after despatch, if sent by courier or post. All notices to be sent to the Company should be sent until further notice to the Company's Contact and Address. All notices to be sent to Emergent under this agreement should be sent, until further notice, to Emergent's Contact and Address, with a copy to Emergent Parent's Contact and Address. All notices to be sent to Emergent Parent under this agreement should be sent, until further notice, to Emergent Parent's Contact and

Address. No notice of default or termination shall be deemed effective unless delivered by two (2) of the aforementioned delivery routes.

22.6 **Force Majeure** – If performance by either Party of any of its obligations under this agreement (not including an obligation to make payment) is prevented by circumstances beyond its reasonable control, that Party will be excused from performance of that obligation for the duration of the relevant event.

22.7 **Assignment** – No Party may assign any of its rights or obligations under this agreement in whole or in part, without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; provided that this clause shall not prevent Emergent granting sub-licences under the Licensed Technology as permitted by this agreement or appointing any sub-contractors to perform any of its obligations under this agreement, provided further that the appointment of a sub-contractor shall not relieve Emergent in any way whatsoever from its obligations under this agreement, and Emergent shall remain liable for the acts or omissions of any sub-contractor.

22.8 **Severability** – If any of the provisions of this agreement is or becomes invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions will not in any way be affected or impaired. The Parties will, however, negotiate to agree the terms of a mutually satisfactory provision, achieving as nearly as possible the same commercial effect, to be substituted for the provision found to be void or unenforceable.

22.9 **No Partnership etc** – Nothing in this agreement creates, implies or evidences any partnership or joint venture between the Company and Emergent or the relationship between them of principal and agent.

22.10 **Entire Agreement** – This agreement (including the recitals and schedules), the SSA and all the agreements entered into pursuant to the SSA constitute the entire agreement between the Parties relating to their subject matter, and supersede all prior written or oral agreements, representations or understandings between the Parties relating to that subject matter, except to the extent repeated in these agreements. Each Party confirms that, in agreeing to enter into this agreement, it has not relied on any representation, warranty, collateral contract or other assurance except those set out in these agreements. To the extent any previous representation, warranty, collateral contract or assurance was made to a Party (and is not repeated in this or any other agreement to which either Party is a party), such Party unconditionally and irrevocably waives all rights and remedies with respect thereto. Nothing in this agreement will operate to limit or exclude a Party's liability for fraud.

22.11 **Variation** – Any variation of this agreement must be in writing and signed by authorised signatories for both parties. For the avoidance of doubt, the Parties may rescind or vary this agreement without the consent of any party that has the benefit of clause 22.12.

22.12 **Rights of Third Parties** – The Parties intend that, by virtue of the Contracts (Rights of Third Parties) Act 1999, the University and each of Emergent's sub-licensees will be able to enforce the terms of, respectively clause 21.1 and clause 21.2 for their benefit as if they were party to this agreement.

22.13 **Isis** – Isis is a party to this agreement solely for the purposes of accepting its obligations under, and being able to enforce, for its benefit, the terms of, clauses 2.3, 13 and 19.6, subject to the limitations of liability in clause 21.

22.14 **Expert Opinion** – Any matter which may arise out of or in connection with this agreement and which is to be determined by an expert will be referred to a person suitably qualified to determine that matter who will be nominated by the Party seeking the Expert Opinion or resolution by an expert and approved by the other Party, such approval not to be unreasonably withheld, conditioned or delayed. The Expert will act as an expert and not as an arbitrator and his terms of appointment will include:

22.14.1 a requirement on the Expert to act fairly;

22.14.2 unless otherwise agreed by the Parties, a requirement on the Expert to hold adequate professional indemnity insurance both then and for at least the period of statutory limitation following the date of his determination;

22.14.3 confidentiality obligations reasonably acceptable to the Parties; and

22.14.4 a commitment by the Parties to supply to the expert all such assistance, documents and information as he may reasonably require for the purpose of his determination.

The decision of the Expert shall be final and conclusive, absent manifest error.

22.15 **Expedited Arbitration** – With respect to any matter which may arise out of or in connection with this agreement and which is to be determined by an Expert in accordance with this clause 22.15:

22.15.1 The Expert shall be appointed in accordance with clause 22.14.

22.15.2 Within fifteen (15) days after the designation of the Expert, the Parties shall each simultaneously submit to the Expert and one another a written statement (not to exceed fifteen thousand (15,000) words) of their respective positions on such disagreement. Each Party shall have five (5) days from receipt of the other Party's submission to submit a written response (not to exceed ten thousand (10,000) words) thereto, which shall include any scientific and technical information in support thereof. The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination.

22.15.3 No later than thirty (30) days after the designation of the Expert, the Expert shall make a determination by selecting the resolution proposed by one of the Parties that as a whole is the most fair and reasonable to the Parties in light of the totality of the circumstances and shall provide the Parties with a written statement setting forth the basis of the determination in connection therewith. The decision of the Expert shall be final and conclusive, absent manifest error.

22.16 **Governing Law** – This agreement is governed by and shall be construed in accordance with English Law.

22.17 **Dispute Resolution** – Subject to clause 22.18 and 22.19 any dispute which may arise out of or in connection with this agreement will be:

22.17.1 first referred by either Party to the President of the Company and the President of Emergent (or in each case, if there is no President at the relevant time, the equivalent senior officer) who will use their commercially reasonable efforts to negotiate with each other in good faith to reach a just and equitable settlement satisfactory to both Parties;

22.17.2 if, and to the extent that, they are unable to resolve the dispute within one (1) month of such referral, either Party may refer the dispute to arbitration in accordance with the London Court of International Arbitration Rules, such arbitration to be by three (3) arbitrators and held in the English language in London. The decision of the arbitrators will be final and binding on the parties in the absence of fraud or manifest error.

22.18 **Injunctive relief** – Either Party may seek injunctive relief in any court of competent jurisdiction at any time in relation to any dispute which may arise out of or in connection with this agreement.

22.19 **Disputes relating to Intellectual Property** – Matters relating to the initial ownership, validity, enforceability or infringement of Intellectual Property Rights in any country shall be determined in accordance with the intellectual property laws of that country and, subject as set out in this clause, shall be subject to the exclusive jurisdiction of the courts in that country and the parties hereby consent to the jurisdiction of such courts. If the Parties are unable to resolve a dispute relating to the ownership (including any dispute which relates to the allocation of ownership of Intellectual Property Rights as between the Parties as provided for in this agreement), validity, enforceability or infringement of Intellectual Property Rights, the Parties shall upon written request by either Party to the other, appoint a mutually acceptable disinterested, conflict-free individual not affiliated with either Party, with relevant experience necessary to mediate the resolution of such dispute (the "**IP Expert**"). The IP Expert shall enter into a confidentiality obligation reasonably acceptable to each of the Parties. The fees and costs of the IP Expert shall be shared equally by the parties. No Party may commence any court proceedings in relation to any such dispute arising out of this agreement (or, with respect to the allocation of ownership of Intellectual Property Rights as between the Parties as provided for in this agreement, an arbitration in accordance with clause 22.17.2) until it has attempted to settle the dispute by expert determination and either the expert determination has terminated or the other Party has failed to participate in the expert determination unless such delay would prejudice the right to issue proceedings. With respect to any court proceeding, the Parties hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) with respect to such disputes in the courts in the jurisdiction of the relevant Intellectual Property Rights and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in clause 22.5, or any other lawful means, shall be effective service of process for any action, suit or proceeding brought against it in any such court with respect to any such dispute.

22.20 **Export Control Regulations** – The rights and obligations of the Parties under this agreement shall be subject in all respects to United States laws and regulations, as shall from time to time govern (i) the licence and delivery of technology and products

between the United States and other countries in the Territory, or (ii) the disclosure in the United States to a foreign national, unless such individual has been granted U.S. citizenship, permanent residence, or asylee status (a “deemed export,” as that term is defined in 15 C.F.R. § 734.2(b)(2)(ii)), including in each case ((i) and (ii)) the United States Foreign Assets Control Regulations, Transaction Control Regulations and Export Control Regulations, as amended, and any successor legislation issued by the Department of Commerce, International Trade Administration, Office of Export Licensing. Each Party agrees that, unless prior authorisation is obtained from the Office of Export Licensing, it shall not export, re-export, transship, or “release” (as that term is defined in 15 C.F.R. § 734.2(b)(3)), directly or indirectly, to any country, any of the Licensed Technology, Data, Emergent Improvements or Confidential Information disclosed to it by the other Party if such export would violate the laws of the United States or the regulations of any department or agency of the United States Government.

SCHEDULE 1 - DEFINITIONS AND INTERPRETATION

1 Definitions

Adolescent Indication means adolescent and young adult humans between ten (10) and twenty-four (24) years of age (or any range of ages therein), or such other age ranges for adolescents as Regulatory Authorities may determine.

Adolescent Marketing Approval means the first Marketing Authorisation to Market a Licensed Product for the Adolescent Indication in the EEA.

Aeras means Aeras Global TB Vaccine Foundation whose principal offices are at 1405 Research Blvd., Rockville, MD 20850, United States.

Aeras Agreement means the development and distribution agreement entered into by the Company and Aeras pursuant to the SSA.

Approved Alternative Strategy has the meaning set out in clause 10.9.

Applicable Law means the laws, rules and regulations (including the Regulations and any rules, regulations, guidelines or other requirements of any Ethics Committee, Regulatory Authority or national and international patent offices) that may be in effect from time to time in the Territory, to the extent applicable including cGCP, cGMP and any other laws, rules and regulations relating to the conduct of clinical research and the protection of the privacy of those involved in any such clinical research.

Board means the board of directors of the Company from time to time.

Bridging Study means the bridging study (TB016A1) described in the Overall Development Plan.

Budget means the budget of the Company adopted by the Company from time to time.

Business Day means a day (other than a Saturday or Sunday) on which the banks are ordinarily open for business in the City of London.

cGCP means the then-current standards of good clinical practice established under Applicable Law which for the purpose of this definition shall be deemed to include standards of good clinical practice at least equivalent to European Community Directives 2001/20/EC and 2005/28/EC, relevant national implementations of such Directives and applicable guidelines, including but not limited to the then-current version of ICH Topic E6: Good Clinical Practice: Consolidated Guideline.

cGMP means the then-current standards of good manufacturing practices established under Applicable Law which for the purpose of this definition shall be deemed to include a standard of good manufacturing practice at least equivalent to the good manufacturing practices set forth in European Community Directives 2003/94/EC, 2001/83/EC, 2001/20/EC and 2005/28/EC, all relevant implementations of such directives, and relevant guidelines including Volume 4 of the Rules Governing Medicinal Products in the European Union: Medicinal products for human and veterinary use: Good manufacturing practices and the national implementations of these rules.

Combination Product means a Company Combination Product or an Emergent Combination Product.

Company Combination Product means a Licensed Product sold (or being Developed for sale) in a co-formulated combination with an Other Product Controlled by the Company.

Company Data means the Existing Data and the Company New Data.

Company Know-how means all Know-how Controlled by the Company at (i) the Effective Date; or (ii) any time during the Term, in each case that is necessary or reasonably useful for the Exploitation of Licensed Products or Combination Products, including any Know-how vesting in the Company pursuant to clause 12 but excluding Company Data, Company Regulatory Documents, Company Manufacturing Technology and Emergent ODP Technology.

Company Manufacturing Technology means all Manufacturing Technology Controlled by the Company at the Effective Date or at any time during the Term.

Company New Data means all data, protocols, standard operating procedures and written documentation generated for or as a result of (i) activities performed by or on behalf of the Company (other than by an Emergent Company) under the Overall Development Plan; or (ii) a clinical trial or other scientific study relating to the Licensed Product which is Controlled by the Company at any time during the Term.

Company Patent Rights means the Isis Applications at the Effective Date and all Patent Rights Controlled by the Company at any time during the Term that are necessary or reasonably useful for the Exploitation of Licensed Products or Combination Products. Any Patent Rights vesting in the Company pursuant to clause 12, including any Patent Rights that claim Company Manufacturing Technology, shall on vesting be Company Patent Rights.

Company Regulatory Documents means all applications, registrations, governmental licences, authorisations and approvals (including any Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities relating to a Licensed Product or Combination Product and all supporting documents and all data contained in any of the foregoing, Controlled by the Company at the Effective Date or at any time during the Term.

Company Seed Stock means the seed stock of any Licensed Product or Combination Product Controlled by the Company, but excluding the Master Seed Stock.

Company's Contact and Address means the address for the Company set out in schedule 2.

Confidential Information means, in relation to each Party, all information and Know-how and any tangible embodiments thereof provided by or on behalf of such Party to another Party either in connection with the discussions and negotiations pertaining to, or in the course of performing, this agreement, including the terms of this agreement; marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For purposes of this agreement, notwithstanding the Party that disclosed such information or Know-how, (a) all Company Data, Company Know-how, Company Manufacturing Technology and Emergent ODP Technology shall be Confidential Information of the Company, and (b) all Emergent Data and Emergent Manufacturing Technology shall be Confidential Information of Emergent.

Contracts means for the purpose of clause 19.6, any and all agreements and arrangements disclosed to Emergent by the Company in accordance with clause 19.6.7, and for the purpose of clause 19.7, any and all agreement arrangements disclosed to the Company by Emergent in accordance with clause 19.7.8.

Control means, with respect to any Intellectual Property Right, documents, materials or other property or right, possession of the right, whether directly or indirectly, and whether by ownership, license (other than pursuant to this agreement) or otherwise, to transfer, assign, or grant a licence, sub-licence or other right (including a right of reference) to or under, such Intellectual Property Right, documents, materials or other property or right as provided for herein, without violating the terms of any agreement, or other arrangement, with any Third Party. "**Controls**" and "**Controlled by**" shall be construed accordingly.

Correlate means any surrogate or correlate of protective immunity against *Mycobacterium tuberculosis* disease in humans.

Data means the Company Data and Emergent Data.

De-escalation Study means the age de-escalation study (TB016A2) described in the Overall Development Plan.

Developed World means all the countries outside the Developing World, including private markets in China and India and, subject to clause 6.4, the public markets in China and India. The countries in the Developed World as at the Effective Date are listed in schedule 5, part A.

Developing World means the countries listed in schedule 5, part A and subject to clause 6.4, the public markets in China and India. With the exception of China and India, any countries which are reclassified from high income or upper middle income countries to low income or lower middle income countries by Organisation for Economic Co-operation Development (OECD) will be added to the list of Developing World. With the exception of China and India, any countries which are reclassified from low or lower middle income countries to high income or upper middle income countries by OECD will be removed from the list of Developing World. Developing World excludes private markets in China and India but, unless and until otherwise agreed by the Parties and Aeras in accordance with clause 6.4, includes public markets in India and China, and Humanitarian Organisations, which work with supplying vaccines to such countries.

Developing World Distributor means Aeras and/or any other Humanitarian Organisation to whom the Company sells or intends to sell a Licensed Product or Combination Product for use in the Developing World.

Development means all activities related to research, pre-clinical trials and other non-clinical testing, test method development, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control and clinical trials, including manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of any application for Regulatory Approval, regulatory affairs with respect to the foregoing and all other activities reasonably necessary or useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval and "**Develop**" and "**Developing**" shall be construed accordingly.

Documents means the documents and materials set out in schedule 2.

EEA means the European Economic Area, comprising the twenty-seven (27) Member States of the European Union, plus Norway, Iceland and Liechtenstein and any other countries forming part of the European Economic Area from time to time.

Efforts means taking no less steps and committing no less resources than the greater of those steps and resources commonly used by either Emergent or comparable companies in the vaccine industry, to achieve the same task for a comparable product having regard to the Overriding Aims, its safety and efficacy, its cost to Develop, the competitiveness of alternative

products, its proprietary position, the likelihood of regulatory approval, its profitability and other relevant factors.

EMEA means the European Medicines Agency and any successor authority.

Emergent Combination Product means a Licensed Product sold in a co-formulated combination with an Other Product Controlled by Emergent.

Emergent Company means Emergent or any entity directly or indirectly controlling, controlled by or under common control with, Emergent (other than the Company and any entity controlled by the Company). For purposes of this definition, the term "control" means (i) direct or indirect ownership, or the right to acquire ownership of more than fifty percent (50%) of the voting interest in the entity in question, (ii) the right to receive the majority of the income of that entity on any distribution by it of all of its income or the majority of its assets on a winding up of more than fifty percent (50%) of the voting interest in the entity in question, or (iii) otherwise the ability of a person to ensure that the activities and business of the entity in question are conducted in accordance with the wishes of that person.

Emergent Data means all data, protocols, standard operating procedures and written documentation generated for or as a result of a clinical trial or other scientific study carried out by an Emergent Company or its sub-licensees (other than the Company) or sub-contractors under the Overall Development Plan.

Emergent Improvement has the meaning set out in clause 12.7.

Emergent Licence means the licences granted by Emergent to the Company under clause 3.

Emergent Manufacturing Technology means all Manufacturing Technology necessary or reasonably useful (i) for the development of the Manufacturing Process, (ii) on development of such process, to Manufacture MVA85A using the Manufacturing Process, and/or (iii) to obtain or maintain Regulatory Approval for the Manufacturing Process, in each case owned by an Emergent Company at the Effective Date or at any time during the Term including any Emergent Improvements.

Emergent ODP Technology means all Intellectual Property Rights (including any Manufacturing Technology), other than with respect to Trademarks, conceived, discovered, developed, or otherwise made solely by or on behalf of an Emergent Company in the performance of activities under the Overall Development Plan that are necessary or reasonably useful for the Exploitation of Licensed Products or Company Combination Products including all Manufacturing Technology arising from any sub-contracts entered into by Emergent for the Development of the Manufacturing Process, but excluding Emergent Data, Emergent Regulatory Documents and Emergent Improvements.

Emergent Parent's Contact and Address means the address for Emergent Parent set out in schedule 2.

Emergent Regulatory Documents means all applications, registrations, governmental licences, authorisations and approvals (including any Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities relating to a Licensed Product or a Combination Product and all supporting documents and all data contained in any of the foregoing, Controlled by Emergent at any time during the Term.

Emergent Seed Stock means the seed stock of any Licensed Product or Combination Product Controlled by Emergent, but excluding the Master Seed Stock and the Company Seed Stock.

Emergent's Contact and Address means the address for Emergent set out in schedule 2.

Enabling Third Parties means all Third Parties to whom Emergent pays royalties for the right to Exploit any Licensed Product or Combination Product in the Territory.

Ethics Committee means any applicable federal, national, regional, state or provincial institutional review board, independent ethics committee or other group formally designated by an institution or relevant authority in compliance with Applicable Law, to approve the initiation of, and conduct periodic review of, a clinical trial.

Existing Data means all data, protocols, standard operating procedures and written documentation generated for or as a result of a clinical trial or other scientific study relating to the Licensed Product which exist at the Effective Date and which (i) are Controlled by the Licensor at the Effective Date, including the data listed in schedule 4, part A; and (ii) relate to trial TB012 (conducted at the MRC site in Gambia) and trial GM920 (conducted at the MRC site in Gambia) as soon as the Licensor obtains Control of such data, protocols, standard operating procedures and written documentation.

Expert means an expert appointed in accordance with clause 22.14.

Expert Opinion means an opinion given by an expert in accordance with clause 22.14.

Exploit means all or any of the activities described in clause 2.1, and "**Exploitation**" shall be construed accordingly.

FDA means the United States Food and Drug Administration and any successor authority.

Field means the field set out in schedule 2.

HIV Indication means HIV infected humans.

HIV Marketing Approval means the first Marketing Authorisation to Market a Licensed Product for the HIV Indication in the EEA.

Humanitarian Organisation means any supranational, governmental, non-governmental, or non-profit organisation, including the United Nations Children's Fund (UNICEF), the GAVI Alliance (GAVI), and the Pan American Health Organisation (PAHO).

IDT means IDT Biologika GmbH, a German company whose principal offices are at Am Pharmapark, D-06861 Dessau-Rosslau, Germany.

Improvement means any development of the Licensed Product which would, if commercially practised, infringe and/or be dominated by or rendered unpatentable by the Patent Application at the Effective Date or by the Isis Applications in any country at any time during the Term.

Indications mean the Infant Indication, the Adolescent Indication and the HIV Indication and Indication shall mean any one of them as the context may require.

Infant Indication means human infants of less than one (1) year of age, or such other age ranges for infants as Regulatory Authorities may determine.

Infant Marketing Approval means the first Marketing Authorisation to Market a Licensed Product for the Infant Indication in the EEA.

Infant Phase IIb Study means the Phase IIb Clinical Trial described in the protocol attached as schedule 9.

Infant Phase III Study has the meaning set forth in clause 7.1.1.

Intellectual Property Rights means any and all rights in inventions, patents, trade marks, service marks, copyright, database rights, moral rights, rights in designs, Know-how,

confidential information and all or any other intellectual or industrial property rights, whether or not registered or capable of registration.

Invention means any discovery, development, Know-how, invention or improvement (whether or not patented or patentable) made or generated in the course of performing activities under the Overall Development Plan, other than Data, Regulatory Documents, Correlates, Emergent ODP Technology, Emergent Improvements and Manufacturing Technology.

Inventors means the inventors named in the Patent Application and identified in schedule 2, and **Inventor** shall mean any of them.

Isis Applications means the Patent Application and any Patent Rights relating to the Patent Application.

Isis Licence Agreement means the exclusive licence agreement entered into by Isis, the Company, and Emergent.

Key Countries means Brazil, China, Russia, Bulgaria, Czech Republic, Finland, France, Germany, UK, Greece, Ireland, Latvia, Portugal, Romania, Slovakia, Turkey, Bosnia & Herzegovina, Croatia, Serbia & Montenegro, Indonesia, India, Japan, Morocco, United States of America, Vietnam and South Africa.

Know-how means, to the extent not generally known, all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, apparatuses, specifications, data, results and other material, including pre-clinical and clinical trial results, manufacturing procedures and test procedures (whether patented or patentable) in written, electronic or any other form now known or hereafter developed.

Licence means the licences granted by the Company to Emergent under clause 2.

Licence Year means each twelve (12) month period beginning on the first day of the first Quarter commencing after the Effective Date and each anniversary of such date provided that the first Licence Year shall include the period from the Effective Date to the first day of such first Quarter.

Licensed Product means any form or dosage of pharmaceutical composition or preparation for use in humans which is intended to prevent or treat *Mycobacterium tuberculosis* but no other disease and which contains:

(a) a recombinant replication-impaired or non-replicating MVA, containing heterologous nucleotide sequence encoding all or an immunogenic fragment or fusion protein of antigen 85A of *Mycobacterium tuberculosis* and no other non-MVA expressed gene (aside from a marker gene); or

(b) a Multivalent TB Product.

For the avoidance of doubt, a Combination Product is a product that contains a Licensed Product, but for the purposes of this agreement a Combination Product shall not be deemed to be a Licensed Product.

Licensed Technology means all Intellectual Property Rights Controlled by the Company in:

(a) the Company Patent Rights;

(b) the Company Know-how;

(c) the Master Seed Stock;

(d) Company Seed Stock;

(e) Company Manufacturing Technology;

(f) Emergent ODP Technology; and

(g) the Documents.

Licensor Combination Product means a Licensed Product sold (or being Developed for sale) in a co-formulated combination with an Other Product with respect to which Isis or the University has made an inventive contribution.

Manufacture means, with respect to a product, all steps in propagation or manufacture and preparation of that product and includes the manufacturing, processing, filling, formulating, testing (including in-process testing), packaging, labelling, holding and storing and quality control testing of such product.

Manufacturing Process means a process to Manufacture MVA85A using an avian cell line or primary chicken embryo fibroblast cells for subsequent formulation and administration to humans.

Manufacturing Technology means all Intellectual Property Rights necessary or reasonably useful (i) for the Development, or use, of a Manufacturing Process or a process to Manufacture any other MVA based product or (ii) for the Manufacture of MVA85A or any other MVA based product; or (iii) to obtain or maintain any regulatory approval relating to such process or Manufacture.

Market means, in relation to a Licensed Product or Combination Product, offering to import, export, market, sell, promote, distribute, lease, license, or otherwise commercially exploit the Licensed Product or Combination Product or the marketing, sale, promotion, distribution, lease, licence, or other commercial exploitation of the Licensed Product or Combination Product.

Marketing Authorisation means a marketing authorisation granted by the European Commission in accordance with the procedure for the authorisation and supervision of medicinal products for human use set forth in Regulation (EC) No. 726/2004, and any corresponding Regulatory Approval necessary to Market a Licensed Product or Combination Product in any country, but not including pricing and reimbursement approvals.

Marketing Plan means the plan to be prepared and delivered by Emergent in accordance with clause 10.2 as amended from time to time in accordance with clause 10.3.

Master Seed Stock means the progenitor seed stock and any master seed stock of any Licensed Product existing at the Effective Date and any additional master seed stock of any Licensed Product generated or manufactured by or on behalf of Isis, the Company or an Emergent Company during the Term.

Milestone and **Milestone Fee** means the milestones, and the amounts payable on achievement of each of the milestones, set out in schedule 2.

MRC means the Medical Research Council with head office at 22 Park Crescent, London W1B 1AL.

Multivalent TB Product means a recombinant replication-impaired or non-replicating MVA containing a heterologous nucleotide sequence encoding all or an immunogenic fragment or fusion protein of antigen 85A of *Mycobacterium tuberculosis* and any promoter or leader nucleotide sequences required for expression of that antigen; and one or more of the following (whether co-formulated or co-administered with such viral vector):

(a) one or more heterologous nucleotide sequences encoding all or an immunogenic fragment or fusion protein of an antigen or antigens, other than 85A, of *Mycobacterium tuberculosis* and any promoter or leader nucleotide sequences required for expression of that antigen and no antigens (other than MVA antigens and a marker, if present) from any other pathogen;

(b) one or more full length protein(s) or immunogenic fragment(s) or fusion protein(s), of a *Mycobacterium tuberculosis* antigen or antigens (and including lipoproteins, glycoproteins polysaccharides and protein – polysaccharide conjugates) other than antigen 85A;

(c) an additional vector system for the expression of *Mycobacterium tuberculosis* antigens, enabling expression within viral, prokaryotic and/or eukaryotic cells;

(d) a delivery system for *Mycobacterium tuberculosis* antigens including Bacterial RNA capsids, microparticles, vesicles and liposomes.

MVA means modified vaccinia virus Ankara.

MVA85A means a recombinant replication-impaired or non-replicating MVA, containing heterologous nucleotide sequence expressing all or an immunogenic fragment or fusion protein of a major secreted antigen from *Mycobacterium tuberculosis*, antigen 85A, and no other non-MVA expressed gene (aside from a marker gene), and known as the MVA85A vaccine and described in the Patent Application.

Net Sales means, for any period, the gross amount invoiced by Emergent Companies for sales of Licensed Products and Combination Products in the Territory after deduction of:

(a) trade, quantity and cash discounts and sales returns and allowances and amounts repaid or credited, including (i) those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns and rebates (including rebates in kind and rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority), (ii) administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organisations, health care insurance carriers and other institutions, (iii) allowances, rebates and fees paid to distributors and (iv) chargebacks;

(b) sales, value added or other excise taxes paid or allowed;

(c) import and export duties, charges, taxes and other amounts paid to a governmental authority in respect of the sale (other than income taxes due and payable);

(d) charges for insurance against loss while in transit or storage, handling, freight and distribution; and

(e) any invoiced amounts which are not collected by Emergent Companies, including bad debts, provided that Emergent Companies have used their Efforts to collect such uncollected amounts.

Any of the deductions listed above that involves a payment by an Emergent Company shall be taken as a deduction in the Quarter in which the payment is accrued by such entity. Deductions pursuant to clause (e) above shall be taken in the Quarter in which such sales are no longer recorded as a receivable.

For purposes of determining Net Sales, a "sale" shall not include transfers between Emergent Companies or transfers by Emergent Companies of free samples of Licensed Products or Combination Products or clinical trial materials or other transfers or dispositions for charitable, promotional, pre-clinical, clinical, manufacturing, testing or qualification or regulatory purposes.

Net Sales of Combination Products and Multivalent TB Products shall be subject to further adjustment in accordance with schedule 6.

Non-Commercial Use means academic and research purposes and other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not involve the production or manufacture of products for sale or the performance of services for a fee or for the commercial benefit of Isis, the University or any Third Parties. (Neither the receipt of reimbursements for the costs of preparation and shipping of samples of materials provided to Third Parties as a professional courtesy, in response to publication requests or otherwise, in accordance with academic custom nor the receipt of funding for research shall constitute sale of products or performance of service for a fee.) This includes the right to use the relevant technology as enabling technology in other research projects (including clinical patient care which is not for the commercial benefit of Third Parties and clinical trials).

OMP Designation means the designation by the European Commission of MVA85A as an Orphan Medicinal Product.

Other Product means any form or dosage of pharmaceutical composition or preparation for use in humans which contains therapeutic or antigenic levels of one or more active ingredients intended to prevent or treat any disease in humans not being caused by *Mycobacterium tuberculosis*.

Overall Development Plan means the development plan set out in schedule 3 as amended from time to time by the Company in accordance with clause 5.

Overriding Aims means, in respect of:

(a) the Developing World (including the public markets in China and India), to make MVA85A or if MVA85A is no longer being Developed an alternative Licensed Product or a Combination Product available to the greatest number of people at prices affordable to Humanitarian Organisations; and

(b) countries in the Developed World (other than public markets in China and India), to Exploit a Licensed Product or Combination Product in the Field with a viewing to maximising the financial return to the Company.

Party means the Company or Emergent or, with respect only to clause 15 Isis, and **Parties** means the Company and Emergent or, with respect only to clause 15, the Company, Emergent and Isis.

Past Patent Costs means the past patent costs incurred with respect to countries in the Territory set out in schedule 2.

Patent Application means the patent application set out in schedule 2.

Patent Rights means, with respect to any patent application:

(a) any national or regional stage progeny of that patent application;

(b) any patents granted on any progeny of that patent application;

(c) any patents and applications which may be granted to the owner of such patent application based on and claiming priority to or through that patent application; and

(d) any addition, continuation, continuation-in-part, division, reissue, renewal or extension (including supplementary protection certificates) based on or claiming priority to or through that patent application.

Phase I Clinical Trial means a human clinical trial for which the primary endpoints include a determination of safety and tolerability.

Phase IIb Clinical Trial means a human clinical trial for which the primary endpoints include a determination of the safety and efficacy in that indication.

Phase IIb Period means the period commencing on the Effective Date and ending on the date when the final results of the Infant Phase IIb Study are communicated to Emergent in writing.

Phase III Clinical Trial means a pivotal human clinical trial in any country the results of which could be used to establish safety and efficacy of a Licensed Product as a basis for an application for a Marketing Authorisation submitted to the FDA, or that would otherwise satisfy requirements of 21 C.F.R. § 312.21(c), or its foreign equivalent.

Public Funder means a charitable organisation, research council, the European Commission, non-governmental organisation and any other public body which regularly makes grants of funding for research including clinical trials or any other body or organisation which the Parties may from time to time agree shall be deemed to be a public funder for the purposes of this agreement.

Quarter means a period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31.

Regulations means the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006.

Regulatory Approval means any and all approvals, registrations or authorisations of any Regulatory Authority necessary or desirable for the Development, Manufacture, supply and Marketing of Licensed Products and Combination Products in the Territory and any notifications or registrations necessary to legitimise the processing of personal data for these purposes.

Regulatory Authority means the FDA, EMEA or any other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority with respect to clinical research involving, or the Exploitation of, Licensed Products and Combination Products in the Territory.

Royalty Rate means the royalty rate set out in schedule 2.

ROT means the Territory other than (i) the EEA, and (ii) the public markets in China and India.

Royalty Report means the report to be prepared by Emergent under clause 18.1.

Steering Committee means the committee to be formed pursuant to clause 5.3.2.

Study Subject means a person participating in a clinical trial.

Successful Completion Date means, with respect to a clinical trial, the date of delivery to Emergent of a final report for such clinical trial showing achievement of the Trial Success Criteria for that clinical trial.

SUSAR means a suspected, unexpected, serious adverse reaction.

Term means the term of this agreement, beginning on the Effective Date and ending on the expiry of this agreement in accordance with clause 19.1 or, if earlier, the Termination Date.

Termination Date means the date on which any termination of this agreement becomes effective.

Territory means the territory set out in schedule 2.

Third Party means any corporation, unincorporated organisation, persons or other legal entity other than Emergent Companies, the Company, the University and Isis.

Trademark means any word, name, symbol, colour, designation or device or any combination thereof for use in the course of trade, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol used in connection with the Licensed Products or Combination Products.

Trial Success Criteria means, with respect to a particular clinical trial, the success criteria agreed by the Parties in writing following Regulatory Approval for, and prior to commencement of, the relevant clinical trial.

University means the Chancellor, Masters and Scholars of the University of Oxford whose administrative offices are at the University Offices, Wellington Square, Oxford OX1 2JD.

University Collaborators means any and all academic or research institutions, non-profit or governmental institutions with which the University undertakes a scientific collaboration where both parties have a material scientific input to the collaboration and the University has material decision making rights.

University Personnel means every employee of, student of and individual appointed by the University.

Valid Claim means a claim of (a) (i) an issued and unexpired patent, (ii) an issued patent the term of which has been extended pursuant to an extension of term or equivalent right anywhere in the world, or (iii) a patent listed in a supplementary protection certificate or equivalent instrument anywhere in the world, or (b) a claim included in a pending patent application that has not been (i) cancelled, (ii) withdrawn from consideration, (iii) pending for more than ten (10) years from the earliest claimed priority date; in each case (a) and (b) which has not been withdrawn, cancelled, abandoned, disclaimed, revoked or held unpatentable, invalid or unenforceable by final decision of a court or other governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal.

Wellcome Grant means the grant of £4,000,000 from the Wellcome Trust made pursuant to a funding agreement between the Wellcome Trust, the University and Isis dated 4 July 2008.

Wellcome Trust means The Wellcome Trust, which has its principal place of business located at Gibbs Building, 215 Euston Road, London NW1 2BE, United Kingdom.

2. Interpretation

In this agreement, unless the context otherwise requires:

(a) references to “this agreement” shall mean this agreement and any and all schedules to it, each as amended from time to time in accordance with the provisions of this agreement;

(b) references to a particular clause, schedule or paragraph shall be a reference to that clause, schedule or paragraph in or to this agreement;

(a) words in the singular shall include the plural and vice versa and references to the masculine gender shall include the feminine gender and vice versa;

(b) headings are for convenience only and shall be ignored in interpreting this agreement;

(c) reference to a person shall mean any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality;

(d) the words “include”, “including” or “in particular” are to be construed without limitation to the generality of the preceding words;

(e) any reference to “writing” includes a reference to any communication effected by facsimile transmission, e-mail (subject to clause 22.5) or similar means and includes where applicable X-rays, photos and similar depictions of information and data;

(f) any covenant by a Party not to do an act or thing shall be deemed to include an obligation not to permit or suffer such act or thing to be done by another person;

(g) all references to statutes or statutory instruments or EC directives shall be to those statutes, statutory instruments or EC directives as they may be amended, consolidated or repealed from time to time.

SCHEDULE 2

Patent Application:	**PCT patent application number PCT/GB2006/000023 entitled "Method for generating a memory T-cell response" filed on 5 January 2006.**
Inventors:	Professor Adrian Hill, Dr Helen McShane, Dr Sarah Gilbert and Dr Ansar Pathan.
Territory:	The Developed World.
Field:	Prevention and treatment of *Mycobacterium tuberculosis* disease (and only *Mycobacterium tuberculosis* disease) in humans; provided that with respect to a Combination Product, the Field shall also include such other indications as are treated or prevented by the Other Product.
Documents:	The Patent Application, its filing history (including all priority applications claimed in one Patent Application) and the file histories of all regional and national stage progeny in existence at time of delivery.
Past Patent Costs:	[**] (as at 3 July 2008).
Signing Fee:	[**].

Royalty Rate (as adjusted in accordance with clause 16:

Annual Net Sales	**Royalty Rate (**subject to adjustment in accordance with clause 16**)**	
	Sales in EEA	Sales in ROT
On Annual Net Sales (other than in the public markets in China and India) up to or equal to [**]	[**]	[**]
On that portion of Annual Net Sales (other than in the public markets in China and India) above [**] and up to or equal to [**]	[**]	[**]
On that portion of Annual Net Sales (other than in the public markets in China and India) above [**] and up to or equal to [**]	[**]	[**]
On that portion of Annual Net Sales (other than in the public markets in China and India) above [**] and up to or equal to [**]	[**]	[**]
On that portion of Annual Net Sales (other than in the public markets in China and India) above [**]	[**]	[**]

Milestones and Milestone Fees:

Milestone	Milestone Fee
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

AGGREGATE NET SALES	
Milestone: First achievement of aggregate Net Sales (other than in the public markets in China and India) of:	**Milestone Fee**
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
Maximum Milestone Fees with respect to aggregate Net Sales	[**]

For the avoidance of doubt, each of the Milestone Fees shall be payable no more than once, irrespective of the number of Licensed Products or Combination Products or trigger events associated with any such given Milestone and irrespective of whether the milestone is triggered by the activities of the Company, an Emergent Company or any sub-licensee.

Company's Contact and Address:

Contact	General Manager

Address	Oxford-Emergent Tuberculosis Consortium Limited 545 Eskdale Road Winnersh Triangle Wokingham Berkshire, RG41 5TU with a copy to: Managing Director Isis Innovation Limited Ewert House Ewert Place Summertown Oxford OX2 7SG
Fax	0118 944 3310

Emergent's Contact and Address:

Contact	President
Address	Emergent Product Development UK Limited 545 Eskdale Road Winnersh Triangle Wokingham Berkshire, RG41 5TU
With a copy to:	
Contact	General Counsel
Address	Emergent BioSolutions Inc, 2273 Research Boulevard Suite 400 Rockville MD 20850, USA

Emergent Parent's Contact and Address:

Contact	General Counsel
Address	Emergent BioSolutions Inc, 2273 Research Boulevard Suite 400 Rockville MD 20850, USA

Schedule 3 – Overall Development Plan

Confidential Materials omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

A total of twenty-six pages have been omitted.

[**]

Schedule 4 – Data

Confidential Materials omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

A total of two pages have been omitted.

[**]

Part A. Developed World and Developing World

Developed World Country	Geographic Region	Income Classification
Armenia	EUR	Low
Aruba	Unclassified	High
Australia	WPR	High
Austria	EUR	High
Azerbaijan	EUR	Low
Bahamas	AMR	High
Bahrain	MED	High
Bangladesh	SEA	Low
Belarus	EUR	Middle
Belgium	EUR	High
Bosnia and Herzegovina	EUR	Middle
Brazil	AMR	Middle
Brunei Darussalam	WPR	High
Bulgaria	EUR	Middle
Canada	AMR	High
Channel Islands	Unclassified	High
China (private markets only)	SEA	Low
Croatia	EUR	Middle

Cyprus	EUR	High
Czech Republic	EUR	Middle
Denmark	EUR	High
Estonia	EUR	Middle
Finland	EUR	High
France	EUR	High
French Polynesia	Unclassified	High
Georgia	EUR	Low
Germany	EUR	High
Greece	EUR	High
Guam	Unclassified	High
Hungary	EUR	Middle
Iceland	EUR	High
India (private markets only)	SEA	Low]
Indonesia	SEA	Low
Ireland	EUR	High
Israel	EUR	High
Italy	EUR	High
Japan	WPR	High
Jordan	EMR	Middle
Kazakhstan	EUR	Middle

Kuwait	EMR	High
Kyrgyzstan	EUR	Low
Latvia	EUR	Middle
Lebanon	EMR	Middle
Lithuania	EUR	Middle
Luxembourg	EUR	High
Malaysia	WPR	Middle
Malta	EUR	High
Mexico	AMR	Middle
Montenegro	EUR	Middle
Nepal	SEA	Low
Netherlands	EUR	High
Netherlands Antilles	Unclassified	High
New Caledonia	Unclassified	High
New Zealand	WPR	High
North Korea	WPR	High
Norway	EUR	High
Pakistan	SEA	Low
Philippines	SEA	Middle
Poland	EUR	Middle
Portugal	EUR	High
Puerto Rico	Unclassified	High

Qatar	MED	High
Republic of Moldova	EUR	Low
Romania	EUR	Middle
Russian Federation	EUR	Middle
Saudi Arabia	MED	High
Serbia	EUR	Middle
Singapore	SEA	High
Slovakia	EUR	Middle
Slovenia	EUR	High
South Africa	AFR	Middle
South Korea	SEA	High
Spain	EUR	High
Sri Lanka	SEA	Low
Sweden	EUR	High
Switzerland	EUR	High
Thailand	SEA	Middle
Tunisia	EMR	Middle
Turkey	EUR	Middle
Turkmenistan	EUR	Middle
Ukraine	EUR	Low
United Arab Emirates	EMR	High
United Kingdom	EUR	High

US Virgin Islands	Unclassified	High
USA	AMR	High
Uzbekistan	EUR	Low
Vietnam	SEA	Low

Developing World Country	**Geographic Region**	**Income Classification**
Afghanistan	EMR	Low
Albania	EUR	Middle
Algeria	AFR	Middle
Angola	AFR	Low
Argentina	AMR	Middle
Barbados	AMR	Middle
Belize	AMR	Middle
Benin	AFR	Low
Bhutan	SEA	Low
Bolivia	AMR	Low
Botswana	AFR	Middle
Burkina Faso	AFR	Low
Burundi	AFR	Low
Cambodia	WPR	Low
Cameroon	AFR	Low
Cape Verde	AFR	Middle
Central African Republic	AFR	Low
Chad	AFR	Low
Chile	AMR	Middle
China (public markets only)	SEA	Low
Colombia	AMR	Middle
Comoros	AFR	Low

Congo	AFR	Low
Costa Rica	AMR	Middle
Côte d'Ivoire	AFR	Low
Cuba	AMR	Low
Djibouti	EMR	Low
Dominican Republic	AMR	Middle
DR Congo	AFR	Low
Ecuador	AMR	Middle
Egypt	EMR	Middle
El Salvador	AMR	Middle
Equatorial Guinea	AFR	Middle
Eritrea	AFR	Low
Ethiopia	AFR	Low
Federated States of Micronesia	WPR	Middle
Fiji	WPR	Middle
Former Yugoslav Republic of Macedonia	EUR	Middle
French Guiana	Unclassified	Middle
Gabon	AFR	Middle
Gambia	AFR	Low
Ghana	AFR	Low
Grenada	AMR	Middle
Guadeloupe	Unclassified	Middle
Guatemala	AMR	Middle
Guinea	AFR	Low
Guinea-Bissau	AFR	Low
Guyana	AMR	Low
Haiti	AMR	Low
Honduras	AMR	Low
India (public markets only)	SEA	Low
Iran (Islamic Republic of)	EMR	Middle

Iraq	EMR	Middle
Jamaica	AMR	Middle
Kenya	AFR	Low
Kiribati	WPR	Low
Lao People's Democratic Republic	WPR	Low
Lesotho	AFR	Low
Liberia	AFR	Low
Libyan Arab Jamahiriya	EMR	Middle
Madagascar	AFR	Low
Malawi	AFR	Low
Maldives	SEA	Middle
Mali	AFR	Low
Martinique	Unclassified	Middle
Mauritania	AFR	Low
Mauritius	AFR	Middle
Mongolia	WPR	Low
Morocco	EMR	Middle
Mozambique	AFR	Low
Myanmar	SEA	Low
Namibia	AFR	Middle
Nicaragua	AMR	Low
Niger	AFR	Low
Nigeria	AFR	Low
Oman	EMR	Middle
Panama	AMR	Middle
Papua New Guinea	WPR	Low
Paraguay	AMR	Middle
Peru	AMR	Middle
Réunion	Unclassified	Middle
Rwanda	AFR	Low
Saint Lucia	AMR	Middle
Saint Vincent and the Grenadines	AMR	Middle

Samoa	WPR	Middle
Sao Tome and Principe	AFR	Low
Senegal	AFR	Low
Sierra Leone	AFR	Low
Solomon Islands	WPR	Low
Somalia	EMR	Low
Sudan	EMR	Low
Suriname	AMR	Middle
Swaziland	AFR	Middle
Syrian Arab Republic	EMR	Middle
Tajikistan	EUR	Low
Timor-Leste	SEA	Low
Togo	AFR	Low
Tonga	WPR	Middle
Trinidad and Tobago	AMR	Middle
Uganda	AFR	Low
UR Tanzania	SEA	Low
Uruguay	AMR	Middle
Vanuatu	WPR	Middle
Venezuela	AMR	Middle
Western Sahara	Unclassified	Middle
Yemen	EMR	Low
Zambia	AFR	Low
Zimbabwe	AFR	Low

Part B

Groups of Patent Territories

Non-Key Patent Territories

Country	Regional
[**]	[**]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment. A total of 3 pages were omitted.

Key Countries

Key countries - European Territories	
[**]	[**]
[**]	
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[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

[**]	

SCHEDULE 6 – NET SALES ADJUSTMENT FOR MULTIVALENT TB PRODUCTS AND COMBINATION PRODUCTS

If a Licensed Product is sold in any country in the form of a Multivalent TB Product or as part of a Combination Product, Net Sales of such Multivalent TB Product or Combination Product shall be calculated by multiplying actual Net Sales of such Multivalent TB Product or Combination Product in such country calculated pursuant to the definition of Net Sales in schedule 1 ("**Actual Net Sales**") by the fraction A/(A+B) where A is the average invoice price in such country of (a) the Licensed Product containing only MVA85A (and not any other active ingredient), in the case of a Multivalent TB Product; or (b) the Licensed Product in the Combination Product, in the case of a Combination Product, (in each case, the "**Base Licensed Product**") , if sold separately in such country, and B is the average invoice price in such country of (i) the Multivalent TB Product without MVA85A (the "**Other TB Product**"), in the case of the Multivalent TB Product; or (ii) the Other Product(s) contained in that Combination Product in the case of the Combination Product, in each case, if sold separately in such country.

If, in a specific country, the Other TB Product, or the Other Product(s) in the Combination Product, as the case may be, are not sold separately, Net Sales shall be adjusted by multiplying Actual Net Sales of the Multivalent TB Product or Combination Product by the fraction A/C, where A is the average invoice price in such country of the Base Licensed Product and C is the average invoice price in such country of the Multivalent TB Product or Combination Product.

If, in a specific country, the Base Licensed Product is not sold separately, Net Sales shall be calculated by multiplying Actual Net Sales of the Multivalent TB Product or Combination Product by the fraction (C-B)/C, where B is the average invoice price in such country of the Other TB Product (in the case of a Multivalent TB Product), or the Other Product(s) in such Combination Product, if sold separately in such country, and C is the average invoice price in such country of the Multivalent TB Product or the Combination Product (as the case may be).

Where applicable, the invoice price for the Other TB Product or the Other Product, when sold separately shall be for a quantity comparable to that used in the relevant Multivalent TB Product or Combination Product and of the same class, purity and potency.

If, in a specific country, neither the Base Licensed Product nor (x) the Other TB Product, in the case of a Multivalent TB Product; or (y) the Other Product(s) in the relevant Combination Product, are sold separately, the Parties shall negotiate in good faith an equitable downward adjustment to Net Sales based upon the manufacturing costs, overhead and profit for such Multivalent TB Product or Combination Product and all similar substances then being made and marketed and having an ascertainable market price.

If the Licensed Product in a Combination Product is a Multivalent TB Product, the Parties shall make an adjustment for the Other TB Product in the Multivalent TB Product prior to adjusting Net Sales for the Other Product in the Combination Product.

If the Parties are unable to agree an appropriate downward adjustment to Net Sales within three (3) months, either Party may refer the matter for determination by an Expert in accordance with clause 22.15.

Examples of application of adjustment for Net Sales of a Combination Product

Formulae:

A = Average invoice price of the Base Licensed Product included in the Combination Product

B = Average invoice price of the Other Product included in the Combination Product

C = Average invoice price of the Combination Product

(1) Base Licensed Product and Other Product are sold separately, A and B are known:

Net Sales = Actual Net Sales x A / (A + B)

(2) Base Licensed Product is sold separately but Other Product is not, A and C are known:

Net Sales = Actual Net Sales x (A / C)

(3) Base Licensed Product is not sold separately, Other Product is sold separately, B and C are known:

Net Sales = Actual Net Sales x ((C – B) / C)

(4) Neither Base Licensed Product nor Other Product are sold separately:

Negotiate in good faith

Possible Scenarios for Combination Products and formula most likely to be applicable:

MVA85A + Paediatric Vaccine: *Use (1)*

MVA85A + Company Derived MVA: *Use (2)*

MVA85A + Other non-TB Antigen and:

Antigen 100% Oxford University Derived: New Licence will be required for additional new antigen

Antigen 100% Company / 3rd Party: Use (2)

Antigen Jointly Derived: Either subject to Services Agreement or a new licence will be required.

New licences of Intellectual Property Rights Controlled by the Company will be on terms no less favourable to the Parties than those in this agreement except that new milestone payments will be included.

Examples of application of adjustment for Net Sales of a Multivalent TB Product

Formulae:

A = Average invoice price of the Base Licensed Product

B = Average invoice price of the Multivalent TB Product without antigen 85A

C = Average invoice price of the Multivalent TB Product

(1) Base Licensed Product and the Multivalent TB Product without antigen 85A are sold separately, A and B are known:

Net Sales = Actual Net Sales x A / (A + B)

(2) Base Licensed Product is sold separately but the Multivalent TB Product without antigen 85A is not, A and C are known:

Net Sales = Actual Net Sales x (A / C)

(3) Base Licensed Product is not sold separately, Multivalent TB Product without antigen 85A is sold separately, B and C are known:

Net Sales = Actual Net Sales x ((C – B) / C)

(4) Neither Base Licensed Product nor Multivalent TB Product without antigen 85A are sold separately:

Negotiate in good faith

Possible Scenarios for Multivalent TB Products and the formula most likely to be applicable

Additional antigen 100% Oxford University: Either an improvement covered by the Licence (no adjustment required) or a new licence will be required

Additional antigen 100% Company Derived: Use (2)

Additional antigen Jointly Derived: Either an improvement covered by the Licence (no adjustment required) or a new licence will be required

New licences of Intellectual Property Rights Controlled by the Company will be on terms no less favourable to the Parties than those in this agreement except that new milestone payments will be included.

Schedule 9 – Infant Phase IIb Study Protocol

Confidential Materials omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

A total of sixty pages have been omitted.

[**]

AS WITNESS this agreement has been signed by the duly authorised representatives of the parties.

SIGNED for and on behalf of

BADHUL LIMITED:

Name:Adrian Hill

Position:Director

Signature:/s/Adrian Hill

Date:14-7-2008

SIGNED for and on behalf of

EMERGENT PRODUCT DEVELOPMENT UK LIMITED:

Name:Fuad El-Hibri

Position:Director

Signature:/s/Fuad El-Hibri

Date:18-7-2008

Emergent Biosolutions Inc. joins this agreement solely for purposes of agreeing to the payment obligation set forth in clause 17.

SIGNED for and on behalf of

EMERGENT BIOSOLUTIONS INC.:

Name:Fuad El-Hibri

Position:Director/CEO

Signature:/s/Fuad El-Hibri

Date:18-7-2008

SIGNED for and on behalf of

ISIS INNOVATION LIMITED:

Name:David Baghurst

Position:Head of ISIS Enterprise

Signature:/s/David Baghurst

Date:14-7-2008

EXHIBIT 10.6

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
			1 | 36

2. CONTRACT (Proc. Inst. Indent.) NO. HHSO100200800091C
3. EFFECTIVE DATE September 30, 2008
4. REQUISITION/PURCHASE REQUEST/PROJECT NO.

5. ISSUED BY CODE

HHS/OS/ASPR/BARDA
330 Independence Avenue, SW, Room G644
Washington, DC 20201

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

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

Emergent BioDefense Operations Lansing, Inc.
3500 N. Martin Luther King, Jr. Blvd
Lansing, MI 48906

8. DELIVERY
☐ FOB ORIGIN ☒ Other *(See below)*

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES *(4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN* ITEM See G.3

CODE FACILITY CODE

11. SHIP TO/MARK FOR CODE
Strategic National Stockpile or as determined by the United States Government

12. PAYMENT WILL BE MADE BY CODE
Centers for Disease Control and Prevention/FMO
PO Box 15580
Atlanta, GA 30333

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:
☐ 10 U.S.C. 2304(c) ( ) ☒ 41 U.S.C. 253(c) (1)

14. ACCOUNTING AND APPROPRIATION DATA
Appro: 75X0943 Allow: 5664311101 OCs: 26402 CAN: 921ZAZN Amt: $139,963,658.20
Appro: 7580943 Allow: 5623RF1101 OCs: 26402 CAN: 921ZENB Amt: $11,125,000.00
Appro: 7580943 Allow: 5623RF1101 OCs: 26402 CAN: 921ZFGD Amt: $1,396,533.80

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	TITLE: AVA FOR THE SNS Total Not-To-Exceed Contract Value (See B.4.8)				

15G. TOTAL AMOUNT OF CONTRACT ▷ $ 152,485,192.00

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		PART I – THE SCHEDULE	
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	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	L	INSTRS, CONDS., AND NOTICES TO OFFERORS	
	M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ 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. ☐ AWARD *(Contractor is 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 terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER *(Type or Print)*

R. Don Elsey, CFO

19B. NAME OF CONTRACTOR 19C. DATE SIGNED

BY /s/ R. Don Elsey 9/30/2008
(Signature of person authorized to sign)

20A. NAME OF CONTRACTING OFFICER

Michelle T. Gray

20B. UNITED STATES OF AMERICA 20C. DATE SIGNED

BY /s/ Michelle T. Gray 9/30/2008
(Signature of Contracting Officer)

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is usable

STANDARD FORM 26 (REV. 4/2008)
Prescribed by GSA – FAR (48 CFR) 53.214(a)

TABLE OF CONTENTS

HHSO100200800091C

Section B – Supplies or Service and Price/Costs

B.1. Brief description of supplies or services

The Federal Response Plan of the Department of Homeland Security designates the Department of Health and Human Services (HHS) as the lead agency for public health and medical response to manmade or natural disasters. Within HHS, the Division of the Strategic National Stockpile (DSNS) and the BioMedical Advanced Research & Development Authority (BARDA) under the Office of the Assistant Secretary for Preparedness and Response are combining their efforts to respond to, acts of bioterrorism and other public health emergencies threatening the civilian population. This responsibility within HHS is to contract for large-scale manufacturing and delivery of licensed and licensable products to the Strategic National Stockpile (SNS) in preparation for response(s) to a public health emergency.

Significant changes in both the nature, regularity, and degree of the threat posed by the use of infectious agents as weapons of biological warfare have generated increased concern for the safety of the general American populace. Following the deliberate exposure of citizens of the United States to *Bacillus anthracis (B. anthracis)* spores in 2001, there is an urgent need to stockpile appropriate and effective medical countermeasures to safeguard against this potential threat. The USG has established a requirement for the procurement of licensed Anthrax Vaccine Adsorbed (here after referred to as BioThrax**()** to meet this urgent need.

B. 2. Project Identification and Purpose

The purpose of this contract is to provide up to 14.5 million doses of FDA licensed BioThrax(in multi-dose vials with 3 year dating product stability (or 4 year if FDA approved) which shall be delivered during the contract period of performance in appropriately packaged containers under controlled and secure conditions to the SNS.

B.3. Specific Technical Requirements

The Contractor shall provide the necessary qualified personnel, facilities, material, equipment (except Government property) and services to produce, test, bottle, package, and prepare for BioThrax (delivery. The manufacture, formulation, filling, and testing of BioThrax(shall be done in accordance with the contractor's Standard Operating Procedures, and the contractor's Food and Drug Administration Biologics License, and all federal statutory requirements.

B.4. Base Prices:

The pricing for four-year dated product is set forth in each CLIN, with alternative pricing for three-year dated product set forth in each alternative CLIN (A*). If four-year dated lots of BioThrax® are available at the time of delivery, Contractor shall deliver four-year dated product to the SNS. The minimum remaining shelf-life at time of delivery for four-year dated product will be [**] months, unless otherwise agreed in writing by the Contracting Officer in connection with a particular delivery; the Contractor shall target a minimum remaining shelf-life of [**] months for four-year dated product.

If FDA has not approved four-year dating at the time of delivery, Contractor may instead deliver three year dated product to the SNS, at the discounted pricing set for in each alternative CLIN (A*). Contractor shall target a minimum remaining shelf-life of [**] months at time of delivery for three-year dated product. If the minimum remaining shelf-life at time of delivery of a particular lot or shipment is less than [**] months, the price of such product will be discounted by $[**] per dose for each month below [**] months of remaining shelf life.

B.4.1 Pricing for Funded Doses of BioThrax® under CLINs 0001 and 0001A

In consideration for the completion of the work to be performed under CLIN 0001, for the delivery of [**] doses of four-year dated BioThrax® in accordance with the statement of work, the Contractor shall be paid an amount not to exceed $[**] (Firm Fixed Price). If four-year dating has not yet been approved, the Contractor shall be paid the discounted per dose price set forth in CLIN 0001A for any of the [**] doses that are delivered to the SNS as three-year dated product (See Section B.4.8).

B.4.2 Pricing for Funded Doses of BioThrax(under CLINs 0002 and 0002A

In consideration for the completion of the work to be performed under CLIN 0002, for the delivery of [**] doses of four-year dated BioThrax® in accordance with the statement of work, the Contractor shall be paid an amount not to exceed $[**] (Firm Fixed Price). If four-year dating has not yet been approved, the Contractor shall be paid the discounted per dose price set forth in CLIN 0002A for any of the [**] doses that are delivered to the SNS as three-year dated product (See Section B.4.8).

B.4.3 Pricing for Funded Doses of BioThrax® under CLINs 0003 and 0003A

In consideration for the completion of the work to be performed under CLIN 0003, for the delivery of [**] doses of four-year dated BioThrax® in accordance with the statement of work, the Contractor shall be paid an amount not-to-exceed $[**] (Firm Fixed Price). If four-year dating has not yet been approved, the Contractor shall be paid the discounted per dose price set forth in CLIN 0003A for any of the [**] doses that are delivered to the SNS as three-year dated product (See Section B.4.8).

B.4.4 Pricing for Doses of BioThrax® under CLINs 0004 and 0004A

In consideration for the completion of the work to be performed under CLIN 0004, for the delivery of up to [**] doses of four-year dated BioThrax® in accordance with the statement of work, which is subject to the availability of funding, the Contractor shall be paid an amount not to exceed $[**] (Firm Fixed Price). If four-year dating has not yet been approved, the Contractor shall be paid the discounted per dose price set forth in CLIN 0004A for any of the [**] doses that are delivered to the SNS as three-year dated product (See Section B.4.8).

B.4.5 Pricing for Doses of BioThrax® under CLINs 0005 and 0005A

In consideration for the completion of the work to be performed under CLIN 0005, for the delivery of up to [**] doses of four-year dated BioThrax® in accordance with the statement of work, which is subject to the availability of funding, the Contractor shall be paid an amount not-to-exceed $[**] (Firm Fixed Price). If four-year dating has not yet been approved, the Contractor shall be paid the discounted per dose price set forth in CLIN 0005A for any of the [**] doses that are delivered to the SNS as three-year dated product (See Section B.4.8).

B.4.6 Prices for Shipping to the SNS (CLINs 0006 - 0008)

In consideration for the completion of the work to be performed under CLINs 0001-0005, for the shipment of BioThrax® to the SNS sites in accordance with the statement of work, the Contractor shall be paid an amount not-to-exceed $1,936,512 (Firm Fixed Price).

B.4.7. Cancellation Ceiling Fee (CLIN 0009)

For consideration should the USG cancel the entire performance of work under CLIN 0004 and/or CLIN 0005, the Contractor shall be paid the amount, or percentage thereof, of the cancellation ceiling fee not-to-exceed $1,000,000. (See Section B.5.d. Advanced Understanding)

B.4.8. Contract Pricing

CLIN #	Type	#/range of doses	Price per dose	Price
1	[**]	[**]	$[**]	$[**]
0001A*	[**]		$[**]	$[**]
2	[**]	[**]	$[**]	$[**]
0002A*	[**]		$[**]	$[**]
3	[**]	[**]	$[**]	$[**]
0003A*	[**]		$[**]	$[**]
4	[**]	[**]	$[**]	$[**]
0004A*	[**]		$[**]	$[**]
5	[**]	[**]	$[**]	$[**]
0005A*	[**]		$[**]	$[**]

* CLINs designated “A” are alternative CLINs; if Contractor has not obtained four-year dating by the time of delivery of a particular lot, the “A” unit prices are applicable for each three-year dated dose delivered to the SNS.

CLIN#		Type	Requirement	Delivery Date	Per Truck	Total Price
	6	[**]	Shipping to SNS (CLINs 0001~0003)	[**] [**]	$ [**]	$[**]
	7	[**]	Shipping to SNS (CLIN 0004)	[**] [**]	$[**]	$[**]
	8	[**]	Shipping to SNS (CLIN 0005)	[**] [**]	$ [**]	$[**]
			Total Estimated Price ([**] trucks)			$ 1,936,512
			Total Estimated Contract Value			$404,685,512
0009*	Fee		Cancellation Ceiling (CLINs 0004/*4A and 0005/*5A)		$ 1,000,000	

B.5. Advanced Understandings:

a. Subcontracts

The Contractor shall provide the Contracting Officer with an annual summary of small businesses used as subcontractors.

b. Ranges of doses manufactured and shipped

The targeted delivery schedules are based on Contractor's anticipated production schedule, projections regarding manufacturing variables, and assumptions regarding lot release dates. Lot numbers, quantities, and dates are not guaranteed and may change as a result of lot failures, FDA lot release dates, lots dedicated to BioThrax® to improvement programs, including the fill/finish and manufacturing process improvements described in Contractor's Technical Proposal, and other factors. Should the projected number of doses not be delivered on any projected delivery date, the Contractor shall adjust the delivery schedule to make up for deficiencies in prior deliveries, so long as the Contractor delivers up to a total of 14.5 million doses at a total contract price of $402,749,000 (assuming 4 year dating approval) during the period of performance. Contractor may accelerate deliveries within each CLIN of production if production capacity permits with the prior approval of the Contracting Officer.

c. Data Rights

Data provided by or obtained from the contractor shall be solely for the purposes of award of this contract. All such data shall be proprietary and confidential and, except or unless required by federal law, shall not be distributed outside of the USG without the advance written consent of the contractor.

d. Multi-Year Contract and Advanced Notice

This is a multi-year contract for the delivery of up to 14.5 million doses of BioThrax®, with a period of performance from September 30, 2008 through September 30, 2011. The total not-to-exceed cancellation ceiling is applicable to CLINs 0004/4A and 0005/0005A in the event that funds are not available for performance of those CLINs, as referenced in FAR 52.217-2 (incorporated by reference into this contract) is $1,000,000.

The Contracting Officer agrees to provide the Contractor with the advanced notice of funds availability for CLINs 0004/*4A and/or 0005/*5A no later than [**] months prior to the first scheduled delivery under the applicable CLIN(s). The Contractor's obligation to perform under CLINs 0004/*4A and/or 0005/*5A is contingent upon receiving notice of funding in a timely manner.

e. Use of product by the USG

To the extent that third parties contact DSNS to obtain doses of BioThrax, DSNS will notify such third parties that Emergent sells AVA at prices not greater than $[**] per dose.

Because DoD will obtain BioThrax from the SNS going forward, BARDA and DSNS agree to work with Contractor to develop a process for notifying Contractor of all FMS of BioThrax.

Section C. Statement of Work

C.1 Vaccine Production and cGMP Compliance:

a) The Contractor shall manufacture BioThrax(in accordance with current Good Manufacturing Practices (cGMP) guidelines. The Contractor shall manufacture 5,700,000 doses of Final Drug Product (FDP) in 5 mL, ten dose vials in accordance with the estimated delivery schedule under Section J Attachment 7. At the time the Government notifies the Contractor that funds have been obligated funds for the performance of CLINs 0004/*4A and/or 0005/*5A, the Contractor shall manufacture those doses of Final Drug Product in 5 mL, ten dose vials in accordance with the proposed delivery schedule applicable to those CLINs.

b) BioThrax shall be delivered on any business day, except Federal holidays, within the scheduled month in accordance with the delivery schedule. All changes to the delivery schedule must be approved by the Contracting Officer and/or the Project Officer.

c) Quantities for each scheduled delivery shall be of a specific quantity.

d) The Contractor shall perform all requisite assays and release tests, including but not limited to potency, identity, and stability testing in accordance with the most current FDA approved Biologic License Application (BLA-License Number 1755, STN 103821, and/or any approved change).

e) All BioThrax(delivered under this contract shall be labeled with an expiration date consistent with its current product license at the time of manufacture.

f) The Contractor shall provide primary and secondary points of contact who will be available 24 hours per day, seven days per week to be notified in case of a public health emergency.

g) The Contractor shall report to the Government material correspondence from the FDA regarding the quality, safety, or efficacy of BioThrax(.

h) The Contractor shall provide the Government at least 72 hours (during normal business hours) to review and provide comments and on material submissions to the BLA for BioThrax (e.g., Building 55 supplement for BioThrax(BLA) prior to the Contractor

submitting such documents to the FDA (with confidentiality restrictions and /or redactions as applicable). The Government reserves the right to have additional review time for submissions greater than 10 pages.

i) The Contractor shall provide the Government with access to and/or provide copies (with confidentiality restrictions and/or redactions as applicable) of the following documents: (1) Form 483s from FDA inspections of Contractor's Lansing facility, (2) Establishment Inspection Reports (EIRs) from FDA inspections of Contractor's Lansing facility; (3) Warning Letters relating to BioThrax(; and Contractor's Annual Safety Report to FDA regarding BioThrax(. These documents will be provided to the Contracting Officer with the submission of the periodic reports due under the Contract, with the exception of Warning Letters relating to BioThrax(, which shall be provided within [**] business days of receipt.

j) The Government reserves the right to be in attendance at all material regulatory meetings between the FDA and the Contractor relating to the safety and efficacy of BioThrax(and/or manufacturing or quality at the Lansing facility.

k) The Contractor shall notify the Contracting Officer of anticipated material meetings with the FDA relating to the safety and efficacy of BioThrax(and/or manufacturing or quality at the Lansing facility. On request of the Contracting Officer, the Contractor will recommend to FDA that a representative of the SNS be invited to participate in all meetings between the FDA and the Contractor relating to BioThrax ® Warning Letters or Notices of Intent to Revoke Contractor's license to manufacture BioThrax®.

l) The Contractor may be subject to quarterly inspections by the Project Officer or the Project Officer designee(s).

m) If the contractor should obtain FDA approval for the manufacture and production of BioThrax ® having 4 year expiry dating while under this contract, the USG will accept delivery of those doses with the longer shelf life. Contractor may invoice only for those doses actually delivered under contract.

n) The product shall be delivered and shipped in accordance with cGMP (current Good Manufacturing Practices). The USG shall make payment for shipping to the SNS as set forth in CLINs 0006 (CLINs 0007 ~ 0008 are applicable only to those doses under CLIN 0004/*4A and 0005/*5A respectively).

o) At least [**] prior to each delivery to the SNS, the Contractor shall provide to the Contracting Officer:

- Certificate(s) of Analysis
- FDA Lot Release(s)
- Number of pallets, vials, and doses to be shipped

p) With each shipment, the Contractor will provide:
- Bill of Lading
- Packing Slip
- Shipping directives
- Completed (signed off) shipping instructions
- Identification number for all trucks
- Instructions given to the drivers
- Diagram of product shipment pallet (how many vials per box, per pallet, and positioning)

q) Within [**] business days of each delivery, the Contractor shall provide to the Contracting Officer:

- Confirmation from the Contractor's Quality Department that product remained within the acceptable temperature range during shipping
- The remaining ambient exposure time for each lot from the Contractor's Quality Department
- Post transit product delivery checklist

r) Funds provided shall be paid on a price per dose basis only on those products delivered to the SNS inventory under contract.

s) Under CLINs 0001, 0002, 0003, 0004 and 0005 the product shall have an expiry period of 48 months. The Contractor shall target [**] months of the total expiration period remaining when the USG takes delivery of the product. Under CLIN 0001A, 0002A, 0003A, 0004A and/or 0005A, the product shall have an expiry period of [**] months. The Contractor shall target [**] months of the total expiration period remaining when the USG takes delivery of the product.

t) The USG shall notify the Contractor of its security requirements applicable to the shipping service and/or drivers for delivery of BioThrax® to the SNS. The Contractor shall select the source of transportation to be used for the delivery of BioThrax® to the SNS, shall notify the Contracting Officer in advance of the shipping carrier for each delivery, and shall ensure that the services provided meet the stated requirements.

C.2. Anticipated Delivery Schedule:

CLIN	Delivery Period	# of Doses
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

The number under quantity shows the number of doses that the Contractor anticipates delivering during the period shown. The Contractor shall ship BioThrax® to the SNS in accordance with Section B.5.b (Range of Doses Manufactured and Shipped), F.2 (Place and Method of Delivery), and the Delivery Schedule, which will be provided to the Contracting Officer and updated periodically. Should the projected number of doses not be delivered in a specific period, the Contractor shall adjust the delivery schedule to make up for deficiencies in prior deliveries, so long as the Contractor delivers a total of 5,700,000 doses during the period of performance of CLINs 0001 through 0003. For the anticipated number of doses under CLINs 0004/4A and 0005/5A, the Contractor shall ship BioThrax® to the SNS in accordance with Section B.5.b (Range of Doses Manufactured and Shipped), F.2. (Place and Method of Delivery) and the delivery schedule upon notice from the Contracting Officer regarding the availability of funds. Contractor may accelerate deliveries within each CLIN of production if production capacity permits with prior approval of the Contracting Officer.

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C.3. Audits/Site Visits:

a) Pre-award Site Visit: The USG reserves the right to conduct a pre-award site visit of the manufacturing plant, if deemed necessary.

b) Site Visits/Audits: The USG shall perform annual site visits/security audits as deemed necessary by the USG throughout the period of performance of the contract.

c) Quality: The USG may visit the Lansing site for purposes of assessing quality on an annual basis or as deemed necessary by the USG throughout the period of performance of the contract.

d) The contractor (s) shall facilitate cGMP site-visits or inspections as requested by FDA/CBER at the time of production of product lots destined for the SNS.

e) Quality Management System (QMS): Contractor(s) shall submit evidence of its QMS to the Contracting Officer within 90 days after contract award.

f) Notice: The USG shall provide at least 2 weeks advance notice to the Contractor of all site visits and audits. The notice will include a statement concerning the intended scope of the audit and a list of the required documents or access to personnel.

g) All audits shall be conducted between normal business hours i.e. 8 a.m. through 4 p.m., Monday through Friday.

C.4 Meetings and Reports:

a) The contractor shall participate in a quarterly meeting (teleconference and/or face-to-face) to discuss performance under the contract. These meetings should provide the status updates and discuss on-going manufacturing, clinical, regulatory, and shipment issues as applicable. These meetings shall be coordinated by the Project Officer and/or Contracting Officer.

b) Risk Mitigation Plan. The plan should identify manufacturing, quality, regulatory, and shipment risks and countermeasures to mitigate these risks. This report should be updated annually or as deemed necessary by the USG.

c) Additional reporting requirements:

1. Contractor will notify DSNS in its quarterly reports if Contractor undertakes post-marketing commitments for Phase 4 studies in the event of emergency use authorization.

2. Contractor will provide DSNS with drafts of supplements to its BLA for BioThrax(that are material to the manufactured product and to the contract.

Section D – Packaging and Marking

D.1 Method of Delivery

Unless otherwise specified by the Contracting Officer, delivery of items other than BioThrax**(** that are to be furnished to the government under this contract (including invoices), shall be made by first class mail, overnight carrier, or e-mail.

D.2 Packaging

Packaging shall be consistent with the FDA approved labeling and packaging for this product at the time of manufacture.

Section E – Inspection and Acceptance

FAR Source	Title and Date
FAR Clause 52.243-1	Changes – Fixed Price (Aug 1987)
FAR Clause 52.246-1	Contractor Inspection Requirements (Apr 1984)
FAR Clause 52.246-2	Inspection of Supplies – Fixed Price (Aug 1996)
FAR Clause 52.246-16	Responsibility of Supplies (Apr 1984)

E.1 Inspection and Acceptance (July 1999)

Inspection and acceptance of the articles, services, and documentation called for herein shall be accomplished by the Contracting Officer, or their duly authorized representative (who for the purposes of this contract shall be the Project Officer) at the destination of the articles, services or documentation.

Section F - Deliveries or Performance

FAR Clause	Title and Date
FAR 52.211-17	Delivery of Excess Quantities (Sept 1989)
FAR 52.242-15	Stop Work Order (Aug 1989)
FAR 52.242-15, Alt 1	Stop Work Order, Alternate 1 (Apr 1984)
FAR 52.242-17	Government Delay of Work (Apr 1984)
FAR 52.247-34	FOB Destination (Nov 1991)

F.1 Period of Performance

The period of performance of this contract shall be from September 30, 2008 to September 30, 2011.

F. 2. Place and Method of Delivery

a. The delivery of this BioThraxÂproduct shall be F.O.B. Destination to the SNS site(s).

b. The place of delivery shall be at a Strategic National Stockpile site that will be provided to the Contractor at least [**] prior to shipping. This notification will be provided by the Contracting Officer.

F.3 Contract Deliverables

a. The following deliverables are applicable to CLINs 0001-0005 (and *A):

Up to 14.5 million doses of BioThrax® delivered in accordance with the statement of work.

b. The following deliverables are applicable to CLIN 0006 - 0008:

Invoices submitted in accordance with the shipping requirements.

F.4 Reporting Requirements

The Contractor shall submit to the Contracting Officer and to the Project Officer quarterly 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 format:

(1) Quarterly Progress Reports: On the fifteenth (15^{th}) day of each quarter, the Contractor shall submit a quarterly progress report to the Project Officer and the Contracting Officer. The Contractor shall submit one copy of the quarterly progress report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word or WordPerfect 9 or a compatible version. A quarterly report will not be required for the quarter where a final report is due. Such reports shall include the following specific information:

a. The contract number and title, the period of performance being reported, the contractor's name 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 in performance of requirements of this contract during the period covered, and include a summary of work planned for the next reporting period. Production capacity assessment problems and recommendations to include:

i. Raw material procurement status;
ii. Inventory report of product manufactured and delivered to the USG under this contract;
iii. Quality control testing and purity;
iv. Quality control potency assessment;
v. Quality manufacturing deviations – summary;
vi. FDA inspections and consultation results or recommendations;
vii. Security assessment, problems and recommendations;
viii. Physical storage monitoring and calibration reports for manufactured products.
ix. Overall project assessment, problems encountered and recommended solutions, etc.

d. Section III – 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 project plan and delivery schedule will be updated in each Quarterly Report and compared to the baseline plan and delivery schedule.

(2) Risk Mitigation Plan: The contractor shall submit a risk mitigation plan within 90 days after contract award and shall provide an updated plan on the anniversary of the contract award.

(3) Final Report: A final report is due 30 days prior to the end of the period of performance of the contract.

The Contractor shall deliver, within the time frames specified above, an original to the Contracting Officer and a copy to the Project Officer (See Section G.1. for the Project Officer's address).

F.5 Excusable Delay

The contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. Furthermore, the Contractor will not be in default under this contract if it is unable to deliver AVA doses in accordance with any delivery schedule because of the action or inaction of the FDA, except to the extent that such action or inaction is a direct consequence of the negligence or willful misconduct of the Contractor. Additionally, the Contractor will not be in default of this contract in the event that deliveries are delayed as a result of another Government agency placing an order for AVA doses that is determined to have priority over this contract under the Defense Priority Allocation System or under any other reasonable legal justification or as a result of allocating up to ten lots of BioThraxÒ to improvement programs, including fill/finish and manufacturing process improvements. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement or any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch and shall promptly give written notice of the Contracting Officer of the cessation of such occurrence.

Section G – Contract Administration

G.1 Project Officer

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

CDR Jacqueline K. Thomas
1600 Clifton Road, NE
Atlanta, GA 30333
Email: gtv4@cdc.gov

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

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

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

G.2 Payment by Electronic Funds Transfer – Central Contractor Registration (Oct 2003)

(a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-34, Payment by Electronic Funds Transfer in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

(b) The contractor shall make the designation by submitting the form titled “ACH Vendor/Miscellaneous Payment Enrollment Form” to the address indicated below. Note: The form may be either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer or the CDC Financial Management Office at (404)498-4050.

(c) In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form may not required.

(d) The completed form shall be mailed after contract award, but no later than 14 calendar days before an invoice is submitted, to the following address:

Centers for Disease Control and Prevention (FMO)
PO Box 15580
Atlanta, GA 30333
(404) 498-4050 or (800) 335-2455

G.3. Invoice Submission

(a) The Contractor shall submit an original contract invoice/voucher to the address shown below:

The Centers for Disease Control and Prevention
Financial Management Office (FMO)
PO Box 15580
Atlanta, GA 30333

Alternatively, the Contractor may submit invoices electronically via email to fmoapinv@cdc.gov. Invoices may also be faxed to (404) 638-5324. In any event, an invoice must be submitted to the Financial Management Office in order for it to be paid.

(b) The Contractor shall submit one (1) copy of the invoice/voucher to the Contracting Officer.

(c) The Contractor agrees to include (as a minimum) the following information on each invoice:

(1) Contractor's Name & Address
(2) Contractor's Tax Identification Number (TIN)
(3) Purchase Order/Contract Number and Task Order Number, if appropriate
(4) Invoice Number
(5) Invoice Date
(6) Contract Line Item Number and Description of Item
(7) Quantity
(8) Unit Price & Extended Amount for each line item
(9) Shipping and Payment Terms
(10) Total Amount of Invoice
(11) Name, title and telephone number of person to be notified in the event of a defective invoice
(12) Payment Address, if different from the information in (c)(1)
(13) DUNS + 4 Number
(14) The following certification:

I certify that this voucher reflects (fill in Contractor's name) request for reimbursement of allowable and allocable costs incurred in specific performance of work authorized under Contract (fill in contract number)/Task (fill-in task order number, if applicable), and that these costs are true and accurate to the best of my knowledge and belief.

(Original Signature of Authorized Official)
Typed Name and Title of Signatory

d.

In accordance with 5 CFR part 1315 (Prompt Payment), CDC's Financial Management Office is the designated billing office for the purpose of determining the payment due date under FAR 32.904.

G.4 Evaluation of Contractor Performance (Service)

(a) *Purpose:* In accordance with FAR 42.1502, the contractor's performance will be periodically evaluated by the government, in order to provide current information for source selection purposes. These evaluations will therefore be marked “Source Selection Information.”

(b) *Performance Evaluation Period*: The contractor's performance will be evaluated at least annually.

(c) *Evaluators*: The performance evaluation will be completed jointly by the Project officer and the Contracting officer.

(d) *Performance Evaluation Factors*: The contractor's performance will be evaluated in accordance with the attachment listed in Section J titled Contractor Performance Evaluation Report.

(e) *Contractor Review*: A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.

(f) *Resolving Disagreements Between the Government and the Contractor*: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) *Release of Contractor Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated as well as impede the efficiency of Government operations.

(h) *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) *Retention Period*: The agency will retain past performance information for a maximum period of three years after completion of contract performance for the purpose of providing source selection information for future contract awards.

G.5 Contracting Officer

(a) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

(b) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

G.6 Contract Communications/Correspondence

The contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

G.7. Notice Prior to Publication

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Contracting Officer; provided however, that no such notice is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity; for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to 3rd parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. .

G.8. Press Releases

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

2.

Public Law and Section No.	**Fiscal Year**	**Period Covered**
P.L. 108-447, Title V - General Provisions, Section 506	2007	10/1/06 - 9/30/07

G.9. 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

G.10. Notification of Utilization

The USG agrees to notify the contractor of any ultimate use of the government owned vaccine provided by the Contractor to the SNS with the exception of classified information. This information is necessary for the investigation of adverse event claims and adverse event reporting.

The notice shall include the recipient, intended purpose of the use, projected date of use, number of doses, and the lot number from which the product will be used.

Section H – Special Contract Requirements

H.1 Prohibition on the Use of Appropriated Funds for Lobbying Activities (Jul 1999)

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

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

(End of Clause)

H.2 Representations, Certifications and Other Statements of Offerors (Jul 1999)

The Representations, Certifications and Other Statements of Offerors submitted by the Contractor dated on September 10, 2008 are hereby incorporated by reference, with the same force and effect as if they were given in full text.

(End of Clause)

H.3 Privacy Act Applicability (Apr 2000)

(a) Notification is hereby given that the contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at

http://www.gpoaccess.gov/cfr/index.html

(b) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

(c) The contractor shall follow the Privacy Act guidance as contained in the Privacy Act system notice to be provided by the Government (See Section J, List of Attachments).

(End of Clause)

Note: Clinical trials cannot be initiated until the System Notice has been published and the Contracting Officer notifies the contractor.

H.4 Laboratory License Requirements (May 1998)

The contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

(End of Clause)

H.5 Dissemination of Information

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

H.6 Identification and Disposition of Data

The contractor shall be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.7 Incorporation of Technical Proposal

The Contractor's Technical Proposal included in its Proposal or Final Proposal Revision if necessary dated September 10, 2008, along with subsequent change pages, if any, dated September 25, 2008 submitted in response to RFP-BARDA-08-26 is hereby incorporated into the contract by reference. The contractor shall perform the work substantially as set forth in the technical proposal. Any revisions to the technical proposal that would significantly alter the technical approach must be approved in writing by the Contracting Officer. In the event of a conflict between Section C, Statement of Work, and the Contractor's technical proposal, Section C will take precedence.

(End of Clause)

H.8 Year 2000 Compliance (Jul 1999)

Unless elsewhere exempted, information technology (if any) to be acquired under this contract/purchase order, which will be required to perform date/time processing involving dates subsequent to December 31, 1999, shall be Year 2000 compliant as defined in Federal Acquisition Regulation Part 39.002.

(End of Clause)

H.9 Security Plan Requirements

The work to be performed under this contract will involve access to sensitive DSNS program/logistics information. Therefore, the Offeror(s) shall develop and submit a written Security Plan that describes their procedures and policies to defend against theft, tampering, or destruction of product-related material, equipment, documents, information, and data. The Security Plan will include, at a minimum:

a. Personnel Security Policies and Procedures including but not limited to: recruitment of new employees; interview process; background checks; suitability / adjudication policy; access determination; rules of behavior; termination procedures; and non-disclosure agreements.

b. Physical Security Policies and Procedures including but not limited to: internal / external access control; identification policies; facility visitors; parking areas; barriers; shipping, receiving and transport; security lighting; restricted areas; signage; intrusion detection systems; closed circuit television; other control measures. The plan shall include the security measures to be used to protect the product to be stored at the Contractor's facility (e.g., refrigeration/freezer alarm systems, backup electrical power generator systems, etc.), and the contingency plan to accommodate any manufacturing and storage problems caused by natural or man-made disasters, power loss, refrigerant loss, equipment failures, etc..

c. Information Security Policies and Procedures including but not limited to: identification of sensitive information; access control / determination; secure storage procedures; document control; destruction procedures.

d. Information Technology Security Policies and Procedures including but not limited to: intrusion detection and prevention systems; encryption systems; identification of sensitive information; passwords; removable media; laptop policy; access control / determination; secure storage procedures; document control; backup procedures; disaster recovery.

e. Security Reporting Requirement - Violations of established security protocols will be reported to the Contracting Officer upon discovery. The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. DSNS will determine if the severity of the violation requires further government intervention.

Performance of the work under this contract shall be in accordance with this written Security Plan. The Contractor shall submit this plan to the Contracting Officer within 90 days after contract award. The Contracting Officer will notify the Contractor that the Security Plan is acceptable.

H.10 Protection of Human Subjects

No contract involving human subjects research shall be awarded until acceptable assurance has been given that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee(s) as described in 45 CFR Part 46. Contracts involving human subjects will not be awarded to an individual unless the individual is affiliated with or sponsored by an institution that has an Office for Human Research Protections (OHRP) approved assurance of compliance in place and will assume responsibility for safeguarding the human subjects involved. The OHRP web site is: http://www.hhs.gov/ohrp. The contractor further agrees to provide certification at least annually that the institutional review board has reviewed and approved the procedures which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.
The contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the contractor or any subcontractor, agent or employee of the contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the contractor or its employees.
If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OHRP, that the contractor if not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.
If the contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OHRP, terminate this contract in whole or in part, and the contractor name may be removed from the list of those contractors with approved Health and Human Services Human Subject Assurances.

H.11 Information on Compliance with Animal Care Requirements

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

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

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

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

H.12 Requirements for Adequate Assurance of Protection of Vertebrate Animal Subjects

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines “animal” as “any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes.” This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.
No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval.

H.13 Care of Live Vertebrate Animals

1. Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The contractor shall furnish evidence of such registration to the Contracting Officer.

2. The contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

3. The contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care and Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the contractor's name may be removed from the list of those contractors with approved Public Health Service Animal Welfare Assurances.

The contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program, may be obtained by contacting: Animal Care Staff USDA/APHIS 4700 River Road, Unit 84 Riverdale, MD 20737 (301) 734-4980. Contractors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance with the PHS. Contractors are encouraged to visit the OLAW website at http://grants.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the National Institutes of Health at (301) 594-2289.

H.14 Approval of Required Assurance by OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Division of the Strategic National Stockpile (DSNS) shall not be expended by the contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/olawaddr.htm.

H.15 Liability Protection under the PREP Act

The Public Readiness & Emergency Preparedness Act (PREP Act), Pub. L. 109-148, Division C, 119 Stat. 2818 to 2832, amended the Public Health Service Act, 42, U.S.C. 243 et seq., to provide targeted liability protections. The Government agrees that the medical countermeasure delivered by the contractor under this contract will not be administered in humans, unless the Secretary executes a

declaration in accordance with section 319F-3(b) of the Public Health Service Act, 42, U.S.C. 247-d-6d, that the medical countermeasure delivered under this contract is a covered countermeasure to which section 319-F3(a) applies subject to the terms and conditions of the declaration.

H.16 Manufacturing Standards

The Current Good Manufacturing Practice Regulations (cGMP)(21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packaging of this product.

If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by CBER and CDER, the contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

H.17. Prohibition on Contractor Involvement with Terrorist Activities

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 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.

H.18. HHSAR 352.270-5 Key Personnel (APR 1984)

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

Contractor Key Personnel

Name:	Position:
1. [**]	[**]
2. [**]	[**]

H.19. Registration with the Select Agent Program for Work Involving the Possession, Use, and/or 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 prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with BARDA, 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 performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, 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 Government 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. The Government 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 shall 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 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/sap/.

PART II – CONTRACT CLAUSES

Section I – CONTRACT CLAUSES

I.1. 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jun 2008)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).

(2) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Pub. L. 108-77, 108-78)

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate*.]

_X_ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 253g and 10 U.S.C. 2402).

__ (2) 52.219-3, Notice of Total HUB Zone Set-Aside (Jan 1999) (15 U.S.C. 657a).

__ (3) 52.219-4, Notice of Price Evaluation Preference for HUB Zone Small Business Concerns (JULY 2005) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

__ (4) removed

__ (ii) Alternate I (Mar 1999) of 52.219-5.

__ (iii) Alternate II (June 2003) of 52.219-5.

__ (5) (i) 52.219-6, Notice of Total Small Business Set-Aside (June 2003) (15 U.S.C. 644).

__ (ii) Alternate I (Oct 1995) of 52.219-6.

__ (iii) Alternate II (Mar 2004) of 52.219-6.

__ (6) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).

__ (ii) Alternate I (Oct 1995) of 52.219-7.

__ (iii) Alternate II (Mar 2004) of 52.219-7.

_X_ (7) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d) (2) and (3).

_X_ (8) (i) 52.219-9, Small Business Subcontracting Plan (Apr 2008) (15 U.S.C. 637(d) (4).

__ (ii) Alternate I (Oct 2001) of 52.219-9.

__ (iii) Alternate II (Oct 2001) of 52.219-9.

__ (9) 52.219-14, Limitations on Subcontracting (Dec 1996) (15 U.S.C. 637(a) (14).

__ (10) 52.219-16 Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637 (d)(4)(f)(i)

__ (11) (i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (SEPT 2005) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).

__ (ii) Alternate I (June 2003) of 52.219-23.

__ (12) 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (Apr 2008) (Pub). L. 103-355, section 7102, and 10 U.S.C. 2323).

__ (13) 52.219-26, Small Disadvantaged Business Participation Program—Incentive Subcontracting (Oct 2000) (Pub). L. 103-355, section 7102, and 10 U.S.C. 2323).

__ (14) 52.219-27, Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (May 2004).

__ (15) 52.219-28, Post Award Small Business Program Representative (June 2007) (15 U.S.C. 632(a)(2)

_X_ (16) 52.222-3, Convict Labor (Jun 2003) (E.O. 11755)

_X_ (17) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Feb 2008) (E.O. 13126).

_X_ (18) 52.222-21, Prohibition of Segregated Facilities (Feb 1999).

_X_ (19) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246).

_X_ (20) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sept 2006) (38 U.S.C. 4212).

_X_ (21) 52.222-36, Affirmative Action for Workers with Disabilities (Jun 1998) (29 U.S.C. 793).

_X_ (22) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sept 2006) (38 U.S.C. 4212).

__ (23) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201).

__ (24) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C. 6962(c) (3) (A) (ii)).

__ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i) (2) (C)).

__ (25) 52.225-1, Buy American Act—Supplies (June 2003) (41 U.S.C. 10a-10d).

__ (26) (i) 52.225-3, Buy American Act—Free Trade Agreements—Israeli Trade Act (AUG 2007) (41 U.S.C. 10a-10d, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, Pub. L. 108-77, 108-78, 108-286).

__ (ii) Alternate I (Jan 2004) of 52.225-3.

__ (iii) Alternate II (Jan 2004) of 52.225-3.

__ (27) 52.225-5, Trade Agreements (NOV 2007) (19 U.S.C. 2501,et seq., 19 U.S.C. 3301 note).

__ (28) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.o.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

___ (29) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (42 U.S.C. 5150) (Nov 2007)

___ (30) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area.(Nov 2007)

___ (31) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 255(f), 10 U.S.C.

2307 (f)

__ (32) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).

_X_ (33) 52.232-33, Payment by Electronic Funds Transfer—Central Contractor Registration (Oct 2003) (31 U.S.C. 3332).

__ (34) 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration (May 1999) (31 U.S.C. 3332).

__ (35) 52.232-36, Payment by Third Party (May 1999) (31 U.S.C. 3332).

__ (36) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (37) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. App. 1241 and 10 U.S.C. 2631).

__ (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Act of 1965, as Amended (Nov 2007) (41 U.S.C. 351, *et seq.*).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 1989) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq.*).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts) (Nov 2006) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq.*).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Feb 2002) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq.*).

(d) *Comptroller General Examination of Record*. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in paragraphs (i) through (vii) of this paragraph in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(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 (Mar 2007) (E.O. 11246).
(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sept 2006) (38 U.S.C. 4212).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (June 1998) (29 U.S.C. 793).
(v) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201).
(vi) 52.222-41, Service Contract Act of 1965, as Amended (Nov 2007), flow down required for all subcontracts subject to the Service Contract Act of 1965 (41 U.S.C. 351, *et seq*.).
(vii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. App. 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 include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

Alt 1 (FEB 2000). As prescribed in 12.301(b)(4), delete paragraph (d) from the basic clause, re-designate paragraph (e) as paragraph (d), and revise the reference to “paragraphs (a), (b), (c), or (d) of this clause in the re-designated paragraph (d) to read “paragraphs (a), (b), and (c) of this clause”.

I.2. FAR Addenda

Federal Acquisition Regulation (FAR) (48 CFR CHAPTER 1) Clauses

FAR Clause No.	Title	Date
1. FAR 52.202-1	Definitions	Jul 2004
2. FAR 52-212-4	Contract Terms and Conditions - Commercial Items	Feb 2007
3. FAR 52.217-2	Cancellation under Multi-Year Contracts	Oct 1997
3. FAR 52.243-1	Changes-Fixed Price	Aug 1987
3. FAR 52.249-2	Termination for Convenience of the Government (Fixed Price)	May 2004
4. FAR 52.249-8	Default (Fixed Price Supply and Service) (over $100,000)	Apr 1984

I.3. HHSAR Addenda

Department of Health & Human Services Acquisition Regulation (HHSAR)
(48 CFR CHAPTER 3) Clauses

HHSAR Clause No.	Title	Date
1. HHSAR 352.202-1	Definitions	Jan 2001
2. HHSAR 352.223-70	Safety and Health	Jan 2001
3. HHSAR 352.224-70	Confidentiality of Information	Apr 1984
4. HHSAR 352.232-9	Withholding of Contractor Payments	Apr 1984
5. HHSAR 352.270-4	Pricing of Adjustments	Jan 2001
6. HHSAR 352.270-5	Key Personnel	Apr 1984
7. HHSAR 352.270-6	Publication & Publicity	Jul 1991
8. HHSAR 352.270-7	Paperwork Reduction Act	Jan 2001
9. HHSAR 352.270-8	Protection of Human Subjects	Jan 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.

10. HHSAR 352.270-9	Care of Live Vertebrate Animals	Jan 2001
11. HHSAR 352.270-10	Anti-Lobbying	Jan 2006

PART III – List of Documents, Exhibits, and other attachments

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this contract:

1. Summary of Related Activities
2. Protection of Human Subjects
3. Disclosure of Lobbying Activities
4. Contractor Performance Evaluation Report
5. ACH Vendor/Miscellaneous Payment Enrollment Form
6. Subcontracting Plan
7. Forecast Delivery Schedule as of 9/29/2008

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the Offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals* in this proposal.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*If an individual has no obligation(s), so state.

b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*If no commitment of effort is intended, so state.

c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

Name	Title/Position	Total Proposed Effort
1.		
2.		
3.		
4.		

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[] ORIGINAL [] CONTINUATION [] EXEMPTION	[] GRANT [] CONTRACT [] FELLOWSHIP [] COOPERATIVE AGREEMENT [] OTHER:_____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

Approved for use through 07/31/2005

6. Assurance Status of this Project *(Respond to one of the following)*

[] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. , the expiration date IRB Registration No. _____

[] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [] Full IRB Review on (date of IRB meeting) _____ or [] Expedited Review on (date)
[] If less than one year approval, provide expiration date _____
[] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* 12. Fax No. *(with area code)* 13. Email:	
14. Name of Official	15. Title
16. Signature	17. Date

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DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	2. Status of Federal Action:	3. Report Type:
a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	a. bid/offer/application b. Initial award c. post-award	a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report_____

4. Name and Address of Reporting Entity:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime
__ Prime __ Subawardee Tier_____, if known: Congressional District, if known:	Congressional District, if known:
6. Federal Department/Agency:	7. Federal Program Name/Description CFDA Number, if applicable: _____
8. Federal Action Number, if known:	9. Award Amount, if known: $
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): (attach Continuation Sheet(s)	b. Individual Performing Services (including address if different from No. 10a) (last name, first name, MI) SF-LLL-A, if necessary)
11. Amount of Payment (check all that apply): $_____ __ actual __ planned	13. Type of Payment (check all that apply): __ a. retainer __ b. one-time fee __ c. commission __ d. contingent fee __ e. deferred __ f. other; specify: _____
12. Form of Payment (check all that apply): __ a. cash __ b. in-kind; specify: nature_____ value_____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for payment indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached:

Yes No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each failure.	Signature:_____ Print Name:_____ Title:_____ Telephone No.:_____Date:_____
Federal Use Only	Authorized for Local Reproduction Standard Form—LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing of attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

(b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

Standard Contractor Evaluation Performance Report

Evaluation Type: Interim __ Final __ (*check one)*		
Evaluating Organization:	**Reporting Period: From to**	
Contracting Office:	**Contract Number:**	**Order Number:**

Contractor Name:	**Contractor Address:**	
DUNS:	**City:**	**State:**
Additional or Alternate Contractor Name:	**Zip/Postal Code:**	**Country:**

TIN:	**Industrial Code (NAICS):**	**Commodity Code:**	**Contract Type:**

Contract Award Date:	**Contract Expiration Date:**	**Contract Value:**

Requirement Description:

Ratings

Summarize contractor performance and check the number which corresponds to the rating for each rating category (*See attached Rating Guidelines)*.

Quality of Product or Service

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Quality of Product or Service (2000 characters maximum):

Cost Control (*Rating and Comments for Cost Control are not required if contract type is Fixed-Price)*

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Cost Control (2000 characters maximum):

Timeliness of Performance

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Timeliness of Performance (2000 characters maximum):

Business Relations

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Business Relations (2000 characters maximum):

Additional Info

Subcontracts

Are subcontracts involved? **__Yes __No (*Check one)***
Government Comment on subcontracts (2000 characters maximum):

Contractor Key Personnel

Contractor Manager/Principal Investigator (*name):*
Government Comment on Contractor Manager/Principal Investigator (2000 characters maximum):

Contractor Key Person (*name):*
Government Comment on Contractor Key Person (2000 characters maximum):

Contractor Key Person (*name):*
Government Comment on Contractor Key Person (2000 characters maximum):

Small Business Subcontracting Plan

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, reporting and other aspects of the plan? _Yes_No_N/A (*Check one)*

If this is a bundled contract, did the contractor meet the goals and objectives for small business participation?
_Yes _No _N/A (*Check one)*

Government Comments on Small Business Subcontracting Plan (2000 characters maximum):

Small Disadvantaged Business Goals

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, for small disadvantaged business (SDB) participation, monetary targets for SDB participation, and required notifications? _Yes_No_N/A (*Check one)*

Government Comments on Small Disadvantaged Business Goals (2000 characters maximum):

Customer Satisfaction

Is/was the contractor committed to customer satisfaction? _Yes _No (*Check one)*

Would you recommend the selection of this firm again? _Yes _No (*Check one) – FINAL REPORT ONLY*

Government Comments on Customer Satisfaction (2000 characters maximum):

Admin Info

Project Officer/COTR
Name:
Phone:
Fax:
E-mail Address:

Contractor Representative
Name:
Phone:
Fax:
E-mail Address:

Alternate Contractor Representative (*Required to insure that at least one person is notified of evaluation)*
Name:
Phone:
Fax:
E-mail Address:

Contracting Officer:
Name:
Phone:
Fax:
E-mail Address:

Contractor Comments

Quality of Product of Service

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Cost Control

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Timeliness of Performance

___Contractor has elected not to comment

Contractor Comments for Timeliness of Performance (2000 characters maximum):

Business Relations

___Contractor has elected not to comment

Contractor Comments for Business Relations (2000 characters maximum):

Overall Comment

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Rating Guidelines

Quality of Product or Service

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Non-conformances are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards containing similar requirements.
Poor	Overall compliance requires significant Agency resources to ensure achievement of contract requirements.
Fair	Overall compliance requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, quality problems, and the Contractor has met the contract requirements.
Excellent	There are no quality issues, and the Contractor has substantially exceeded the contract performance requirements without commensurate additional costs to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that was significantly in excess of anticipated achievements and is commendable as an example for others, so that it justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Cost Control

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Ability to manage cost issues is jeopardizing performance of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, this level of ability to manage cost issues constitutes a significant impediment in consideration for future awards.
Poor	Ability to manage cost issues requires significant Agency resources to ensure achievement of contract requirements.
Fair	Ability to control cost issues requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, cost management issues and the Contractor has met the contract requirements.
Excellent	There are no cost management issues and the Contractor has exceeded the contract requirements, achieving cost savings to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where the contractor achieved cost savings and performance clearly exceeds the performance levels described as "Excellent".

Timeliness of Performance

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Delays are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards.
Poor	Delays require significant Agency resources to ensure achievement of contract requirements.
Fair	Delays require minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or minimal, delays that impact achievement of contract requirements.
Excellent	There are no delays and the contractor has exceeded the agreed upon time schedule.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Business Relations

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Response to inquiries and/or technical, service, administrative issues is not effective. If not substantially mitigated or corrected it should constitute a significant impediment in considerations for future awards.
Poor	Response to inquiries and/or technical, service, administrative issues is marginally effective.
Fair	Response to inquiries and/or technical, service, administrative issues is somewhat effective.
Good	Response to inquiries and/or technical, service, administrative issues is consistently effective.
Excellent	Response to inquiries and/or technical, service, administrative issues exceeds Government expectation.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Department of Health and Human Services
Center for Disease Control

Payment Information Form

The information requested on this form concerns your financial institution, your account at that institution, and personal information which needs to verified and completed.

Privacy Act Statement

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of $_{31}$ USC $_{33}$22 and $_{31}$ CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to your financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

Check one of the following:

[ ] Federal Employee: [X] Contractor: [ ] Vendor:
Name: Emergent BioDefense Operations Lansing, Inc.
Address: 3500 North Martin Luther King Jr. Boulevard
Lansing, MI 48906-9910

Remit To
(If same as above, leave blank. Must match address on invoice for internal control purposes.)
Address :

Taxpayer Identification # (TIN): 3 8 3 4 1 2 7 8
(If you are an individual, this may be your Social Security number)

1. Payee's Telephone Number: (517) 327-6886

The following information must be completed by your financial institution representative:

2. Name of Financial Institution: Fifth Third Bank
3. Address of Financial Institution: 2501 Coolidge Road
   East Lansing, MI 48823

4. Financial Institution's 9-digit ABA Routing Number for Transfer of Funds: 0 7 2 4 0 0 0 5 2
5. Depositor Account Title: Emergent BioDefense Operation
6. Depositor Account Number: [***]
7. Type of Account: [X] Checking [ ] Savings
8. Signature and Title of Authorized Official of Financial Institution:
   Leu Tierney, Vice President
9. Telephone Number: (517) 351-5217 Date: 9/10/08

**********The following must be signed by the payee**********

I have verified the information on this form.

Signature Date

SUBCONTRACTING PLAN

DATE: September 25, 2008

CONTRACTOR: Emergent BioDefense Operations Lansing Inc.

ADDRESS: 3500 N. Martin Luther King Jr. Blvd., Lansing, MI 48906-9910

DUNN & BRADSTREET NUMBER: [**]

SOLICITATION OR CONTRACT NUMBER: RFP-BARDA-08-26

ITEM/SERVICE (Description): The supply of BioThrax® (Anthrax Vaccine Adsorbed) to meet the nation's urgent need to stockpile countermeasures to safeguard against the threat of a deliberate anthrax attack.

TOTAL CONTRACT AMOUNT: $ 404,685,512.00

PERIOD OF CONTRACT PERFORMANCE: September 26, 2008 through September 30, 2011

- **Type of Plan (check one)**

X ***Individual plan*** (all elements developed specifically for this contract and applicable for the full term of this contract).

Master plan (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

Commercial products/service plan (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year. The contractor must provide a copy of the initial agency approval and must enter an annual SSR into the electronic Subcontracting Reporting System (eSRS) with a breakout of subcontracting prorated for HHS and other Federal agencies.

- **Goals**

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is: $41,760,000

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBz and SDVOSB: $2,088,000 and 5.00%

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: $417,600 and 1.00%

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: $1,252,800 and 3.00%

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: $208,800 and .5%

f. Total estimated dollar and percent of planned subcontracting with SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES: $208,800 and .5%

g. Total estimated dollar and percent of planned subcontracting with “OTHER THAN SMALL BUSINESSES” $ 39,672,000 and 95%

h. Description of Services and Supplies to be Subcontracted Under This Contract:

	Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	SDVOSB
1	Professional Services	X	X		X		
2	Legal Expenses	X					
3	Animal and Animal Supplies	X	X				
4	Clothing and Uniforms	X					
5	Communications	X					
6	Insurance	X					
7	Office Expense	X	X				
8	Supplies	X	X	X	X	X	X
9	Utilities/Waste Mgmt	X					
10	Repairs and Maintenance	X	X		X		
11	Recruiting and Relocation	X					

i. The subcontracting goals for small, HUBZone, small disadvantaged, women-owned small business concerns and service disabled veteran-owned small businesses were derived from current spending patterns by product and service area as of August 2007 and estimate of supplier diversity program impact. The product and service areas correspond to with the major expense categories in EBOL’s accounting software. Products and services exclude: salaries and benefits, depreciation, license fees, taxes, interest, FAR non-allowable costs, capital costs, cGMP raw materials, travel, meals and entertainment . EBOL’s procurement department seeks to obtain the lowest responsible and responsive bid for all goods and services. Competitive quotes from any sources must meet the business’ specifications for all such requirements including quality, capability, service, competitive cost, performance expectations, and other relevant criteria. Because BioThrax© is an FDA-regulated biopharmaceutical product, the available service providers and suppliers are limited. Thus, specific goals for small business subcontracting may not be achievable.

j. Indirect costs have have not X been included in the dollar and percentage subcontracting goals above (check one)

k. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone and SDVOSB concerns: N/A

- **Program Administrator:**

[**]
Emergent BioDefense Operations Lansing Inc.
3500 N. Martin Luther King Jr. Blvd., Lansing, MI 48906-9910
Telephone: [**]
E-Mail: [**]

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? (If NO is checked, please indicate who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing. X yes ___ no

b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone and SDVOSB concerns from all possible sources x yes __ no

c. Ensuring periodic rotation of potential subcontractors on bidder's lists; ___x__ yes

__ no

d. Assuring that SB, SDB, WOSB, HUBZONE and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing,___x__ yes _____no

e. Ensuring that requests for proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone and SDVOSB concerns. ___x___ yes no

f. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, Hubz and SDVOSB small business participation ___x___yes no

g. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone and SDVOSB concerns to include the Central Contractor Registration (http://www.ccr,gov/), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices; __x__ yes no

h. Establishing and maintaining contract and subcontract award records; ___x___ yes __ no

i. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; ___x__yes _____ no

j. Ensuring that SB, SDB, WOSB, HUBZone and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company ___x__ yes ___ no

k. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; ___x___ yes ____ no

l. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; ___x___ yes _____ no

m. Preparing and submitting timely, required subcontract reports; ___x___ yes no

n. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures; ___x___ yes _____ no

o. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and ___x___ yes _____ no

- **Equitable Opportunity**

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone and SDVOSB procurement conferences and trade fairs; 4) review sources from the Central Contractor Registration (http://www.ccr.gov/); 5) review sources from the Small Business Administration (SBA), Central Contractor Registration (CCR); 6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC),. (http://epic.od.nih.qov/). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and 7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;

2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone and SDVOSB source lists, guides, and other data for soliciting subcontractors; and

3. Monitor activities to evaluate compliance with the subcontracting plan.

- **Flow Down Clause**

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $550,000 ($1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow-down clause FAR 52.219.-9 if it is subcontracting commercial items.

- **Reporting and Cooperation**

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and (4) ensuring that subcontractors agree to submit ISRs and SSRs. The ISR and SSR shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website https://esrs.svmplicitv.com/index? tab=siqnin&cck=l

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	ISR	30-Apr
Apr 1 - Sept 30	ISR	30-Oct
Oct 1 - Sept 30	SSR	30-Oct
Contract Completion	OF 312	30 days after completion

See FAR 19.7 for instruction concerning the submission of a Commercial Plan: SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit ISR (bi-annually) for the cognizant awarding Contracting Officer's review and acceptance via the eSRS website https://esrs.symplicity.com/index? tab=siqnjn&cck=l.

b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website https://esrs.symphclty.com/lndex? tab=slanln&cck=l. (Note: Log onto the OSDBU website to view the HHS Agency Coordinator contact information (http://www.hhs.qov/osdbu/staff.html).

c. Contractors that do not use the eSRS to submit its reports must also submit a paper copy of the SSR to the appropriate Commercial Market Representative (contact the contracting official (CO) or the CO's eSRS Point of Contact).

- **Record keeping**

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

a. SB, SDB, WOSB, HUBZone and SDVOSB source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone and SDVOSB sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards;

d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and

f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This item is not required on a contract - by - contract basis for company or division-wide commercial plans.)

- **Timely Payments to Subcontractors**

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with small business concerns, 8(a), SDB, women-owned small business, HubZone and service disabled veteran-owned small business concerns.

Your company has established and used such procedures: ___x___ yes ___ no

- **Description of Good Faith Effort**

Maximum practicable utilization of small, 8(a), small disadvantaged, woman-owned, HubZone small and service disabled veteran owned concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits. **When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the small, SDB, WOSB, HubZone and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the plan.

1) Develop and implement a supplier diversity program, 2) enhance current vendor system software to allow for improved measurement of small business activities, 3) attend small business seminars to identify qualified candidates, 4) review contracts to ensure terms support the small business subcontracting goals.

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: /s/ R. Don Elsey

Typed Name: R. Don Elsey

Title: CFO

Date: 9/25/2008

This plan was reviewed by:

Signature:

Typed Name:

Title: Contracting Officer

Date:

This plan was reviewed by:

Signature:

Typed Name:

Title: Small Business Specialist (SBS)

Date:

This plan was reviewed by:

Signature:

Typed Name:

Title: Small Business Administration Procurement Center Representative (PCR)

Date:

Is Accepted By:

OPDIV:

Typed Name:

Title:

Date:

Appendix A - Delivery Schedule

CLIN	Delivery #	Lot	Ship Date	Expiry Date	Remaining Expiry (Days)	Remaining Expiry (Months)	Doses	Cum Doses
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

Confidential materials omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment. A total of 2 pages have been omitted.

Exhibit 31.1

CERTIFICATION

I, Fuad El-Hibri, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions 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 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 statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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 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.

Date: November 6, 2008

/s/Fuad El-Hibri
Fuad El-Hibri
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, R. Don Elsey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Emergent BioSolutions 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 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 statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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 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.

Date: November 6, 2008

/s/R. Don Elsey
R. Don Elsey
Senior Vice President Finance, Chief Financial Officer and Treasurer

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Fuad El-Hibri, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(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.

Date: November 6, 2008

/s/Fuad El-Hibri
Fuad El-Hibri
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Emergent BioSolutions Inc. (the "Company") for the period ended September 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, R. Don Elsey, Senior Vice President, Finance and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(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.

Date: November 6, 2008

/s/R.Don Elsey
R. Don Elsey
Senior Vice President, Finance and Chief
Financial Officer, Principal Financial Officer