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File No. 333-136622

Prospectus

5,000,000 shares

Common stock

This is an initial public offering of common stock by Emergent BioSolutions Inc. No public market currently exists for our common stock. We are offering 5,000,000 shares of our common stock.

Our common stock has been authorized for listing on the New York Stock Exchange under the symbol “EBS.”

	Per share	Total
Initial public offering price	$12.500	$ 62,500,000
Underwriting discounts and commissions	$ 0.875	$ 4,375,000
Proceeds to Emergent, before expenses	$11.625	$ 58,125,000

The underwriters have an option for a period of 30 days to purchase up to 480,000 additional shares of common stock from the selling stockholders identified in this prospectus and up to 270,000 additional shares of common stock from us to cover over-allotments. We will not receive any proceeds from the sale of shares by the selling stockholders.

Investing in our common stock involves a high degree of risk. See “Risk factors” beginning on page 9.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about November 20, 2006.

JPMorgan

Cowen and Company

HSBC

November 14, 2006

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You should rely only on the information contained in this prospectus or to which we have referred you. We and the selling stockholders have not authorized anyone to provide you with different information. We and the selling stockholders are offering to sell, and are seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock. Our business, financial conditions, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in any jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

Prospectus summary

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that is important to you. Before investing in our common stock, you should read this prospectus carefully in its entirety, especially the risks of investing in our common stock that we discuss under "Risk factors," and our financial statements and related notes beginning on page F-1.

Our business

We are a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. Immunobiotics are pharmaceutical products, such as vaccines and immune globulins, that induce or assist the body's immune system to prevent or treat disease. We operate in two business segments: biodefense and commercial. In our biodefense business, we develop and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism. In our commercial business, we develop immunobiotics for use against infectious diseases with significant unmet or underserved medical needs.

BioThrax. We manufacture and market BioThrax®, also referred to as anthrax vaccine adsorbed, the only anthrax vaccine approved by the U.S. Food and Drug Administration, or FDA. Our total revenues from BioThrax sales were $55.5 million in 2003, $81.0 million in 2004, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006. The U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, have been the principal customers for BioThrax. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied over nine million doses of BioThrax through September 2006 to the DoD for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.7 million doses of BioThrax. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base contract year plus four option years. In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of $123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of $120 million. We delivered approximately one million doses of BioThrax under this contract modification through September 2006.

The National Institutes of Health, or NIH, originally approved the manufacture and sale of BioThrax in 1970. In December 2005, in reaffirming the approval of BioThrax, the FDA concluded that BioThrax is safe and effective for the prevention of anthrax infection by all routes of exposure, including inhalation. A study published in 2002 by the Institute of Medicine, which is a component of The National Academy of Sciences, supports the FDA ruling. In its study, the Institute of Medicine found that BioThrax is an effective vaccine for protection against anthrax, including inhalational anthrax, caused by any known or plausible engineered strains.

Biodefense market opportunity. The biodefense market for immunobiotics has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The letter attacks involved the delivery of mail contaminated with anthrax spores to government officials and members of the media in the United States. As a result of the letter attacks, 22 people became infected with anthrax, including 11 with inhalational anthrax, and five people died.

The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from procurement of countermeasures by HHS, the Centers for Disease Control and Prevention, or CDC, and the DoD and development funding from the National Institute of Allergy and Infectious Diseases of NIH, or NIAID, and the DoD. In 2004, the Project BioShield Act became law, providing $5.6 billion in appropriations over ten years and authorizing the procurement of countermeasures for biological, chemical, radiological and nuclear attacks.

Biodefense product development. In addition to BioThrax, our biodefense product portfolio includes three biodefense product candidates in preclinical development and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical development. We are developing all of our biodefense product candidates to address category A biological agents, which are the class of biological agents that the CDC has identified as the greatest possible threat to public health. Our biodefense product candidates in preclinical development are:

- *Anthrax immune globulin* — for post-exposure treatment of anthrax infection, which we are developing in part with funding from NIAID;
- *Botulinum immune globulin* — for post-exposure treatment of illness caused by botulinum toxin, which we are developing based on a new botulinum toxoid vaccine that we are developing in collaboration with the U.K. Health Protection Agency, or HPA; and
- *Recombinant bivalent botulinum vaccine* — a prophylaxis for illness caused by botulinum toxin, which we also are developing in collaboration with HPA.

We are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine, featuring attributes such as self administration and a longer shelf life. In September 2006, we submitted three separate proposals in response to a request for proposals issued by NIAID in June 2006 for the advanced development and testing of next generation anthrax vaccine candidates. One of our proposals relates to a vaccine candidate that has completed a Phase I clinical trial.

Commercial market opportunity. Vaccines have long been recognized as a safe and cost-effective method for preventing infection caused by various bacteria and viruses. Because of an increased emphasis on preventative medicine in industrialized countries, vaccines are now well recognized as an important part of public health management strategies. According to Frost & Sullivan, a market research organization, from 2002 to 2005, annual worldwide vaccine sales increased from $6.7 billion to $9.9 billion, a compound annual growth rate of approximately 14%. Frost & Sullivan estimates that the worldwide sales of vaccines will grow at a compound annual rate of approximately 10.5% from 2005 through 2012.

Commercial product development. Our commercial product portfolio includes two product candidates in Phase II clinical development, one vaccine candidate in Phase I clinical development and two vaccine candidates in preclinical development. Our commercial product candidates in clinical development are:

- *Typhoid vaccine* — a single dose, drinkable vaccine, for which we have completed a Phase I clinical program, including trials in the United States, the United Kingdom and Vietnam, and expect to initiate a Phase II clinical trial in Vietnam in the fourth quarter of 2006;
- *Hepatitis B therapeutic vaccine* — a multiple dose, drinkable vaccine for treatment of chronic carriers of hepatitis B infection, for which we have completed a Phase I clinical trial in the United Kingdom and expect to initiate a Phase II clinical trial in the United Kingdom in the fourth quarter of 2006; and
- *Group B streptococcus vaccine* — a multiple dose, injectable vaccine for administration to women of childbearing age for protection of the fetus and newborn babies, for which we have completed a Phase I clinical trial in the United Kingdom.

Our commercial product candidates in preclinical development are a chlamydia vaccine and a meningitis B vaccine.

The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur, the vaccines business of Sanofi-Aventis, under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine candidate.

Our strategy. Our goal is to become a worldwide leader in developing, manufacturing and commercializing immunobiotics that target diseases with significant unmet or underserved medical needs. Key elements of our strategy to achieve this goal are to:

- maximize the commercial potential of BioThrax;
- continue to develop a balanced portfolio of immunobiotic products;
- focus on core capabilities in product development and manufacturing;
- build a large scale manufacturing infrastructure;
- selectively establish collaborations; and
- seek governmental and other third party grants and support.

Our history. We commenced operations in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. We acquired our pipeline of commercial vaccine candidates through our acquisition of Microscience Limited in 2005 and our acquisition of substantially all of the assets of Antex Biologics, Inc. in 2003.

Risks associated with our business

Our business is subject to numerous risks, as more fully described in the section entitled “Risk factors” immediately following this prospectus summary, including the following:

- We have derived substantially all of our revenue from sales of BioThrax under contracts with the DoD and HHS.
- Our ongoing U.S. government contracts do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government.
- We expect that a significant portion of the business that we will seek in the near future, in particular for BioThrax, will be under government contracts that present a number of risks that are not typically present in the commercial contracting process.
- Our U.S. government contracts for BioThrax require annual funding decisions by the government and are subject to unilateral termination and modification by the government.
- We may fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, which would harm our growth opportunities.
- We may not be able to sustain or increase profitability.

- We are spending significant amounts for the expansion of our manufacturing facilities.
- We may not be able to manufacture BioThrax consistently in accordance with FDA specifications.
- Other than BioThrax, all of our product candidates are undergoing clinical trials or are in early stages of development, and failure is common and can occur at any stage of development.
- None of our product candidates other than BioThrax has received regulatory approval.

Our corporate information

We were incorporated as BioPort Corporation under the laws of Michigan in May 1998. In June 2004, we completed a corporate reorganization in which Emergent BioSolutions Inc., a Delaware corporation formed in December 2003, issued shares of class A common stock to stockholders of BioPort in exchange for an equal number of outstanding shares of common stock of BioPort. As a result of this reorganization, BioPort became a wholly owned subsidiary of Emergent. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc.

Our principal executive offices are located at 300 Professional Drive, Suite 250, Gaithersburg, Maryland 20879, and our telephone number is (301) 944-0290. Our website address is www.emergentbiosolutions.com. We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this prospectus.

In this prospectus, unless otherwise stated or the context otherwise requires, references to “Emergent,” “we,” “us,” “our” and similar references refer to Emergent BioSolutions Inc. BioThrax® and *spi*-Vec® are our registered trademarks. Other trademarks, trade names or service marks appearing in this prospectus are the property of their respective owners.

The offering

Common stock offered by us	5,000,000 shares
Common stock to be outstanding after this offering	27,420,404 shares
Over-allotment option	750,000 shares The underwriters have an option for a period of up to 30 days to purchase up to 480,000 additional shares of common stock from the selling stockholders and up to 270,000 additional shares of common stock from us to cover over-allotments.
Preferred stock purchase rights	Each share of common stock offered hereby will have associated with it one preferred stock purchase right under a rights agreement that we are entering into in connection with this offering. The preferred stock purchase rights will initially trade together with the common stock. See “Description of capital stock — Stockholder rights plan.”
Use of proceeds	We expect to use the net proceeds from this offering to fund development of our biodefense and commercial product candidates, a portion of the construction, validation and qualification costs for our new manufacturing facility in Lansing, Michigan and initial engineering design and utility build out of our manufacturing facilities in Frederick, Maryland and the balance for general corporate purposes. See “Use of proceeds.” We will not receive any proceeds from the sale of shares of common stock by the selling stockholders as a result of the exercise by the underwriters of their over-allotment option.
Risk factors	See “Risk factors” and other information in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
New York Stock Exchange symbol	EBS

The number of shares of our common stock to be outstanding immediately after this offering is based on 22,420,404 shares outstanding as of October 20, 2006, and excludes:

- 3,109,932 shares of common stock issuable upon the exercise of stock options outstanding as of October 20, 2006 at a weighted average exercise price of $2.54 per share;
- 369,319 additional shares of common stock reserved for issuance under our employee stock option plan as of October 20, 2006; and
- 503,500 additional shares of common stock that will be reserved for issuance under our 2006 stock incentive plan immediately prior to completion of this offering.

Unless otherwise indicated, all information in this prospectus assumes:

- no exercise of the outstanding options described above; and
- no exercise by the underwriters of their option to purchase up to 750,000 additional shares of common stock to cover over-allotments.

Except in our financial statements included in this prospectus, in the table set forth under “Capitalization,” in “Certain relationships and related party transactions” or where otherwise expressly indicated, all information in this prospectus assumes that, prior to the completion of this offering, our previously existing class A common stock has been reclassified as common stock, all previously outstanding shares of class B common stock have been converted into shares of common stock and each outstanding option to purchase class B common stock has become an option to purchase common stock.

In addition, unless otherwise indicated, all information in this prospectus gives effect to a 2.8771-for-one stock split of our common stock that was effected on October 27, 2006.

Summary consolidated financial data

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Management’s discussion and analysis of financial condition and results of operations” section of this prospectus.

The summary consolidated financial data for the years ended December 31, 2003, 2004 and 2005 have been derived from our historical audited consolidated financial statements. The summary consolidated financial data for the nine-month periods ended September 30, 2005 and 2006 and as of September 30, 2006 have been derived from our unaudited consolidated financial statements. The unaudited summary consolidated financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results for a full fiscal year. The as adjusted consolidated balance sheet data set forth below give effect to the sale by us of 5,000,000 shares of common stock in this offering at the initial public offering price of $12.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Year ended December 31,			Nine months ended September 30,	
(in thousands, except share and per share data)	**2003**	**2004**	**2005**	**2005**	**2006**
Statements of operations data:					
Revenues:					
Product sales	$ 55,536	$ 81,014	$ 127,271	$ 85,807	$ 61,263
Contracts and grants	233	2,480	3,417	1,093	4,580
Total revenues	55,769	83,494	130,688	86,900	65,843
Operating expenses (income):					
Cost of product sales	22,342	30,102	31,603	23,147	11,645
Research and development	6,327	10,117	18,381	9,632	26,640
Selling, general & administrative	19,547	30,323	42,793	28,924	32,952
Purchased in-process research and development	1,824	—	26,575	26,575	477
Settlement of State of Michigan obligation	—	(3,819)	—	—	—
Litigation settlement	—	—	(10,000)	(10,000)	—
Total operating expenses	50,040	66,723	109,352	78,278	71,714
Income (loss) from operations	5,729	16,771	21,336	8,622	(5,871)
Other income (expense):					
Interest income	100	65	485	338	405
Interest expense	(293)	(241)	(767)	(575)	(778)
Other income (expense), net	168	6	55	(24)	291
Total other income (expense)	(25)	(170)	(227)	(261)	(82)
Income (loss) before provision for (benefit from) income taxes	5,704	16,601	21,109	8,361	(5,953)
Provision for (benefit from) income taxes	1,250	5,129	5,325	2,109	(2,617)
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Earnings (loss) per share — basic	$ 0.24	$ 0.61	$ 0.77	$ 0.31	$ (0.15)
Earnings (loss) per share — diluted	$ 0.22	$ 0.56	$ 0.69	$ 0.28	$ (0.15)
Weighted average number of shares — basic	18,904,992	18,919,850	20,533,471	19,930,498	22,370,191
Weighted average number of shares — diluted	20,316,752	20,439,252	22,751,733	22,048,412	22,370,191

(in thousands)	As of September 30, 2006	
	Actual	As adjusted
Balance sheet data:		
Cash and cash equivalents	$ 19,906	$ 74,581
Working capital	18,726	73,401
Total assets	130,831	185,506
Total long-term liabilities	35,606	35,606
Total stockholders' equity	56,759	111,434

Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information included in this prospectus, including the financial statements and related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the following risks actually occurs, our business, prospects, financial condition and operating results could be materially harmed. In that event, the market price of our common stock could decline and you could lose part or all of your investment.

Risks related to our dependence on U.S. government contracts for BioThrax

We have derived substantially all of our revenue from sales of our BioThrax anthrax vaccine, our only marketed product, under contracts with the U.S. Department of Defense and the U.S. Department of Health and Human Services. If we are unable to obtain new contracts with and deliver BioThrax to these customers, 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 our only marketed product. We currently supply BioThrax to the DoD for immunization of military personnel and to HHS for placement into the strategic national stockpile. In 2005 and the nine months ended September 30, 2006, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. Our current contract with the DoD provides for the supply of BioThrax to the DoD through September 2007. Although the DoD has issued a notice that it intends to pursue a sole source fixed price contract to purchase up to an additional 11 million doses of BioThrax over one base contract year plus four option years, the DoD has not issued a formal request for proposals for such a contract. We may not be awarded a follow-on contract on favorable terms or at all. For example, the DoD's minimum purchase obligations under any follow-on contract could be less than under our current contract with the DoD. We have delivered all of the five million doses of BioThrax that HHS agreed to purchase under a contract that we entered into with HHS in May 2005. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007. Our ongoing contracts do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. The success of our business and our operating results for the foreseeable future are substantially dependent on the number of doses of BioThrax that the U.S. government purchases from us.

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; 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, in November 2004, HHS awarded VaxGen, Inc., one of our competitors in the anthrax vaccine market, a contract for the supply of 75 million doses of a recombinant protective antigen anthrax vaccine for inclusion in the strategic national stockpile. If VaxGen is able to deliver product under its contract, HHS may eliminate or reduce future orders for other anthrax vaccines, including BioThrax. If any other company is successful in developing a next generation anthrax vaccine, U.S. government customers may purchase only the next generation vaccine and not BioThrax.

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.

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

Our principal customer for BioThrax, our only marketed product, is the U.S. government. We sell to the U.S. government under contracts with the DoD and HHS. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Accordingly, we are subject to a range of risks arising out of being a contractor to the U.S. government under U.S. government programs.

Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of government programs is subject to Congressional appropriations. Congress generally appropriates funds on a fiscal year basis even though a program may continue for several years. For example, our DoD contracts for BioThrax have been structured with one base year during which the DoD agrees to purchase a minimum number of doses of BioThrax with options for the DoD to purchase further quantities in future years. We expect that any future contract that we enter into with the DoD will be structured in a similar manner. Government programs are often only partially funded initially, and additional funds are committed only as Congress makes further appropriations. The termination of a program or failure to commit funds to a program would result in a loss of anticipated future revenues attributable to that program, which could materially harm our business. Our government customers are subject to stringent budgetary constraints and political considerations. If annual 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.

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

Our business with the U.S. government is subject to specific procurement regulations and a variety of other legal compliance obligations. These obligations 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.

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 current contracts for the supply of BioThrax with the DoD and HHS are fixed price contracts. In addition, we expect that our future contracts with the U.S. government for biodefense product candidates that we successfully develop 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 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;
- 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 in products, including intellectual property, developed under the contract;
- 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 U.S. government 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 ongoing or future legal proceedings could reduce demand for BioThrax by the U.S. government. Prior to the issuance of an order in December 2005 by the FDA and an appellate court ruling in February 2006, the DoD had been enjoined by a court order from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver. Although we are not a party to this lawsuit, if further proceedings or any similar lawsuits result in another injunction or otherwise restrict the administration of BioThrax by the DoD, the amount of future purchases of BioThrax by the DoD could be limited. In October 2006, the DoD announced that it is resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency-essential and comparable civilian personnel. Lawsuits brought against us by third parties, even if not successful, require us to spend time and money defending the related litigation. Furthermore, contractual indemnification provisions and statutory liability protections may not fully protect us from all related liabilities.

Risks related to our financial position and need for additional financing

We have a limited operating history and may not maintain profitability in future periods or on a consistent basis.

We have a limited operating history. We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing, Michigan in December 2001. Although we were profitable for each of the last three fiscal years, we have not been profitable for every quarter during that time. In addition, we were not profitable for the nine months ended September 30, 2006. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters and may continue to fluctuate significantly from quarter to quarter based on the timing of our fulfilling orders from the U.S. government. If we are unable to maintain profitability on a consistent basis, the market price of our common stock may decline, and you could lose part or all of your investment.

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

As of September 30, 2006, we had $36.5 million principal amount of debt outstanding and remaining borrowing availability of $7.8 million under our revolving lines of credit. Our business plan also contemplates that we will raise $10 million to $20 million of additional external debt financing to fund our facility expansion in Lansing, Michigan and to provide additional financial flexibility. We also may incur additional indebtedness beyond such amount.

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. Because of the covenants under our existing debt instruments and the pledge of our existing assets as collateral, we have a limited 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. In addition, we incur significant commercialization expenses for BioThrax product sales, marketing and manufacturing. We expect these 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, Michigan. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We anticipate that we will incur up to approximately $35 million for these purposes during 2006, of which we had incurred approximately $21 million through September 2006. In addition, we expect to incur substantial capital expenditures in connection with our planned build out of two buildings in Frederick, Maryland as future manufacturing facilities. We anticipate that we will incur up to $1 million related to initial engineering design and preliminary utility build out for these facilities during 2006, of which we had incurred approximately $234,000 through September 30, 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project.

We expect to continue to fund a significant portion of our development and commercialization costs for our product candidates with internally generated funds from sales of BioThrax. If we do not obtain future contracts with, and deliver BioThrax to, the DoD and HHS, we may be forced to find additional sources of funding and to do so earlier than we currently anticipate. Our business plan currently contemplates that we will raise $10 million to $20 million of additional external debt financing to fund our facility expansion in Lansing and to provide additional financial flexibility. We may not be able to obtain this financing or otherwise be able to raise capital 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.

As of September 30, 2006, we had $19.9 million of cash and cash equivalents. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funds, will be sufficient to enable us to fund our anticipated operating expenses and capital expenditure and debt service requirements for at least the next 24 months. 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, constructing our new manufacturing facility in Lansing, Michigan and 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, such as our collaboration with Sanofi Pasteur.

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. In addition to purchase obligations and orders under our contracts with the DoD and HHS for BioThrax sales, our only committed external sources of funds are remaining borrowing availability under our revolving lines of credit, development funding under our collaboration agreement with Sanofi Pasteur, funding from NIAID for animal efficacy studies of our anthrax immune globulin candidate and funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate in Vietnam. 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 spending significant amounts for the construction of a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which is being designed to enable us to manufacture BioThrax on a large scale for our existing and potential future customers. We are also constructing this new facility to accommodate large scale commercial manufacturing of multiple vaccine products, subject to complying with appropriate change-over procedures. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We anticipate that we will incur up to approximately $35 million for these purposes during 2006, of which we had incurred approximately $21 million through September 30, 2006. In addition, we own two buildings in Frederick, Maryland that we plan to build out as future manufacturing facilities. We anticipate that we will incur up to $1 million related to initial engineering design and preliminary utility build out for these facilities during 2006, of which we had incurred approximately $234,000 through September 30, 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project.

Constructing and preparing a facility for commercial vaccine manufacturing is a significant project. For example, constructing the new Lansing facility with increased manufacturing capacity requires that we scale up both fermentation and downstream processing compared to levels at our existing production facility. These projects may result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. The FDA must approve our new manufacturing facilities before they can be used to commercially manufacture our products. For example, we are required to show that the product we manufacture in our new Lansing facility is comparable to BioThrax manufactured at our existing facility. 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 United States, may be significant. If construction or regulatory approval of our new facility in Lansing is delayed, 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. If construction or regulatory approval of our new manufacturing facilities at our Frederick site is delayed, we may not be able to independently manufacture our commercial product candidates for clinical trials or commercial sale. Cost overruns associated with constructing either our Lansing or Frederick 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 immunobiotic product candidates are difficult to manufacture 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 substantial 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 filling, labeling and packaging and quality control and testing, may result in lot failures or product recalls. From time to time, we experience deviations during the manufacturing process of BioThrax that can affect our release of the production lot according to our release protocols and other acceptance criteria. Lot failures or product recalls could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

For example, in late 2005, our standard product release testing identified BioThrax production lots for which follow up testing was required to determine whether we can submit these lots to the FDA for release for sale. We waited to conduct final release testing of these lots pending FDA review of an application that we submitted to amend the BioThrax release specifications. The FDA approved our amendment to the release specifications in May 2006, and we subsequently reinitiated release testing of these BioThrax lots. All of these BioThrax lots have since been released for sale by the FDA. We will not be able to sell any lots that in the future fail to satisfy release testing specifications or that are not released for sale by the FDA.

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, Michigan 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;
- damage to or destruction of the facility due to natural disasters;
- regional power shortages;
- product tampering; or
- terrorist activities.

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.

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, under our BioThrax supply contract with the DoD, the DoD is obligated to acquire a minimum number of doses of BioThrax and has the right to acquire up to a maximum number of doses. If the DoD elects to purchase the maximum number of doses of BioThrax under the contract, we may not have sufficient available production capacity at our existing manufacturing facility in Lansing to allow us to increase sales of BioThrax to customers other than the U.S. government. In addition, 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, we could incur significant unrecoverable costs from creating excess capacity. For example, if we do not maintain and increase sales of BioThrax to the U.S. government and other customers, we may not be able to generate an adequate return on the significant amounts that we are spending for construction of our new manufacturing facility in Lansing. 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 at our Frederick site.

If third parties do not manufacture our product candidates 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 immunobiotic product candidates that we require for preclinical and clinical development. 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 and plan to construct a pilot plant in Maryland 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 immune globulin product candidates and contract fill and finish operations. 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.

Our only long-term manufacturing agreements are our agreement with Talecris Biotherapeutics, Inc., for fractionation and purification of plasma for our anthrax immune globulin candidate, and our collaboration with HPA, under which HPA provides specialized manufacturing capabilities for our recombinant bivalent botulinum vaccine candidate and the bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate. Third party manufacturers under our 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 to satisfy our requirements. If these alternative suppliers are not available or are delayed in fulfilling our requirements, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers may require review from the FDA and satisfaction of comparable foreign requirements. 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 United States. 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. 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. 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 umbrella insurance policies provide for coverage up to annual aggregate limits of $12 million with a deductible of $15,000 per occurrence, but 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 other than storage tank liability insurance for our Lansing, Michigan facility with a $1 million annual aggregate limit and a deductible of $10,000 per claim. 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 extraordinary or unanticipated events.

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, 2007. We have not established internal redundancy for our filling functions and currently have no substitute provider that can handle our filling needs. If Hollister-Stier is unable to perform filling services for us or we are unable to enter into a new contract with Hollister-Stier, we would need to identify and engage an alternative filling company. Any new contract filling company will need to obtain FDA approval for filling BioThrax at its facilities. Identifying and engaging a new contract filling company 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.

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 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 immunobiotic product candidates. In addition to BioThrax product sales, our ability to generate near term revenue is particularly dependent on the success of our anthrax immune globulin candidate, which is currently in preclinical development. The commercial success of our product candidates will depend on many factors, including:

- successful completion of preclinical development;
- 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 strategic national stockpile prior to FDA approval;
- establishing commercial manufacturing processes or arrangements;
- 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 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 immunobiotic product candidates in humans. In addition, our development plans for our botulinum immune globulin candidate require the development of a new botulinum toxoid vaccine that we would use to vaccinate individuals who would then donate plasma for use in our botulinum immune globulin candidate. If the development of this new botulinum toxoid vaccine is delayed or not completed, for regulatory or other reasons, we may not be able to successfully develop our botulinum immune globulin candidate.

If we are not successful in completing the development and commercialization of our immunobiotic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

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. 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 may be greater than we currently anticipate;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable; 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.

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.

For example, the FDA could require us to conduct additional clinical development in our botulinum immune globulin program that we currently do not plan to conduct. We expect to rely on safety and immunogenicity data from a pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan in the development of a new bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate. We plan to conduct a Phase I clinical trial to evaluate the safety of the botulinum toxoid vaccine. If the results are favorable, we expect that the Phase I clinical trial will provide data sufficient to support an acceptable dose for the vaccine and the optimal dosing schedule. As a result, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the botulinum toxoid vaccine before permitting us to initiate a donor stimulation program for our botulinum immune globulin candidate. However, the FDA has not approved our plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial for the botulinum toxoid vaccine and may not do so. If the FDA requires us to conduct a Phase II clinical trial for the botulinum toxoid vaccine, the development plans for our botulinum immune globulin candidate will be delayed.

In addition, our development plan for BioThrax as a post-exposure prophylaxis for anthrax infection contemplates that we will conduct a nonhuman primate efficacy study in late 2007. However, the timing of our nonhuman primate efficacy study depends upon the successful development of a nonhuman primate model by NIAID. If NIAID does not successfully develop a nonhuman primate model, our development plans for BioThrax as a post-exposure prophylaxis for anthrax infection will be delayed, possibly significantly.

Our product development costs will also increase if we experience delays in testing or approvals. 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 Project BioShield, the Secretary of HHS can contract to purchase countermeasures for the strategic national stockpile 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, as has occurred in the case of the HHS procurement contract for VaxGen's anthrax vaccine candidate and as discussed below under "— Risks related to commercialization — We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do."

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 the U.S. Postal Service, foreign governments, state and local governments, which we expect will be interested in BioThrax to protect first 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 minimal sales to these customers.

In particular, we have supplied small amounts of BioThrax directly to several foreign governments. In 2005, our sales of BioThrax to customers other than the U.S. government represented only one percent 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 and the terms of our U.S. government contracts may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, 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, 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, the DoD has contractual and statutory rights that could interfere with sales of BioThrax to customers other than the U.S. government. 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 more doses than are otherwise specified in our contract with the DoD. If the DoD required delivery of these additional doses, it could affect our production schedule and deplete BioThrax supplies that would otherwise be available for commercial sales. In addition, the DoD could either sell BioThrax directly to foreign governments at a lower price than we may offer or donate BioThrax to foreign governments under the DoD's Foreign Military Sales program.

Our ability to meet any 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, Michigan to manufacture BioThrax for sale to U.S. government customers. We expect to complete construction of our new manufacturing facility in Lansing in mid 2007. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. We anticipate that we will be able to demonstrate in nonclinical studies that BioThrax manufactured at our new facility is comparable to BioThrax manufactured at our existing facility. As a result, we expect that the FDA will not require us to complete a human bridging trial demonstrating that BioThrax manufactured at our new facility is bioequivalent to BioThrax manufactured at our existing facility. However, the FDA has not approved our plan to rely on nonclinical studies without conducting a human bridging trial and may not do so. If the FDA requires us to conduct a human bridging trial, the initiation of large scale manufacturing of BioThrax for commercial sale at our new facility will be delayed and we will incur additional unanticipated costs. Until the new manufacturing facility is available for commercial use, we will not have sufficient available production capacity to allow us to significantly increase sales of BioThrax to customers other than the U.S. government.

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 immunobiotic 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. For example, in 2004, HHS issued a request for proposals for the supply of anthrax vaccine for the strategic national stockpile. The HHS request was limited to a recombinant anthrax vaccine. Recombinant technology comprises

scientific techniques that allow for the manipulation of genetic material. Scientists apply these techniques to disease-causing organisms known as pathogens. Using recombinant technology, it is possible to delete a virulent gene from a pathogen or isolate the gene directing the production of the component of a pathogen known as an antigen and move the antigen into a harmless organism from which it can be purified and used as a vaccine. Because BioThrax is not a recombinant vaccine, BioThrax was precluded from consideration under that procurement program.

A significant portion of future government anthrax vaccine procurement requests may specify a recombinant anthrax vaccine, which would limit, possibly significantly, the market for BioThrax. In June 2006, NIAID issued a request for proposals for the advanced development and testing of next generation anthrax vaccine candidates with specified properties, including shelf life of three years or longer at room temperature, the ability to generate protective immune response in one or two doses, the ability to be self administered or rapidly inoculated into large numbers of people and a superior safety profile to BioThrax. Although we are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine with these properties, one of which has completed a Phase I clinical trial, and have submitted three separate proposals in response to the NIAID request for proposals, we may not be successful in our development efforts or receive any funding from NIAID.

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the U.S. Government Accountability Office reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the need for a 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.

The use of vaccines carries a risk of adverse health effects that must be weighed against the expected health benefit of the product. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and 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 such adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. These 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;
- 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
- sufficient third party coverage or reimbursement.

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 filed a citizen's petition with the FDA and various lawsuits seeking the revocation of the license for BioThrax and the termination of the DoD program for the mandatory administration of BioThrax to military personnel. In October 2004, a federal court ruled 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. As a result, the court issued an injunction prohibiting the DoD from administering BioThrax to military personnel on a mandatory basis without informed consent of the recipient or a Presidential waiver. Although the FDA issued a final order in December 2005 determining that BioThrax is safe and effective and not misbranded and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved, these actions created negative publicity about BioThrax. Similar or other such lawsuits or publicity campaigns could limit demand for BioThrax and our biodefense product candidates and harm our future business. In October 2006, the DoD announced that it is resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency-essential and comparable civilian personnel.

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 directly to the DoD and HHS 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. In addition, we expect to establish a separate internal organization to market and sell commercial products for which we retain commercialization or co-commercialization rights.

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. Expanding our internal sales and marketing capability will be expensive and time consuming and could delay any product launch. 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 immunobiotics 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 immunobiotics 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 immunobiotic development, such as VaxGen, Cangene, Human Genome Sciences, Acambis, Avant Immunotherapeutics and Avecia Group.

Any immunobiotic 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 receive marketing approval.

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, we face significant competition for the supply of this vaccine to the U.S. government. We believe our most significant competitor for the supply of BioThrax to the U.S. government is VaxGen. HHS has awarded VaxGen a contract to supply 75 million doses of recombinant protective antigen vaccine for the strategic national stockpile.

We also face significant competition for our biodefense immunobiotic product candidates. We face significant competition for NIAID funding for development and testing of a next generation anthrax vaccine from other companies who responded to the NIAID request for proposals issued in June 2006. If we continue to pursue the development of a next generation anthrax vaccine, we also expect that we will face significant competition for the supply of our product candidate to the U.S. government. HHS has awarded strategic national stockpile supply contracts to Cangene for an anthrax immune globulin and Human Genome Sciences for a monoclonal antibody to *Bacillus anthracis* as a post-exposure therapeutic for anthrax infection. Several companies have botulinum vaccines in early clinical or preclinical development. HHS has awarded Cangene a contract to develop a heptavalent botulinum immune

globulin derived from equine plasma and supply a botulinum immune globulin for the strategic national stockpile.

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the United States and Europe. Numerous companies have vaccine candidates in development that would compete with any of our commercial immunobiotic product candidates for which we 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 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, such as us, may not be adequate to protect us from all liabilities associated with the manufacture, sale and use of our products.

Provisions of our BioThrax contracts with the DoD and 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, 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. The declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. Manufacturers are not entitled to this protection in cases of willful misconduct.

Upon a declaration by the Secretary, 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. However, a willful misconduct action could be brought against us if any individuals exhausted their remedies under the compensation program and thereby expose us to liability. Although we may petition the Secretary to make such a declaration with respect to anthrax generally and BioThrax specifically, we do not know if any such petition would be successful or that, if successful, the Act will provide adequate coverage or survive anticipated legal challenges to its validity.

In August 2006, the Department of Homeland Security approved our application under the 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 United States 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 existing contracts with the DoD and HHS provide that the government will indemnify us for any damages resulting from product liability claims, we cannot be certain that we will be able to continue to negotiate similar rights in future contracts or that the U.S. government will honor this obligation. 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 pending resolution of our claims under our product liability insurance.

In addition, members of Congress have proposed and may in the future propose legislation that reduces or eliminates these and other 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. In late 2005 and early 2006, we were named as a defendant in three federal lawsuits filed on behalf of three individuals 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 plaintiff in each of these three lawsuits claimed different injuries and sought varying amounts of damages. The first plaintiff alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million. The second plaintiff alleged that the vaccine caused Bell's palsy and other related conditions and requested damages in excess of $75,000. The third plaintiff alleged that the vaccine caused a condition that originally was diagnosed as encephalitis related to a gastrointestinal infection and caused him to fall into a coma for many weeks and requested damages in excess of $10 million.

If we cannot successfully defend ourselves against claims that our product or product candidates caused injuries and we are not entitled to indemnity by the U.S. government, we will incur substantial liabilities. Regardless of merit or eventual outcome, 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 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. Insurance coverage is 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 deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on contractual indemnification provisions and statutory protections to limit our liability 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 United States 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 United States, 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 nongovernmental, 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 January 2006. These benefits will be provided primarily through private entities, which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

Any products we may develop may also 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 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 United States, which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. 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 successfully sustain or expand our BioThrax operations or develop or 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, our president, chief executive officer and chairman of our board of directors, Steven N. Chatfield, our chief scientific officer and president of Emergent Product Development UK Limited, Edward J. Arcuri, our executive vice president and chief operating officer, and Robert G. Kramer, president and chief executive officer of Emergent BioDefense Operations, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. All of these key employees, other than Dr. Chatfield, are at will employees and can terminate their employment at any time. Our employment agreement with Dr. Chatfield is terminable by him on short notice. 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 be adversely affected by a negative audit by the U.S. government.

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. This litigation was brought against us under a provision of the False Claims Act that allows a private citizen to file a suit in

the name of the U.S. government charging fraud by government contractors and other entities who receive or use government funds and share in any money recovered. Although a federal district court dismissed the litigation, and a federal appeals court subsequently upheld that decision, 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.

Our BioThrax supply contract with the DoD grants us the right to use property and equipment owned by the DoD in the manufacture of BioThrax. This property and equipment, referred to as government furnished equipment, is in service at our Lansing site. Some of this government furnished equipment is important to our business. We pay the DoD a small usage fee for the government furnished equipment based on the number of doses of BioThrax that we produce for sale to customers other than the U.S. government. We have the option to purchase all or part of the government furnished equipment at any time during the contract period for approximately $21 million. If the DoD modifies the terms under which we use the government furnished equipment in a manner unfavorable to us, including raising the usage fee, our business could be harmed. If DoD terminated our contract, we could be required to rent or purchase all or a part of the government furnished equipment to continue production of BioThrax in our current 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 United States 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 only 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 United States, 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 strategic national stockpile, 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 believe that, according to the FDA's current BLA requirements for biologics that cannot be ethically or feasibly tested in humans in Phase III efficacy trials, we may instead be able to obtain BLA approval based on clinical data from Phase II and Phase III trials in healthy subjects that demonstrate adequate safety and immune response and effectiveness data from studies in animals. Specifically, we intend to pursue FDA approval of BioThrax as a post-exposure prophylaxis, our immune globulin candidates, our recombinant bivalent botulinum vaccine candidate and a next generation anthrax vaccine under the FDA animal rule. Under the animal rule, if human efficacy trials are not ethical or feasible, the FDA can approve drugs or biologics used to treat or prevent serious or life threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological or nuclear substances based on human clinical data demonstrating safety and immunogenicity and evidence of efficacy from appropriate non-clinical animal studies and any additional supporting data. Products approved under the animal rule are subject to additional regulation not normally required of other products. Additional regulation may include post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. Our application is based on an interim analysis of data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, will confer adequate immune response over as long as 42 months. In April 2006, the FDA issued a complete response letter to our application, requesting clarification and requiring additional analysis of the data that we submitted. We are in the process of responding to this letter and amending our application. If the FDA does not find our response to be adequate, we might be required to conduct additional independent testing to continue to pursue the development of this dosing regimen. Responding to the FDA's complete response letter will delay potential approval of our application. If we are unable ultimately to respond satisfactorily to the FDA, our application will not be approved. We currently are awaiting the final data from the CDC trial, which we expect at the end of 2007.

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 regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. 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 immunobiotic 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 at reasonable times and in a reasonable manner.

After we acquired BioThrax and related vaccine manufacturing facilities in Lansing, Michigan 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. 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 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. We have filed with the FDA our responses to all inspectional observations relating to the May 2006 inspection. The FDA has acknowledged receipt of our responses and has advised us that it has concluded that the May 2006 inspection is closed. Pursuant to its standard procedures, we expect that the FDA will review and assess our corrective actions at its next inspection. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, 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;
- 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 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 authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for that time period for the same indication. Orphan drug exclusivity in Europe lasts for ten years, but can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable so that market exclusivity is no longer justified. If a competitor 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. None of our products or product candidates have been designated as orphan drugs. 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 have obtained will not block the approval of that competitive product.

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

We intend to have our products marketed outside the United States. 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 United States, 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 file for regulatory approvals and may not receive necessary 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, particularly in international markets, commercialize our product candidates.

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, such as our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate. 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 to access 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 collaborations 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. In particular, the successful development of our meningitis B vaccine candidate will initially depend on the success of our research collaboration with Sanofi Pasteur and whether Sanofi Pasteur selects one or more viable candidates pursuant to the collaboration for development of a product. Thereafter, Sanofi Pasteur will have significant discretion in the development and commercialization of any such candidate. Sanofi Pasteur may choose not to pursue further development and commercialization of any candidate that it selects based on many factors outside our control. Sanofi Pasteur has the ability to suspend development of a candidate under the collaboration in various circumstances. 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; and
- 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.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, Sanofi Pasteur has the right to terminate our meningitis B vaccine collaboration at any time after April 1, 2007 upon six months' prior written notice. Sanofi Pasteur can also terminate the collaboration upon a change of control or insolvency event involving us or upon our uncured material breach. Those terminations or expirations would 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 and 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. For example, the CDC is currently conducting an independent clinical trial to evaluate the administration of BioThrax in a regimen of fewer doses. We participate in monthly meetings with the trial investigators and in the annual review meeting for this trial and provide input to the CDC for responses to FDA questions and requests for additional information. We expect to rely on data from these development efforts in 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, which we expect at the end of 2007. 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 trial.

If we are unable to in license the necessary components of a next generation anthrax vaccine, we will not be successful in developing or commercializing such a product candidate.

If we continue to pursue the development of a next generation anthrax vaccine, including a product candidate relating to any of the proposals we submitted in September 2006 in response to a NIAID request for proposals, we expect that we will need to in license various components of the product candidate, including adjuvants and novel delivery technologies. There are a limited number of companies from whom we can license these components. We may be unable to obtain licenses to the necessary components of a next generation anthrax vaccine on acceptable terms, or at all. If we are unable to obtain these licenses, we could be prevented from continuing further development of a product candidate that we select for development. Ultimately, even if our development efforts are successful, we could be prevented from commercializing a next generation anthrax vaccine if we are unable to enter into licenses on acceptable terms.

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 United States and other countries for the intellectual property covering or incorporated into our technology and products. The patent situation in the field of immunobiotics 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 United States 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 United States 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. Under our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate, we have the right to prosecute and maintain our patent rights under the collaboration agreement. Sanofi Pasteur is responsible for prosecuting and maintaining joint patent rights under the collaboration agreement, although we have the right to support the continued prosecution or maintenance of the joint patent rights if Sanofi Pasteur fails to do so. In addition, Sanofi Pasteur has the first right to pursue claims against third parties for infringement of the patent rights under the collaboration agreement and assume the defense of any infringement claims that may arise, although we have the right to pursue infringement claims against third parties and assume the defense of infringement claims if Sanofi Pasteur fails to do so. Under our licenses with HPA relating to our recombinant bivalent botulinum vaccine candidate and the botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin 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 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. We consider our licenses with HPA relating to our recombinant bivalent botulinum vaccine candidate and the botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate to be material to our business. Under these license agreements, we obtained the exclusive, worldwide right to develop, manufacture and commercialize pharmaceutical products that consist of botulinum toxoid components or recombinant botulinum toxin components for the prevention or treatment of illness in humans caused by exposure to the botulinum toxin, subject to HPA's non-exclusive right to make, use or sell recombinant botulinum products to meet public health requirements in the United Kingdom. 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, the label expansions and improvements that we are pursuing for BioThrax or our anthrax immune globulin candidate, our only intellectual property protection for BioThrax and our anthrax immune globulin candidate 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 United States 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, we are aware of and are monitoring ongoing litigation between Bavarian Nordic and Acambis relating to the manufacture of the modified vaccinia Ankara virus, or MVA, as a smallpox vaccine for biodefense use by the U.S. government. We have licensed from the Bavarian State Ministry of the Environment, Public Health and Consumer Protection rights to materials and technology related to MVA. Our MVAtor™ platform technology, which is based on these licensed rights, could potentially be used as a viral vector for delivery of multiple vaccine antigens for different disease-causing organisms, including influenza, using recombinant technology. As a result, our licensed rights and our ability to use our MVAtor platform technology could be negatively affected by the outcome of this ongoing litigation. It also is possible that we could be named as a defendant in future similar litigation relating to MVA. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office

and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. For example, we have filed an opposition in the European Patent Office against Bavarian Nordic's patent 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 immunobiotics. 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, Michigan 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 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 immunobiotics 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 immunobiotic 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 the offering

Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, will continue to have substantial control over us after this offering, 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.

Even after this offering, Mr. El-Hibri will be able to control the election of the members of our board of directors through his ownership interests and voting arrangements among our significant stockholders. Immediately prior to this offering, Mr. El-Hibri was the beneficial owner of 99.5% of our outstanding common stock. Immediately following this offering, Mr. El-Hibri will be the beneficial owner of 81.4% of our outstanding common stock, or 78.9% of our outstanding common stock if the underwriters exercise their over-allotment option in full.

Because Mr. El-Hibri will be able to control 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 our company 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 you might otherwise receive a premium for your 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 the second anniversary of the completion of this offering, 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 the second anniversary of the completion of this offering, 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 the second anniversary of the completion of this offering, 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 the second anniversary of the completion of this offering, 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 the second anniversary of the completion of this offering, 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% 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 our company.

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

In connection with this offering, we are entering into a rights agreement that establishes our stockholder rights plan. Under the rights agreement, we will issue to 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 our company 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 you purchase shares of our common stock in this offering, you will suffer immediate and substantial dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering. Based on the initial public offering price of $12.50 per share, investors in this offering will incur immediate dilution of $8.43 per share. To the extent outstanding options are exercised, you will incur further dilution. In addition, based on the initial public offering price of $12.50 per share, investors in this offering will have contributed approximately 64% of the total consideration paid by all purchasers of our common stock but will own only approximately 18% of our common stock outstanding after this offering. See “Dilution.”

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. Although our common stock has been authorized for listing on the New York Stock Exchange, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult to sell shares you purchase in this offering without depressing the market price for the shares or at all.

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

Our stock price is likely to be volatile. 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. As a result of this volatility, investors may not be able to

sell their common stock at or above the initial public offering price. 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 United States 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 have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our net proceeds from this offering in a manner that does not produce income or that loses value.

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 your sole source of gain 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, 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. Upon the completion of this offering, we will have outstanding 27,420,404 shares of common stock, after giving effect to the issuance of 5,000,000 shares of common stock in this offering. Of the shares to be outstanding after the completion of this offering, the 5,000,000 shares of common stock sold in this offering will be freely tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, unless purchased by our "affiliates," as

that term is defined in Rule 144 under the Securities Act. The remaining shares of our common stock are “restricted securities” under Rule 144. Substantially all of these restricted securities will be subject to the 180-day lock-up period described below. After the 180-day lock-up period, these restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act.

The holders of substantially all of our currently outstanding capital stock have agreed that, without the prior written consent of J.P. Morgan Securities Inc., they will not, during the period ending 180 days after the date of this prospectus, subject to exceptions specified in the lock-up agreements, offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock. Further, these holders have agreed that, during this period, they will not make any demand for, or exercise any right with respect to, the registration of our common stock or any security convertible into or exercisable or exchangeable for our common stock. The 180-day lock-up period may be extended under specified circumstances. The lock-up restrictions, specified exceptions and the circumstances under which the 180-day lock-up period may be extended are described in more detail under “Underwriting.”

Upon expiration of the 180-day lock-up period, 22,365,166 shares of our common stock outstanding as of October 20, 2006, representing approximately 81.6% of our common stock outstanding after this offering, will be eligible for sale under Rule 144. In general, shares eligible for sale under Rule 144 are subject to volume limitations. However, upon expiration of the 180-day lock-up period, 13,232 shares of our common stock outstanding as of October 20, 2006 will be eligible for sale under Rule 144(k) without regard to volume limitations. In addition, beginning 90 days after the date of this prospectus, 117,124 shares of our common stock outstanding as of October 20, 2006 will be eligible for sale in accordance with Rule 701 under the Securities Act without regard to volume limitations. Mr. El-Hibri has the power to dispose of or direct the disposition of 14,698,292 shares of our common stock outstanding as of October 20, 2006, representing approximately 53.6% of our common stock outstanding after this offering. These shares will be eligible for sale under Rule 144, subject to volume limitations, upon expiration of the 180-day lock-up period.

Moreover, after this offering, holders of an aggregate of 22,303,280 shares of our common stock outstanding as of October 20, 2006 will have the right to require us to register these shares of common stock under specified circumstances.

In addition, of the 3,109,932 shares of our common stock that may be issued upon the exercise of options outstanding as of October 20, 2006, approximately 2,628,982 shares will be vested and eligible for sale within 180 days after the date of this prospectus, subject to any lock-up agreements applicable to these shares. Promptly following this offering, we intend to file a registration statement on Form S-8 registering the sale of up to 7,676,851 shares of common stock subject to outstanding options and options and other awards issuable pursuant to our equity incentive plans. Shares registered under this registration statement on Form S-8 will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

For a further description of the eligibility of shares for sale into the public market following this offering, see “Shares eligible for future sale.”

Special note regarding forward-looking statements

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus 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 performance under existing BioThrax sales contracts with HHS and DoD, including the timing of deliveries under these contracts;
- 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 prospectus, 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 prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, 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.

Use of proceeds

We estimate that the net proceeds to us from this offering will be approximately $54.7 million, based on the initial public offering price of $12.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds from this offering will be approximately $57.8 million. We will not receive any proceeds from the sale of shares of common stock by the selling stockholders as a result of the exercise by the underwriters of their over-allotment option.

If we fund the following solely with the net proceeds from this offering without allocating funds from other sources, we currently estimate that we will use:

- approximately $10 million of these net proceeds to fund development of our biodefense product candidates, comprised of approximately $3 million for label expansions and improvements for BioThrax, approximately $2 million for a next generation anthrax vaccine candidate and approximately $5 million for our anthrax immune globulin candidate;
- approximately $19 million of these net proceeds to fund clinical development of our commercial product candidates, comprised of approximately $6 million for our typhoid vaccine candidate and approximately $13 million for our hepatitis B therapeutic vaccine candidate;
- approximately $25 million of these net proceeds to fund a portion of the construction, validation and qualification costs for our new manufacturing facility in Lansing, Michigan and the initial engineering design and preliminary utility build out of our manufacturing facilities in Frederick, Maryland; and
- the balance of these net proceeds for general corporate purposes, which may include the expansion of our sales and marketing organization, the acquisition or in license of technologies, products or businesses, working capital and capital expenditures.

This expected use of proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending upon numerous factors, including the progress of our development and commercialization efforts, the progress of our clinical trials and our operating costs and capital expenditures, including the timing of, and the costs involved in, constructing our new manufacturing facility in Lansing, Michigan and the build out of our manufacturing facilities in Frederick, Maryland. As a result, we will retain broad discretion in the allocation of the net proceeds from this offering. We have no current understandings, commitments or agreements to acquire or in license any technologies, products or businesses using the net proceeds from this offering.

Based on our planned use of proceeds described above, we expect that the net proceeds from this offering will be sufficient to enable us to complete:

- for our biodefense product candidates, the work necessary to support our applications to the FDA to further extend the shelf life and reduce the number of required doses for BioThrax, stability testing, animal efficacy studies and exploration of an alternative delivery system for a next generation anthrax vaccine candidate and animal efficacy studies and a Phase I safety and pharmacokinetic trial of our anthrax immune globulin candidate; and

- for our commercial product candidates, a Phase II clinical trial and a disease surveillance study and the manufacture of initial clinical material for a Phase III clinical trial of our typhoid vaccine candidate and a Phase II clinical trial of our hepatitis B therapeutic vaccine candidate.

It is possible that we will not achieve the progress that we expect because the actual costs and timing of development, particularly clinical trials, are difficult to predict, subject to substantial risks and often vary depending on the particular indication and development strategy.

We do not expect that our existing cash and cash equivalents, committed sources of funds and net proceeds from this offering alone will be sufficient to enable us to fund the completion of the development of any of our product candidates or all of the construction costs of our new manufacturing facility in Lansing. We expect to continue to fund a significant portion of our development and commercialization costs with internally generated funds from sales of BioThrax. In particular, our planned use of proceeds described above assumes that we will fund continued development of our recombinant bivalent botulinum vaccine candidate, our botulinum immune globulin candidate, our group B streptococcus vaccine candidate and our commercial preclinical product candidates with funds from sales of BioThrax and grant funding without allocating any of the net proceeds from this offering. Accordingly, our need for additional external sources of funds for these purposes will depend significantly on the level and timing of our sales of this product. Our business plan also contemplates that we will raise $10 million to $20 million of additional external debt financing to fund the Lansing facility construction and to provide additional financial flexibility. If we do not obtain this additional debt financing, we may need to reduce spending for other purposes in order to complete this construction project.

Pending use of the proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

Dividend policy

We currently intend to retain all of our future earnings to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

On June 15, 2005, our board of directors declared a special cash dividend to the holders of our outstanding shares of common stock in an aggregate amount of approximately $5.4 million. Our board of directors declared this special dividend in order to distribute the net proceeds of a payment that we received as a result of the settlement of litigation that we initiated against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. We paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. Prior to this special cash dividend, we had never declared or paid any cash dividends on our common stock.

Capitalization

The following table sets forth our capitalization as of September 30, 2006:

- on an actual basis; and
- on an as adjusted basis to give effect to:
  - the reclassification of our previously existing class A common stock as common stock and the conversion of each outstanding share of our class B common stock into one share of common stock prior to the completion of this offering; and
  - the sale of 5,000,000 shares of common stock that we are offering at the initial public offering price of $12.50 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following this offering will be adjusted based on the initial public offering price and other terms of this offering. You should read this table together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's discussion and analysis of financial condition and results of operations" section of this prospectus.

(in thousands, except share and per share data)	As of September 30, 2006	
	Actual	As adjusted
	(unaudited)	
Long-term indebtedness, including current portion	$36,410	$ 36,410
Notes payable to employees	63	63
Stockholders' equity:		
Common stock, class A, $0.001 par value per share; 100,000,000 shares authorized and 22,303,280 shares issued and outstanding, actual; no shares authorized, issued or outstanding, as adjusted	22	—
Common stock, class B, $0.01 par value per share; 2,000,000 shares authorized and 86,340 shares issued and outstanding, actual; no shares authorized, issued or outstanding, as adjusted	1	—
Common stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 100,000,000 shares authorized and 27,389,620 shares issued and outstanding, as adjusted	—	27
Preferred stock, $0.001 par value per share; 3,000,000 shares authorized, actual; 15,000,000 shares authorized, as adjusted; no shares issued or outstanding, actual and as adjusted	—	—
Additional paid-in capital	35,079	89,750
Accumulated other comprehensive loss	(182)	(182)
Retained earnings	21,839	21,839
Total stockholders' equity	56,759	111,434
Total capitalization	$93,232	$ 147,907

The table above gives effect to an adjustment to par value and an increase in the number of authorized shares of the class A common stock upon the reclassification of the class A common stock as common stock and an adjustment to par value of the preferred stock on an actual basis as if the adjustments to par value and the increase in the number of authorized shares were effective as of September 30, 2006.

The table above does not include:

- 3,141,003 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 at a weighted average exercise price of $2.54 per share;
- 369,032 additional shares of common stock reserved for issuance under our employee stock option plan as of September 30, 2006; and
- 503,500 additional shares of common stock that will be reserved for issuance under our 2006 stock incentive plan immediately prior to completion of this offering.

Dilution

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering.

Our actual net tangible book value as of September 30, 2006 was $56.8 million or $2.54 per share of our common stock. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding.

After giving effect to the issuance and sale by us of 5,000,000 shares of common stock in this offering, at the initial public offering price of $12.50 per share, less underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of September 30, 2006 would have been approximately $111.4 million, or $4.07 per share of common stock. This represents an immediate increase in net tangible book value per share of $1.53 to existing stockholders and immediate dilution of $8.43 per share to new investors. Dilution per share to new investors is determined by subtracting the net tangible book value per share after this offering from the initial public offering price per share paid by a new investor. The following table illustrates this dilution on a per share basis:

Initial public offering price per share of common stock		$12.50
Actual net tangible book value per share as of September 30, 2006	$2.54	
Increase in net tangible book value per share attributable to new investors	1.53	
Adjusted net tangible book value per share after this offering		4.07
Dilution per share to new investors		$ 8.43

If any shares are issued in connection with outstanding options, you will experience further dilution.

The following table summarizes as of September 30, 2006 the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by existing stockholders and by new investors in this offering at the initial public offering price of $12.50 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares purchased		Total consideration		Average price per share
	Number	Percentage	Amount	Percentage	
Existing stockholders	22,389,620	82%	$35,102,225	36%	$ 1.57
New investors	5,000,000	18	62,500,000	64	12.50
Total	27,389,620	100%	$97,602,225	100%	

The table above is based on shares outstanding as of September 30, 2006 and excludes:

- 3,141,003 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 at a weighted average exercise price of $2.54 per share;
- 369,032 additional shares of common stock reserved for issuance under our employee stock option plan as of September 30, 2006; and

- 503,500 additional shares of common stock that will be reserved for issuance under our 2006 stock incentive plan immediately prior to completion of this offering.

If the underwriters exercise their over-allotment option in full, the following will occur:

- the number of shares of common stock held by existing stockholders will decrease to 21,909,620, or approximately 79.2% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares of common stock held by new investors will increase to 5,750,000, or approximately 20.8% of the total number of shares of our common stock outstanding after this offering.

Selected consolidated financial data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Management’s discussion and analysis of financial condition and results of operations” section of this prospectus.

We have derived the consolidated statement of operations data for the years ended December 31, 2003, 2004 and 2005 and the consolidated balance sheet data as of December 31, 2004 and 2005 from our audited consolidated financial statements, which are included in this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2001 and 2002 and the consolidated balance sheets data as of December 31, 2001, 2002 and 2003 from our audited consolidated financial statements, which are not included in this prospectus. We have derived the consolidated statement of operations data for the nine-month periods ended September 30, 2005 and 2006 and the consolidated balance sheet data as of September 30, 2006 from our unaudited consolidated financial statements, which are included in this prospectus. The unaudited consolidated financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results for a full fiscal year.

	Year ended December 31,					Nine months ended September 30,	
(in thousands, except share and per share data)	**2001**	**2002**	**2003**	**2004**	**2005**	**2005**	**2006**
Statements of operations data:							
Revenues:							
Product sales	$ 486	$ 61,253	$ 55,536	$ 81,014	$ 127,271	$ 85,807	$ 61,263
Contracts and grants	44,823	17,288	233	2,480	3,417	1,093	4,580
Total revenues	45,309	78,541	55,769	83,494	130,688	86,900	65,843
Operating expenses (income):							
Cost of product sales	34,367	24,569	22,342	30,102	31,603	23,147	11,645
Research and development	382	2,808	6,327	10,117	18,381	9,632	26,640
Selling, general & administrative	10,924	13,397	19,547	30,323	42,793	28,924	32,952
Purchased in-process research and development	—	—	1,824	—	26,575	26,575	477
Settlement of State of Michigan Obligation	—	—	—	(3,819)	—	—	—
Litigation settlement	—	—	—	—	(10,000)	(10,000)	—
Total operating expenses	45,673	40,774	50,040	66,723	109,352	78,278	71,714
Income (loss) from operations	(364)	37,767	5,729	16,771	21,336	8,622	(5,871)
Other income (expense):							
Interest income	122	80	100	65	485	338	405
Interest expense	(193)	(451)	(293)	(241)	(767)	(575)	(778)
Other income (expense), net	(119)	(271)	168	6	55	(24)	291
Total other income (expense)	(190)	(642)	(25)	(170)	(227)	(261)	(82)
Income (loss) before provision for (benefit from) income taxes	(554)	37,125	5,704	16,601	21,109	8,361	(5,953)
Provision for (benefit from) income taxes	—	733	1,250	5,129	5,325	2,109	(2,617)
Net income (loss)	$ (554)	$ 36,392	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Earnings (loss) per share — basic	$ (0.03)	$ 1.97	$ 0.24	$ 0.61	$ 0.77	$ 0.31	$ (0.15)
Earnings (loss) per share — diluted	$ (0.03)	$ 1.75	$ 0.22	$ 0.56	$ 0.69	$ 0.28	$ (0.15)
Weighted average number of shares — basic	16,259,044	18,441,235	18,904,992	18,919,850	20,533,471	19,930,498	22,370,191
Weighted average number of shares — diluted	16,259,044	20,752,243	20,316,752	20,439,252	22,751,733	20,048,412	22,370,191

(in thousands)	2001	2002	2003	2004	As of December 31, 2005	As of September 30, 2006
Balance sheet data:						
Cash and cash equivalents	$ 5,854	$ 4,891	$ 7,119	$ 6,821	$ 36,294	$ 19,906
Working capital	(35,299)	1,130	(3,147)	7,509	29,023	18,726
Total assets	25,423	22,790	37,127	69,056	100,332	130,831
Total long-term liabilities	4,857	4,592	1,228	11,921	10,502	35,606
Total stockholders' equity (deficit)	(32,295)	4,155	8,448	22,949	59,737	56,759

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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 "Risk factors" section of this prospectus 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 immunobiotics. We operate in two business segments: biodefense and commercial. We commenced operations as BioPort Corporation in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to our marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. Following this acquisition, we completed renovations at the Lansing facilities that had been initiated by the State of Michigan. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

In June 2004, we completed a corporate reorganization in which we:

- issued 18,666,479 shares of class A common stock in exchange for 18,017,994 shares of BioPort class A common stock and 648,485 shares of BioPort class B common stock;
- repurchased and retired all other issued and outstanding shares of BioPort class B common stock; and
- assumed all outstanding stock options to purchase BioPort class B common stock and granted option holders replacement stock options to purchase an equal number of shares of our class B common stock.

As a result of the reorganization, BioPort became a wholly owned subsidiary of Emergent. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc. We acquired our portfolio of commercial vaccine candidates through our acquisition of Microscience in a share exchange in June 2005 and our acquisition of substantially all of the assets of Antex for cash in May 2003. We subsequently renamed Microscience as Emergent Product Development UK Limited. We expect to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties.

Our biodefense business has generated net income for each of the last three fiscal years. However, in our commercial business, we have not received approval to market any of our product candidates and, to date, have received no product sales revenues. Our only sources of revenue in our commercial business are development grant funding and an upfront license fee and additional payments for development work under a collaboration agreement with Sanofi Pasteur. As a result, our commercial business has incurred a net loss for each of the last three fiscal years.

Biodefense

In our biodefense business, we develop and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism. Our marketed product, BioThrax, is the only vaccine approved by the FDA for the prevention of anthrax infection. In addition to BioThrax, our biodefense product portfolio includes three biodefense product candidates in preclinical development and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical development. The DoD and HHS have been the principal customers for BioThrax. In addition, we have supplied small amounts of BioThrax directly to several foreign governments. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied over nine million doses of BioThrax through September 2006 for immunization of military personnel. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. Under a contract that we entered into with HHS in May 2005, we supplied five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of $123 million. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of $120 million. We delivered approximately one million doses of BioThrax under this contract modification through September 2006.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax. Our total revenues from BioThrax sales were $55.5 million in 2003, $81.0 million in 2004, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax.

We are collaborating with HPA in the development of a recombinant bivalent botulinum vaccine candidate and a new botulinum toxoid vaccine that we plan to use as the basis for a botulinum immune globulin candidate. We are independently developing an anthrax immune globulin candidate, in part with funding from NIAID. We have submitted three separate proposals for testing and development of three distinct next generation anthrax vaccine product candidates, featuring attributes such as self-administration and a longer shelf life, in response to a request for proposals issued by NIAID. We are actively pursuing additional government sponsored development grants and working with various government agencies to encourage them to conduct studies relating to BioThrax and our other biodefense product candidates.

Commercial

In our commercial business, we develop immunobiotics for use against infectious diseases with significant unmet or underserved medical needs. Our commercial product portfolio includes a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate, both of which are in Phase II clinical development, a group B streptococcus vaccine candidate in Phase I clinical development and a chlamydia vaccine candidate and a meningitis B vaccine candidate, both of which are in preclinical development. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine candidate.

We plan to encourage government entities and non-government and philanthropic organizations to provide development funding for, or to conduct clinical studies of, one or more of our commercial product candidates. For example, the Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam.

Manufacturing infrastructure

To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We anticipate that we will incur up to approximately $35 million for these purposes during 2006, of which we had incurred approximately $21 million through September 2006. We expect to complete construction of this facility in mid 2007, with validation and qualification activities required for regulatory approval continuing thereafter. We are constructing this new facility as a large scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. Our plans assume that the FDA will not require us to complete a human bridging trial demonstrating that BioThrax manufactured at our new facility is bioequivalent to BioThrax manufactured at our existing facility. We currently expect to rely on nonclinical studies for these purposes. However, the FDA has not approved our plan to rely on nonclinical studies without conducting a human bridging trial and may not do so. If the FDA requires us to conduct a human bridging trial, the initiation of large scale manufacturing of BioThrax for commercial sale at our new facility will be delayed and we will incur additional unanticipated costs.

We also own two buildings in Frederick, Maryland that we plan to build out as new manufacturing facilities. We anticipate that we will incur up to $1 million related to initial engineering design and preliminary utility build out for these facilities during 2006, of which we had incurred approximately $234,000 through September 30, 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project.

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 United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair valuation of stock related to 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 cannot sell BioThrax to our customers without written FDA approval for each lot that we manufacture. As part of the FDA review process, we submit a detailed lot protocol for each BioThrax lot that we produce for sale. We also are required to submit product samples to the FDA for testing. Although we generally submit lot protocols and product samples promptly following the satisfactory completion of internal testing, we are permitted to submit product samples in advance of the lot protocols. The length of the FDA review process is approximately four to six weeks. However, individual lots may be released sooner or later depending on factors such as reviewer questions, license supplement approval, reviewer availability and whether our internal testing of product samples is completed before or concurrently with FDA testing. During the period covered by our financial statements included in this prospectus, the FDA has not denied the sale of any BioThrax lots that we have submitted for approval.

We have generated BioThrax sales revenues under U.S. government contracts with the DoD and HHS. Under our DoD contract, we invoice the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We record as deferred revenue the full amount of each progress payment invoice that we submit to the DoD. Title to the product passes to the DoD upon submission of the first invoice. The earnings process is complete upon FDA release of the product for sale and distribution. Following FDA release of the product, we segregate the product for later shipment and recognize 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 invoice the DoD for the final progress payment and recognize the amount of that invoice as period revenue. Our contract with HHS does not provide for progress payments. We invoice HHS and recognize the related revenue upon delivery of the product to the government carrier, at which time title to the product passes to HHS. We do not record allowances for sales returns, rebates or special promotional programs for sales of BioThrax or provisions for sales made in prior periods.

Under the 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 and upon achieving contractually defined development and commercialization milestones. We evaluate the various components of a collaboration in accordance with Emerging Issues Task Force, or EITF, Issue 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 elements in an arrangement. We concluded that under EITF No. 00-21, the upfront license fee, the development work and the milestone payments 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 for Sanofi Pasteur. We invoice Sanofi Pasteur in the beginning of each quarter for the estimated work to occur in that quarter. We record the invoice amount as deferred revenue. As services are completed, we recognize the amount of the related deferred revenue as period revenue. Under the collaboration agreement, we also will be entitled to royalty payments on any future net sales of this product candidate.

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 contract and grant 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 invoicing the sponsoring organization.

Accounts receivable

Accounts receivable are stated at invoice amounts and consist primarily of amounts due from the DoD and HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. Because the prior collection history for receivables from these entities indicate that collection is likely, we do not currently record an allowance for doubtful accounts.

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.

Accrued expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service where we have not yet been invoiced or otherwise notified of actual cost. We make these estimates as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include:

- fees payable to contract research organizations in conjunction with clinical trials;
- fees payable to third party manufacturers in conjunction with the production of clinical trial materials; and
- professional service fees.

In accruing service fees, we estimate the time period over which services were provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon the facts and circumstances known to us.

Purchased in-process research and development

We account for purchased in-process research and development in accordance with Statement of Financial Accounting Standards, or SFAS, No. 2, *Accounting for Research and Development Costs* along with Financial Accounting Standards Board, or FASB, Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method.*

Under these standards, we are required to determine whether the technology relating to a particular research and development project we acquire has an alternative future use. If we determine that the technology has no alternative future use, we expense the value of the research and development project not directly attributed to fixed assets. Otherwise, we capitalize the value of the research and development project not attributable to fixed assets as an intangible asset and conduct an impairment analysis at least annually. In connection with our acquisition of Microscience and our acquisition of substantially all of the assets of Antex and ViVacs GmbH, a German limited liability company, or ViVacs, we allocated the value of the purchase consideration to current assets, current liabilities, fixed assets and development programs. Because we determined that the development programs at Microscience, Antex and ViVacs had no future alternative use, we charged the value attributable to the development programs as in-process research and development. For the Microscience acquisition, which was a share exchange, our board of directors determined the fair value of our shares issued in the exchange for financial statement purposes. For the Antex and ViVacs acquisitions, which were cash transactions, no fair value determination was necessary.

Stock-based compensation

Through December 31, 2005, in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS No. 123, we elected to account for our employee stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, or APB No. 25, rather than the alternative fair value accounting method provided for under SFAS No. 123. Accordingly, we did not record compensation expense on employee stock options granted in fixed amounts and with fixed exercise prices when the exercise prices of the options were equal to the fair value of the underlying common stock on the date of grant. Pro forma information regarding net loss and loss per share is required by SFAS No. 123 and has been determined as if we had accounted for employee stock option grants under the fair value method prescribed by that statement. We provide this pro forma disclosure in our financial statements. We account for transactions in which services are received in exchange for equity instruments based on the fair value of the services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and 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*, or EITF No. 96-18. In accordance with EITF No. 96-18, we periodically remeasure stock-based compensation for options granted to non-employees as the underlying options vest. As of October 20, 2006, we had no outstanding options that had been granted to non-employees other than our directors.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123(R), which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB No. 25 and amends SFAS No. 95, *Statement of Cash Flows.* Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, 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 fair values. Pro forma disclosure is no longer an alternative. We adopted SFAS No. 123(R) on January 1, 2006 using the modified prospective method. We will continue to value our share-based payment transactions using a Black-Scholes valuation model. Under the modified

prospective method, we recognize compensation cost in our financial statements for all awards granted after January 1, 2006 and for all awards outstanding as of January 1, 2006 for which the requisite service had not been rendered as of the date of adoption. Prior period operating results have not been restated. We measure the amount of compensation cost based on the fair value of the underlying common stock on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

As a result of our adoption of SFAS No. 123(R) effective January 1, 2006, we recorded stock-based compensation expense of $385,000 for the nine months ended September 30, 2006 related to stock options that were outstanding and had not completely vested as of January 1, 2006. During the nine months ended September 30, 2006, we granted 258,933 stock options. We recorded additional stock-based compensation expense of $57,000 related to these options during the nine months ended September 30, 2006. Both basic and diluted loss per share for the nine months ended September 30, 2006 are $0.01 less than if we had continued to account for stock-based compensation under APB No. 25. The effect of adopting SFAS No. 123(R) on net loss and net loss per share 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. Based on options granted to employees as of September 30, 2006, total compensation expense not yet recognized related to unvested options is approximately $970,000, after tax. We expect to recognize that expense over a weighted average period of 2.8 years. Based on options granted to employees as of September 30, 2006, we expect to recognize amortization of stock-based compensation, after tax, of approximately $143,000 during the remainder of 2006, $464,000 in 2007, $250,000 in 2008 and $113,000 in 2009.

The factors that most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded, the volatility of fair value of the common stock, the expected life of the instrument and the assumed risk free rate of return. Because shares of our common stock have not been publicly traded, our board of directors has determined the fair value of our common stock for accounting purposes. There is no certainty that the results of our board's determination would be the value at which the shares would be traded for cash. In determining the fair value of our common stock, our board of directors considered:

- the history and nature of our business and results of operations;
- our prospects for growth, including potential contracts for BioThrax product sales;
- our available cash, assets and financial condition;
- prior determinations of the fair value of the common stock underlying stock options granted and the effect of corporate developments, including the progress of our product candidates, that have occurred between the time of the grants;
- rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity;
- values of public companies that we believe are comparable to us, adjusted for the risks related to and the lack of a liquid market for the shares;
- the time frame in which a liquid market would likely be available for the shares;
- business developments involving our direct competitors; and
- general economic trends and the economic outlook and market conditions for our industry.

If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses.

In 2004, in connection with our reorganization, we recorded stock-based compensation expense as a result of the issuance of stock options to purchase our class B common stock to replace the outstanding stock options to purchase BioPort class B common stock. The exercise period of these replacement options was extended to June 2007. Based upon the guidance in APB No. 25, because the stock options granted for our class B common stock provided for an extended term over that of the cancelled BioPort options, a new measurement date was created and we recorded as stock-based compensation expense the excess of the intrinsic value of the modified options over the intrinsic value of the BioPort options when originally issued. This resulted in stock-based compensation expense of $4.3 million for 2004. We did not record any stock-based compensation expense for options granted during 2003 or 2005.

Income taxes

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 financial reporting basis of assets and liabilities. We have historically incurred net operating losses for income tax purposes in some states 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 and 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.

Financial operations overview

Revenues

We have generated substantially all of our revenues from sales of BioThrax. We delivered approximately 5.2 million total doses of BioThrax, representing 97% of our total revenues, in 2005. We delivered approximately 2.5 million total doses of BioThrax, representing 93% of our total revenues, in the nine months ended September 30, 2006. The DoD and HHS have been the principal customers for BioThrax. We also have had limited sales of BioThrax to foreign governments and private industry. In addition, we periodically realize revenues from grants from government entities and non-government and philanthropic organizations and from licensing fees, milestone payments and development reimbursement. These items accounted for 3% of our total revenues in 2005 and 7% of our total revenues in the nine months ended September 30, 2006. If our ongoing development efforts are

successful, we would expect to generate revenues from sales of additional products and milestone payments, development payments and royalties on sales of products that we license to third parties.

In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of $123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of $120 million. We delivered approximately one million doses of BioThrax under this contract modification through September 2006. We delivered approximately 1.5 million doses of BioThrax to HHS in November 2006. We expect to deliver to HHS between 1.25 million and 1.75 million doses of BioThrax in December 2006, with the balance to be delivered in the first half of 2007 prior to expiration of the contract.

In January 2004, we entered into our current contract with the DoD for the delivery of a minimum number of doses of BioThrax over one base contract year plus two option periods for a minimum fixed price of approximately $91 million. Under the original terms of this contract, we were required to deliver a minimum of approximately 3.8 million total doses through September 2006. We delivered approximately 4.9 million total doses under this contract from 2004 through September 30, 2006 pursuant to DoD purchase orders. We have amended our current contract with the DoD to provide for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We expect to deliver to the DoD approximately 480,000 of these doses by December 2006, with the balance to be delivered by September 2007. We have invoiced the DoD, as contemplated under this contract, for progress payments as doses of BioThrax are manufactured for sale to the DoD. In accordance with our revenue recognition policy, we record deferred revenue for invoiced amounts until the FDA releases the product for sale and delivery. As of September 30, 2006, the amount of our deferred revenue for DoD sales was $8.4 million. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base year plus four option years. Although we are in discussions with the DoD, the DoD has not issued a formal request for proposals for such a contract and we have not yet entered into an agreement with the DoD for this procurement.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of our meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialization objectives, payments for development work under the collaboration and royalties on net sales of this product. We recognize the upfront license fee, milestone payments and development payments under this agreement as 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. We expect contracts and grant revenues to increase in 2006 compared to 2005 as we receive reimbursement for development expenses under our meningitis B collaboration with Sanofi Pasteur, funding from the Wellcome Trust for costs associated with our completed Phase I clinical trial and planned Phase II clinical trial of our typhoid vaccine candidate in Vietnam and funding from NIAID for costs associated with our animal efficacy studies in rabbits of our anthrax immune globulin candidate.

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. In 2005, we improved manufacturing efficiencies for BioThrax by extending the hours of operation for our manufacturing facility. As a result, the cost of product sales per dose of BioThrax decreased in 2005 compared to 2004. We do not expect further significant improvements in manufacturing efficiencies for BioThrax until we complete our new manufacturing facility in Lansing, Michigan. We currently are producing BioThrax at close to the maximum capacity of our existing manufacturing facility. We expect our manufacturing costs to remain relatively stable for the remainder of 2006 and during 2007.

We determine the cost of product sales for doses sold for a period based on the average manufacturing cost per dose for that period. We calculate the average manufacturing cost per dose by dividing the actual costs of manufacturing in the applicable 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 any period.

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, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials;
- 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 cost of facilities and the legal costs of pursuing patent protection of our intellectual property.

The successful development of our product candidates is highly uncertain. 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 cannot reasonably estimate or know the nature, timing and projected costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from any of our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- our ability to obtain adequate supplies of our product candidates required for later stage clinical trials, including from third party manufacturers;
- the potential benefits of our product candidates over other products;
- our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;

- future clinical trial results;
- the terms and timing of regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

We expect that development spending will increase for all of our biodefense product candidates as our product development activities continue and we prepare for regulatory submissions and other regulatory activities. We expect our development expenses in our commercial business to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates.

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, cost associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, our ability to use data generated by government agencies, such as the ongoing CDC studies with BioThrax, and our ability to rely upon and utilize clinical and nonclinical data, such as the data generated by CDC from use of the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan. Furthermore, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

Selling, general and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, 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 expect that our general and administrative expenses will increase as we add personnel to support the increased scale of our operations and become subject to the reporting obligations applicable to public companies. Our general and administrative expenses have increased as a result of preparing for this offering and supporting the overall growth of the company. We currently market and sell BioThrax directly to the DoD and HHS with a small, targeted marketing and sales group. Accordingly, our marketing and sales expense for these efforts has been limited. 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 on our cash, cash equivalents and short-term investments, and we incur interest expense on our indebtedness. Our net interest expense will increase in future periods as compared to prior periods as a result of the mortgage loan that we entered into in April 2006 and the term loan that we entered into in August 2006, as well as any borrowings under our revolving lines 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

Nine months ended September 30, 2006 compared to nine months ended September 30, 2005

Revenues

Product sales revenues, which relate only to the biodefense segment, decreased by $24.5 million, or 29%, to $61.3 million for the nine months ended September 30, 2006 from $85.8 million for the nine months ended September 30, 2005. This decrease in product sales revenues was primarily due to a 29% decrease in the number of doses we delivered as a result of the timing of our fulfilling orders from the DoD and HHS. Product sales revenues in the nine months ended September 30, 2006 consisted of BioThrax sales to HHS of $35.4 million, sales to the DoD of $25.3 million and sales to the Canadian government of $630,000. Product sales revenues in the nine months ended September 30, 2005 consisted of BioThrax sales to HHS of $69.9 million, sales to the DoD of $14.5 million, sales to the Canadian government of $1.1 million and other sales of $291,000.

Contracts and grant revenues increased by $3.5 million to $4.6 million for the nine months ended September 30, 2006 from $1.1 million for the nine months ended September 30, 2005. Contracts and grant revenues for the nine months ended September 30, 2006 consisted of $3.2 million in upfront and development program revenue from the Sanofi Pasteur collaboration and $1.5 million in grant revenue from the Wellcome Trust. Contracts and grant revenues for the nine months ended September 30, 2005 resulted from reimbursement from the DoD for expenses related to production development and supply chain management improvements for BioThrax incurred in prior periods, and for additional work that we performed on a project basis for the DoD's Defense Advanced Research Projects Agency, or DARPA, to evaluate a new vaccine adjuvant for BioThrax.

Cost of product sales

Cost of product sales, which relate only to the biodefense segment, consists of expenses incurred in the manufacture of BioThrax. Cost of product sales decreased by $11.5 million, or 50%, to $11.6 million for the nine months ended September 30, 2006 from $23.1 million for the nine months ended September 30, 2005. This decrease was attributable to the delivery of 1.0 million fewer doses of BioThrax in the nine months ended September 30, 2006 and improved utilization of our manufacturing capacity for BioThrax as a result of extending the hours of operation for our manufacturing facility. The reduction in the number of doses delivered resulted in a reduction in costs of approximately $6.8 million. Manufacturing efficiencies resulted in a cost savings of approximately $4.7 million.

Research and development expenses

Research and development expenses increased by $17.0 million to $26.6 million for the nine months ended September 30, 2006 from $9.6 million for the nine months ended September 30, 2005. This increase reflects increased expenses of $9.1 million in the biodefense segment and $8.8 million in the commercial segment, offset by a reduction of $892,000 in other research and development expenses.

The increase in biodefense spending was attributable to increased efforts on all our biodefense programs as we completed various studies and began subsequent studies and trials. This increase primarily reflects additional personnel and contract service costs. The increase in spending for BioThrax enhancements is related to preparing for animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in 2008. The increase in spending for immune globulin development related primarily to costs associated with our plasma donor stimulation program for our anthrax immune globulin candidate. The increase in spending for the recombinant botulinum vaccine

program, which is in preclinical development, resulted from advancing this program to the process development stage and the manufacture of clinical trial material. The increase in spending for the next generation anthrax vaccine program, which has product candidates in preclinical and Phase I clinical development, resulted from formulation development and the manufacture of clinical trial material.

The increase in commercial spending was mainly attributable to spending on the commercial products listed in the table below following our acquisition of Microscience in June 2005. This increase primarily reflects additional personnel and contract service costs. Research and development spending by Microscience prior to our acquisition of Microscience in June 2005 is not included in our results for the nine months ended September 30, 2005. The spending in the nine months ended September 30, 2006 for our typhoid vaccine candidate resulted from ongoing work for the Phase I clinical trial in Vietnam that we recently completed and preparing for our Phase II clinical trial in Vietnam that we plan to initiate in the fourth quarter of 2006. The spending in the nine months ended September 30, 2006 for our hepatitis B therapeutic vaccine candidate resulted from preparing for our Phase II clinical trial that we plan to initiate in the fourth quarter of 2006. The spending in the nine months ended September 30, 2006 for our group B streptococcus vaccine candidate resulted from costs associated with our analysis of results from the Phase I clinical trial that we recently completed for one of the protein components of the vaccine candidate and preparation for Phase I clinical trials for the two other protein components of the vaccine candidate. Both our chlamydia vaccine and meningitis B vaccine candidates are in preclinical development.

The decrease in spending on other research and development expenses was attributable to our discontinuation of preclinical programs that we acquired from Antex and determined not to pursue.

Our principal research and development expenses for the nine months ended September 30, 2005 and 2006 are shown in the following table:

	Nine months ended September 30,	
(in thousands)	**2005**	**2006**
Biodefense:		
BioThrax enhancements	$ 1,815	$ 2,678
Immune globulin development	2,154	6,947
Recombinant bivalent botulinum vaccine	718	1,323
Next generation anthrax vaccine	180	3,032
Total biodefense	4,867	13,980
Commercial:		
Typhoid vaccine	897	4,483
Hepatitis B therapeutic vaccine	727	2,508
Group B streptococcus vaccine	411	1,764
Chlamydia vaccine	431	1,225
Meningitis B vaccine	670	1,943
Total commercial	3,136	11,923
Other	1,629	737
Total	$ 9,632	$ 26,640

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $4.0 million, or 14%, to $33.0 million for the nine months ended September 30, 2006 from $28.9 million for the nine months ended September 30, 2005. Selling, general and administrative expenses related to the biodefense segment decreased by $194,000, or 1%, to $24.4 million for the nine months ended September 30, 2006 from $24.6 million for the nine months ended September 30, 2005. Selling, general and administrative expenses related to the commercial segment increased by $4.2 million, or 98%, to $8.5 million for the nine months ended September 30, 2006 from $4.3 million for the nine months ended September 30, 2005. The increase in the commercial segment was primarily attributable to an increase in general and administrative expenses of $3.6 million resulting from the addition of personnel and facilities for Emergent Product Development UK following our acquisition of Microscience in June 2005.

Purchased in-process research and development

In June 2005, we recorded a non-cash charge for purchased in-process research and development of $26.6 million associated with our acquisition of Microscience. We valued the 3,636,801 shares of class A common stock that we issued in the acquisition at $28.2 million after the inclusion of acquisition costs. Of this amount, we identified $1.4 million as current assets, $0.9 million as fixed assets, $0.7 million as current liabilities and $26.6 million as the value attributable to development programs. Because we determined that the development programs had no future alternative use, we charged the value attributable to the development programs as purchased in-process research and development. We are amortizing this charge for tax purposes over 15 years.

In July 2006, we recorded a non-cash charge for purchased in-process research and development of $477,000 associated with our acquisition of ViVacs. We paid total purchase consideration of $250,000 and assumed a net deficit of liabilities in excess of assets of $47,000. We valued the acquisition at $430,000 after the inclusion of acquisition costs. Of this amount, we identified $153,000 as current assets, $97,000 as fixed assets, $297,000 as current liabilities and $477,000 as the value attributable to development programs and technology. Because we determined that the development programs and technology had no future alternative use, we charged the value attributable to the development programs and technology as purchased in-process research and development. We are amortizing this charge for tax purposes over 15 years.

Litigation settlement

In June 2005, we recorded a gain of $10.0 million relating to a settlement of a litigation matter that we initiated to resolve a contract and intellectual property dispute. There were no settlements for the nine months ended September 30, 2006.

Total other income (expense)

Total other expense decreased by $179,000 to $82,000 for the nine months ended September 30, 2006 from $261,000 for the nine months ended September 30, 2005. The decrease resulted principally from an increase in interest income of $67,000 as a result of higher investment return on increased average cash balances, an increase in interest expense of $203,000 related primarily to the mortgage loan we entered into in April 2006 and the term loan we entered into in August 2006, and an increase in other income (expense) of $315,000.

Income taxes

We recorded a benefit from income taxes of $2.6 million for the nine months ended September 30, 2006 compared to a provision for income taxes of $2.1 million for the nine months ended September 30, 2005. The benefit from income taxes for the nine months ended September 30, 2006 resulted primarily from our loss before benefit from income taxes of $6.0 million and an estimated effective annual tax rate of 44%. The provision for income taxes for the nine months ended September 30, 2005 resulted primarily from our income before provision for income taxes of $8.4 million and an estimated effective annual tax rate of 25%. The increase in the estimated effective annual tax rate by 19% is due primarily to an increase in the valuation allowance related to estimated foreign and state net operating losses. While the net operating losses for foreign and state jurisdictions have been recorded as deferred tax assets, a full valuation allowance also has been recorded for such tax assets due to current uncertainty as to whether we will generate sufficient future taxable income in the applicable jurisdictions to fully utilize these net operating losses.

Year ended December 31, 2005 compared to year ended December 31, 2004

Revenues

Product sales revenues increased by $46.3 million, or 57%, to $127.3 million for 2005 from $81.0 million for 2004. This increase in product sales revenues was primarily due to a 52% increase in the number of doses delivered. Product sales revenues in 2005 consisted of BioThrax sales to HHS of $111.2 million, sales to the DoD of $14.5 million and aggregate sales to the governments of Canada and Taiwan of $1.6 million. Product sales revenues in 2004 consisted of BioThrax sales to the DoD of $80.6 million and sales to the Canadian government of $360,000.

Contracts and grant revenues increased by $937,000, or 38%, to $3.4 million in 2005 from $2.5 million in 2004 primarily as a result of additional work that we performed on a project basis for DARPA to evaluate a new vaccine adjuvant for BioThrax.

Cost of product sales

Cost of product sales increased by $1.5 million, or 5%, to $31.6 million for 2005 from $30.1 million for 2004. This increase was attributable to the delivery of 1.8 million additional doses of BioThrax in 2005 and a decrease in production yield, resulting in a higher average manufacturing cost per dose in 2005, offset by improved utilization of our manufacturing capacity for BioThrax as a result of extending the hours of operation for our manufacturing facility. The increase in the number of doses delivered combined with the decrease in production yield resulted in additional costs of $6.6 million. Manufacturing efficiencies resulted in a cost savings of $5.1 million.

Research and development expenses

Research and development expenses increased by $8.3 million, or 82%, to $18.4 million for 2005 from $10.1 million for 2004. This increase reflects increased expenses of $4.0 million in the biodefense segment and $5.8 million in the commercial segment, offset by a reduction of $1.6 million in other research and development expenses.

The increase in biodefense spending resulted from costs associated with our plasma donor stimulation program for our anthrax immune globulin candidate, process development related to our recombinant botulinum vaccine candidate and evaluation of third party technology related to our next generation anthrax vaccine program for potential acquisition or in license, offset by decreased spending on BioThrax

enhancements. In 2004, the immune globulin program was in initial development and we had not yet begun work on the recombinant botulinum vaccine and next generation anthrax vaccine candidates. The decrease in spending on BioThrax enhancements resulted from substantial completion during 2004 of research regarding manufacturing process development for BioThrax to improve the stability and consistency of production lots.

The increase in spending in the commercial segment was attributable to spending on the commercial programs listed in the table below following our acquisition of Microscience in June 2005. Research and development spending by Microscience is not included in our results prior to the acquisition date. The commercial spending in 2005 resulted from the Phase I clinical trial in Vietnam for our typhoid vaccine candidate, preparation for a planned Phase II clinical trial for our hepatitis B therapeutic vaccine candidate, including the manufacture of clinical trial material, preparation for one of three planned Phase I clinical trials related to one of the protein components of our group B streptococcus vaccine candidate and preclinical work for our chlamydia vaccine and meningitis B vaccine candidates.

The decrease in spending on other research and development expenses was attributable to our discontinuation of preclinical programs that we acquired from Antex and determined not to pursue.

Our principal research and development expenses for 2004 and 2005 are shown in the following table:

(in thousands)	Year ended December 31, 2004	2005
Biodefense:		
BioThrax enhancements	$ 5,929	$ 2,883
Immune globulin development	350	5,309
Recombinant bivalent botulinum vaccine	—	1,708
Next generation anthrax vaccine	—	427
Total biodefense	6,279	10,327
Commercial:		
Typhoid vaccine	—	1,477
Hepatitis B therapeutic vaccine	—	1,884
Group B streptococcus vaccine	—	1,032
Chlamydia vaccine	1,136	837
Meningitis B vaccine	—	1,334
Total commercial	1,136	6,564
Other	2,702	1,490
Total	$ 10,117	$ 18,381

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $12.5 million, or 41%, to $42.8 million for 2005 from $30.3 million for 2004. Selling, general and administrative expenses related to our biodefense segment increased by $6.4 million to $35.4 million for 2005 from $29.0 million for 2004. Selling, general and administrative expenses related to our commercial segment increased by $6.0 million to $7.3 million

for 2005 from $1.3 million for 2004. The increase in the biodefense segment was attributable to an increase in general and administrative expenses of $5.5 million resulting from additional personnel and professional service providers for our headquarters organization who devoted time to the biodefense segment and an increase in sales and marketing expenses of $1.0 million resulting from the addition of sales personnel to investigate potential other markets for BioThrax. The increase in the commercial segment was attributable to an increase in general and administrative expenses of $5.3 million resulting from the addition of personnel for Emergent Product Development UK and legal expenses associated with reorganizing our corporate structure following our acquisition of Microscience in June 2005.

Purchased in-process research and development

In 2005, as described above, we recorded a non-cash charge of $26.6 million for purchased in-process research and development associated with our acquisition of Microscience.

Litigation settlement

In 2005, we recorded a gain of $10.0 million relating to a settlement of a litigation matter that we initiated to resolve a contract and intellectual property dispute. There were no settlements in 2004.

Total other income (expense)

Total other expense increased by $57,000 to $227,000 for 2005 from $170,000 for 2004. This increase resulted primarily from an increase in interest expense associated with our financing of the acquisition costs for one building at our Frederick facility.

Income taxes

Provision for income taxes increased by $196,000, or 4%, to $5.3 million for 2005 from $5.1 million for 2004. The provision for income taxes for 2005 resulted primarily from our income before provision for income taxes of $21.1 million and an effective annual tax rate of 25%. The provision for income taxes for 2004 resulted primarily from our income before provision for income taxes of $16.6 million and an effective annual tax rate of 31%. The provision for income taxes also reflects research and development tax credits of $474,000 for 2005 and $492,000 for 2004 and small amounts of permanent tax differences in each year.

Year ended December 31, 2004 compared to year ended December 31, 2003

Revenues

Product sales revenues increased by $25.5 million, or 46%, to $81.0 million for 2004 from $55.5 million for 2003. This increase in product sales revenues was primarily due to a 45% increase in the number of doses delivered. Product sales revenues in 2004 consisted of BioThrax sales to the DoD of $80.6 million and sales to the Canadian government of $360,000. Product sales revenues in 2003 consisted of BioThrax sales to the DoD of $55.2 million and sales to the Canadian government of $270,000.

Contracts and grant revenues increased to $2.5 million in 2004 from $233,000 in 2003 primarily as a result of additional work that we performed on a project basis for DARPA to evaluate a new vaccine adjuvant for BioThrax.

Cost of product sales

Cost of product sales increased by $7.8 million, or 35%, to $30.1 million for 2004 from $22.3 million for 2003. This increase was attributable to the delivery of approximately 1.0 million additional doses of BioThrax in 2004. We were able to deliver these additional doses as a result of increasing our manufacturing capacity at our Lansing facility in 2004 by extending the hours of operation of the facility. The increase in the number of doses delivered resulted in additional costs of $3.5 million. Increasing manufacturing capacity resulted in additional costs of $4.3 million, primarily for the training of new personnel. Our increase in manufacturing capacity allowed us to spread our fixed manufacturing costs over a greater number of doses, which resulted in a decrease in the cost of product sales per dose of BioThrax in 2004 compared to 2003.

Research and development expenses

Research and development expenses increased by $3.8 million, or 60%, to $10.1 million for 2004 from $6.3 million for 2003. This increase reflects increased expenses of $1.9 million in the biodefense segment and $1.8 million in the commercial segment. The increase in the biodefense segment was attributable to work on the initiation of programs for BioThrax enhancements and consisted primarily of personnel and contract service costs. The increase in the commercial segment was attributable to spending on commercial product candidates acquired from Antex in May 2003. Research and development spending by Antex is not included in our results prior to the acquisition date.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $10.8 million, or 55%, to $30.3 million for 2004 from $19.5 million for 2003. Selling, general and administrative expenses related to the biodefense segment increased by $9.5 million to $29.0 million for 2004 from $19.5 million for 2003. This increase was attributable to growth in corporate staff to support expanding business activity and increased costs for professional service providers. Selling, general and administrative expenses related to the commercial segment increased by $1.3 million for 2004 from an immaterial amount for 2003 as we hired additional employees to support the newly acquired Antex operations. The overall increase in selling, general and administrative expenses was primarily attributable to an increase of $7.0 million in general and administrative expenditures as a result of our corporate reorganization in June 2004 and the formation of our headquarters organization, including a non-cash stock-based compensation charge of $4.3 million. In addition, general and administrative expenses increased $1.1 million as a result of our acquisition of assets from Antex. Selling and marketing expense increased to $843,000 for 2004 from an immaterial amount for 2003. This increase in spending resulted from the addition of personnel and outside consulting fees.

Purchased in-process research and development

In 2003, we recorded a non-cash charge of $1.8 million associated with our acquisition of assets from Antex. We paid total purchase consideration of $3.4 million in cash. We valued the transaction at $3.8 million after the inclusion of acquisition costs. Of this amount, we identified $300,000 as current assets, $1.7 million as fixed assets and $1.8 million as the value attributable to development programs. Because we determined that the development programs had no future alternative use, we charged the value attributable to the development programs as purchased in-process research and development. We are amortizing this charge for tax purposes over 15 years.

Settlement of State of Michigan obligation

In 2004, we recorded a gain of $3.8 million from the satisfaction for less than originally estimated of an obligation to the State of Michigan related to our acquisition of assets from the Michigan Biologic Products Institute in 1998. We have no ongoing obligations to the State of Michigan related to our acquisition of assets from the Michigan Biologic Products Institute. There was no settlement of obligations in 2003.

Total other income (expense)

Total other expense, net, increased to $170,000 for 2004 from $25,000 for 2003. The increase resulted principally from a decrease in other income of $162,000.

Income taxes

Provision for income taxes increased by $3.9 million to $5.1 million for 2004 from $1.3 million for 2003. The provision for income taxes for 2004 resulted primarily from our income before provision for income taxes of $16.6 million and an effective annual tax rate of 31%. The provision for income taxes for 2003 resulted primarily from our income before provision for income taxes of $5.7 million and an effective annual tax rate of 22%. The provision for income taxes also reflects research and development tax credits of $492,000 for 2004 and $441,000 for 2003 and small amounts of permanent tax differences in each year.

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, 2006 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, revenues under our collaboration agreement with Sanofi Pasteur, development funding from government entities and non-government and philanthropic organizations and, to a lesser extent, from the sale of our class B common stock upon exercise of stock options. We have operated profitably for each of the years in the three year period ended December 31, 2005, but incurred a loss in the nine months ended September 30, 2006. As of September 30, 2006, we had cash and cash equivalents of $19.9 million.

Cash flows

The following table provides information regarding our cash flows for the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and September 30, 2006.

	Year ended December 31,			Nine months ended September 30,	
(in thousands)	2003	2004	2005	2005	2006
Net cash provided by (used in):					
Operating activities(1)	$11,072	$ 9,196	$41,974	$21,581	$ (8,032)
Investing activities	(7,917)	(18,175)	(5,841)	(2,317)	(32,741)
Financing activities	(927)	8,681	(6,660)	(6,574)	24,385
Total net cash provided (used)	$ 2,228	$ (298)	$29,473	$12,690	$(16,388)

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

Net cash used in operating activities of $8.0 million in the nine months ended September 30, 2006 resulted principally from our net loss of $3.3 million, an increase in inventories of $11.6 million, reflecting the value of work in process for BioThrax lots being manufactured or awaiting delivery, and a non-cash benefit from income taxes of $4.9 million, reflecting our net loss before provision for income taxes for the period, offset by an increase in accounts payable of $6.1 million related to expenses incurred but unpaid at September 30, 2006 and an increase in deferred revenue of $4.6 million related to amounts billed under our contract with the DoD and deferral of a portion of the upfront license fee from Sanofi Pasteur. The net loss for the period and the increase in inventory are primarily related to the timing of our fulfilling orders from the DoD and HHS. The increase in deferred revenue primarily reflects progress billings to the DoD, pursuant to our contract, for product not yet released or shipped and, therefore, not recorded as revenue during the period.

Net cash provided by operating activities of $21.6 million in the nine months ended September 30, 2005 resulted principally from our net income of $6.3 million, a non-cash charge for purchased in-process research and development relating to the Microscience acquisition, which reduced net income by $26.6 million, and a reduction in accounts receivable of $16.3 million as a result of the collection of amounts due from the DoD during 2005 for invoices outstanding at the end of 2004 for progress in the manufacture of BioThrax lots, offset by a reduction in deferred revenue of $10.9 million, reflecting the recognition of revenue related to the delivery to the DoD of BioThrax lots for which we had previously invoiced the DoD for progress payments and been paid, and an increase in deferred tax assets of $10.3 million, reflecting a deferred tax asset recorded to reflect the timing differences between the book charge and the tax deferral of expense related to the purchased in-process research and development expense related to the Microscience acquisition.

Net cash provided by operating activities of $42.3 million in 2005 resulted principally from our net income of $15.8 million, a non-cash charge for purchased in-process research and development related to the Microscience acquisition, which reduced net income by $26.6 million, and a reduction of accounts receivable of $16.1 million as a result of the collection of amounts due from the DoD during 2005 for invoices outstanding at the end of 2004 for progress in the manufacture of BioThrax lots, offset by a reduction of deferred revenue of $10.9 million, reflecting the delivery to the DoD in the first quarter of 2005 of BioThrax lots for which we had previously invoiced the DoD for progress payments and been paid and an increase in deferred tax assets of $11.0 million, reflecting a deferred tax asset recorded to reflect the timing differences between the book charge and the tax deferral of expense related to the purchased in-process research and development expense related to the Microscience acquisition.

Net cash provided by operating activities of $9.2 million in 2004 resulted principally from our net income of $11.5 million, a non-cash stock based compensation charge that we incurred as a result of our issuance of new stock options in our corporate reorganization in June 2004, which reduced net income by $4.3 million, an increase in income taxes payable of $5.8 million related to the timing of payment of taxes and related deferred tax assets, and an increase in deferred revenue of $3.9 million, reflecting invoices to and payments from the DoD for progress in the manufacture of BioThrax lots, offset by an increase in accounts receivable of $15.7 million, reflecting invoices for amounts due from the DoD for progress in the manufacture of BioThrax lots, and a one-time non-cash gain of $3.8 million resulting from the satisfaction of an obligation to the State of Michigan for less than originally estimated.

Net cash provided by operating activities of $11.1 million in 2003 resulted principally from our net income of $4.5 million and an increase of $11.9 million in deferred revenue reflecting invoices to and payments from the DoD for progress in the manufacture of BioThrax lots, offset by an increase in inventories of $4.7 million reflecting the timing of deliveries to the DoD.

Net cash used in investing activities in the nine months ended September 30, 2006 and 2005 and in 2005, 2004 and 2003 resulted principally from the purchase of property, plant and equipment. Capital expenditures in the nine months ended September 30, 2006 relate primarily to costs for construction of our new building in Lansing, Michigan and the acquisition of our second facility in Frederick, Maryland. Capital expenditures in 2005 were primarily attributable to investments in information technology upgrades and miscellaneous facility enhancements. Capital expenditures in 2004 include infrastructure investments of $4.7 million, $3.8 million for an enterprise resource planning system and $8.5 million for the purchase of one of our facilities in Frederick, Maryland. Capital expenditures in 2003 include infrastructure investments in our Lansing facilities. Net cash used in investing activities in 2003 also includes cash of $3.8 million used for the acquisition of assets from Antex.

Net cash provided by financing activities of $24.4 million in the nine months ended September 30, 2006 resulted primarily from proceeds from notes payable related to the financing of the purchase of our Frederick facility in May 2006 and the financing of a portion of the costs related to the construction of our new building in Lansing. Net cash used in financing activities of $6.6 million in the nine months ended September 30, 2005 resulted principally from the payment of a special dividend from a portion of the proceeds of a litigation settlement and the repayment of notes payable to employees and the repurchase of class B common stock.

Net cash used in financing activities of $6.7 million in 2005 resulted principally from the payment of a special dividend of $5.4 million from a portion of the proceeds of a litigation settlement and the repayment of notes payable to employees.

Net cash provided by financing activities of $8.7 million in 2004 resulted principally from an increase in notes payable as a result of $11.0 million of total debt incurred to finance the purchase of one of our facilities in Frederick, Maryland and to finance the purchase of an enterprise resource planning system, offset by the repayment of non-recurring royalty and product supply obligations to the State of Michigan of $2.4 million.

Net cash used in financing activities of $927,000 in 2003 resulted primarily from the repayment of royalty and product supply obligations to the State of Michigan.

Contractual obligations

The following table summarizes our contractual obligations at September 30, 2006.

							Payments due by period
(in thousands)	**Total**	**2006**	**2007**	**2008**	**2009**	**2010**	**After 2010**
Contractual obligations:							
Short and long-term debt(1)	$ 49,707	$ 3,504	$ 5,627	$ 5,297	$ 5,287	$ 5,286	$ 24,707
Operating lease obligations	15,919	422	1,699	1,801	686	647	10,664
Contractual settlement liabilities	200	100	100	—	—	—	—
Total contractual obligations	$ 65,826	$ 4,026	$ 7,426	$ 7,098	$ 5,973	$ 5,933	$ 35,371

(1) Includes scheduled interest payments.

The preceding table excludes contingent contractual payments that we may become obligated to make upon achievement of specified research, development and commercialization milestones and contingent contractual royalty payments. The amount of contingent contractual milestone payments that we may become obligated to make is variable based on the actual achievement and timing of the applicable milestones and the characteristics of any products or product candidates that are developed, including

factors such as number of products or product candidates developed, type and number of components of each product or product candidate, ownership of the various components and the specific markets affected. Based on our current development plans, we estimate that the maximum amount of these contingent contractual milestone payments under our existing contracts would be approximately $11 million. We are not obligated to pay any minimum royalties under our existing contracts.

Debt financing

As of September 30, 2006, we had $36.5 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 one of our facilities in Frederick, Maryland;
- $7.0 million outstanding under a mortgage loan from Mercantile Potomac Bank used to finance the remaining portion of the purchase price for the Frederick facility;
- $8.4 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for a second facility on the Frederick site;
- $1.3 million outstanding under a term loan from Fifth Third Bank used to finance the purchase of an enterprise resource planning system;
- $2.2 million outstanding under a $10.0 million revolving line of credit with Fifth Third Bank;
- $10.0 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
- $5.0 million outstanding under a $5.0 million revolving line of credit with HSBC Realty Credit Corporation.

We can borrow under the line of credit with Fifth Third Bank through November 2006 and under the line of credit with HSBC Realty Credit Corporation through October 2007.

Some of these debt instruments contain financial and operating covenants. In particular:

- Under our mortgage loan from Mercantile Potomac Bank for our Frederick facility, we are required to maintain at all times a minimum tangible net worth of not less than $5.0 million. In addition, we are required to maintain at all times a ratio of earnings before interest, taxes, depreciation and amortization to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable within the following 12 months, of not less than 1.1 to 1.0.
- Under our forgivable loan from the State of Maryland, we are not required to repay the principal amount of the loan if beginning December 31, 2009 and through 2012 we maintain a specified number of employees at the Frederick site, by December 31, 2009 we have invested at least $42.9 million in total funds toward financing the purchase of the buildings on the site and for related improvements and operation of the facility and we occupy the facility through 2012.
- Under our term loan and revolving line of credit with HSBC Realty Credit Corporation, we are required to maintain on an annual basis a minimum tangible net worth of not less than the sum of 85% of our tangible net worth for the most recently completed fiscal year plus 25% of current net operating profit after taxes. In addition, we are required to maintain on a quarterly basis a ratio of earnings before

interest, taxes, depreciation and amortization for the most recent four quarters to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters, of not less than 1.25 to 1.00.

- Under our line of credit with Fifth Third Bank, our wholly owned subsidiary, Emergent BioDefense Operations, is required to maintain at all times a ratio of total liabilities to tangible net worth of not more than 2.5 to 1.0.

Our debt instruments also contain negative covenants restricting our activities. Our term loan and revolving line of credit with HSBC Realty Credit Corporation limit the ability of Emergent BioDefense Operations to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into mergers or similar transactions and enter into transactions with affiliates. Our term loan and revolving line of credit with HSBC Realty Credit Corporation also limit our ability to incur indebtedness and liens, enter into mergers or similar transactions and enter into transactions with affiliates. Our line of credit with Fifth Third Bank limits the ability of Emergent BioDefense Operations to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into mergers or similar transactions, enter into transactions with affiliates and amend the terms of any government contract.

The facilities and software and other equipment that we purchased with the proceeds of our loans from Mercantile Potomac Bank, the State of Maryland, HSBC Realty Credit Corporation and Fifth Third Bank serve as collateral for these loans. Our line of credit with Fifth Third Bank is secured by accounts receivable under our DoD and HHS contracts. Our term loan and revolving line of credit with HSBC Realty Credit Corporation are secured by substantially all of Emergent BioDefense Operations' assets, other than accounts receivable under our DoD and HHS contracts. The covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

Under our mortgage loan from Mercantile Potomac Bank, we are required to make monthly principal payments beginning in November 2006. A residual principal repayment of approximately $5.0 million is due upon maturity in October 2011. Interest is payable monthly and accrues at an annual rate of 6.625% through October 2009. In October 2009, the interest rate is scheduled to be adjusted to a fixed annual rate equal to 3.20% over the yield on U.S. government securities adjusted to a constant maturity of two years.

Under our mortgage loan from HSBC Realty Credit Corporation, we are required to make monthly principal payments. A residual principal repayment of approximately $7.5 million is due upon maturity in April 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.00%.

Under our term loan from Fifth Third Bank, we make monthly principal payments through maturity in September 2007. Interest is payable monthly and accrues at an annual rate equal to 0.375% less than the prime rate of interest established from time to time by Fifth Third Bank.

Under our revolving line of credit with Fifth Third Bank, any outstanding principal is due upon maturity in November 2006. Interest is payable monthly and accrues at an annual rate equal to 0.375% less than the prime rate of interest established from time to time by Fifth Third Bank.

Under our term loan with HSBC Realty Credit Corporation, we are required to make monthly principal payments beginning in April 2007. A residual principal payment of approximately $4.0 million is due upon maturity in August 2011. Upon our request, the term loan is subject to an extension term in the sole discretion of HSBC Realty Credit Corporation for five additional years until August 2016 for an extension fee of 1.00% of the principal balance of the loan. If the term of the loan were extended, we would be required to continue to make monthly principal payments through maturity in August 2016 in

lieu of the residual principal payment otherwise due in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75%.

Under our revolving line of credit with HSBC Realty Credit Corporation, we are not required to repay outstanding principal until October 2007. In October 2007, the outstanding principal under the revolving line of credit will convert to a term loan with required monthly principal payments through maturity in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75%. We also are required to pay a fee on a quarterly basis equal to 0.50% of the average daily difference between $5.0 million and the amount outstanding under the revolving line of credit. As of September 30, 2006, $5.0 million was outstanding under the revolving line of credit.

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. These tax benefits are based on our $75 million planned additional investment in our Lansing facilities. In addition, we must maintain a specified number of employees in Lansing to continue to qualify for these tax benefits.

Funding requirements

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funds, will be sufficient to enable us to fund our anticipated operating expenses and capital expenditure and debt service requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong. We expect to continue to fund a significant portion of our development and commercialization costs for our product candidates with internally generated funds from sales of BioThrax. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates. Our business plan also contemplates that we will raise $10 million to $20 million of additional external debt financing to fund our facility expansion in Lansing and to provide additional financial flexibility. In addition to purchase obligations and orders under our contracts with the DoD and HHS for BioThrax sales, our only committed external sources of funds are remaining borrowing availability under our revolving lines of credit with HSBC Realty Credit Corporation and Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur, funding from NIAID for animal efficacy studies of our anthrax immune globulin candidate and funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate in Vietnam. 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, constructing our new manufacturing facility in Lansing, Michigan and 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, such as our collaboration with Sanofi Pasteur.

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.

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. 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 any significant impact on the realized value of our investments, but may increase the interest expense associated with our debt.

Effects of inflation

Our most liquid assets are cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Recent accounting pronouncements

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Prior to adoption, we will evaluate the impact of adopting SFAS No. 157 on our financial statements.

In June 2006, the FASB issued 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 clarifies the accounting for uncertainty in income taxes. 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. FIN 48 requires that we recognize in the 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. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

In March 2006, the FASB issued Statement No. 156, *Accounting for Servicing of Financial Assets — an amendment of FASB Statement No. 140*, or SFAS No. 156. SFAS No. 156 requires an entity to recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset by entering into a servicing contract based on certain conditions. The provisions of SFAS No. 156 are effective for fiscal years beginning after September 15, 2006. The adoption of SFAS No. 156 will not have a material impact on our consolidated financial statements.

In February 2006, the FASB issued Statement No. 155, *Accounting for Certain Hybrid Financial Instruments — an amendment of FASB Statements No. 133 and 140*, or SFAS No. 155. SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement No. 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives and amends Statement No. 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. The provisions of SFAS No. 155 are effective for fiscal years beginning after September 15, 2006. The adoption of SFAS No. 155 will not have a material impact on our consolidated financial statements.

Business

Overview

We are a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. Immunobiotics are pharmaceutical products, such as vaccines and immune globulins that induce or assist the body's immune system to prevent or treat disease. We operate in two business segments: biodefense and commercial. In our biodefense business, we develop and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism. In our commercial business, we develop immunobiotics for use against infectious diseases with significant unmet or underserved medical needs. Our marketed product, BioThrax, is the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. In addition to BioThrax, our biodefense product portfolio includes three biodefense product candidates in preclinical development and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical development. Our commercial product portfolio includes a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate, both of which are in Phase II clinical development, one vaccine candidate in Phase I clinical development and two vaccine candidates in preclinical development.

We manufacture and market BioThrax, also referred to as anthrax vaccine adsorbed, the only FDA approved anthrax vaccine. BioThrax was originally approved in the United States in 1970. There have been more than 20 published studies of the use of BioThrax in humans. In December 2005, based on a review of the human efficacy data used to support the approval of BioThrax and other studies of BioThrax, the FDA reaffirmed that BioThrax is safe and effective for the prevention of anthrax infection by all routes of exposure, including inhalation. Our total revenues from BioThrax sales were $55.5 million in 2003, $81.0 million in 2004, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006. The U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, have been the principal customers for BioThrax. Under two contracts with the DoD, we have supplied over nine million doses of BioThrax through September 2006 for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.7 million doses of BioThrax. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base contract year plus four option years. Under a contract that we entered into with HHS in May 2005, we supplied five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of $123 million. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of $120 million. We delivered approximately one million doses of BioThrax under this contract modification through September 2006.

The September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks significantly affected political and budgetary attitudes toward the threat of bioterrorism. Following these attacks, the U.S. government enacted measures to provide incentives for private industry to develop and manufacture biodefense products. In particular, in 2004, the Project BioShield Act became law, providing $5.6 billion in appropriations over ten years and authorizing the procurement of countermeasures for biological, chemical, radiological and nuclear attacks. Project BioShield provides for the procurement of countermeasures for anthrax and botulism, which are two of the biological agents that the Centers for Disease Control and Prevention, or CDC, has identified as the greatest possible threat to public health. The U.S. government procures most biodefense countermeasures through HHS, the CDC and the DoD and provides biodefense research and development funding through the National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or NIH, and the DoD.

In addition to BioThrax, we have three biodefense immunobiotic product candidates in preclinical development and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical development. Our biodefense product candidates in preclinical development are:

- *Anthrax immune globulin* — for post-exposure treatment of anthrax infection, which we are developing in part with funding from NIAID;
- *Botulinum immune globulin* — for post-exposure treatment of illness caused by botulinum toxin, which we are developing based on a new botulinum toxoid vaccine that we are developing in collaboration with the U.K. Health Protection Agency, or HPA; and
- *Recombinant bivalent botulinum vaccine* — a prophylaxis for illness caused by botulinum toxin, which we also are developing in collaboration with HPA.

We are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine, featuring attributes such as self administration and a longer shelf life. In September 2006, we submitted three separate proposals in response to a request for proposals issued by NIAID in June 2006 for the advanced development and testing of next generation anthrax vaccine candidates. One of our proposals relates to a vaccine candidate that has completed a Phase I clinical trial.

In our commercial business, we are developing a range of immunobiotic product candidates for use against infectious diseases with significant unmet or underserved medical needs. Our commercial product candidates in clinical development are:

- *Typhoid vaccine* — a single dose, drinkable vaccine, for which we have completed a Phase I clinical program, including trials in the United States, the United Kingdom and Vietnam, and expect to initiate a Phase II clinical trial in Vietnam in the fourth quarter of 2006;
- *Hepatitis B therapeutic vaccine* — a multiple dose, drinkable vaccine for treatment of chronic carriers of hepatitis B infection, for which we have completed a Phase I clinical trial in the United Kingdom and expect to initiate a Phase II clinical trial in the United Kingdom in the fourth quarter of 2006; and
- *Group B streptococcus vaccine* — a multiple dose, injectable vaccine for administration to women of childbearing age for protection of the fetus and newborn babies, for which we have completed a Phase I clinical trial in the United Kingdom.

In addition, we are developing a chlamydia vaccine and a meningitis B vaccine, each of which is currently in preclinical development.

The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur, the vaccines business of Sanofi-Aventis, under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine candidate.

Our strategy

Our goal is to become a worldwide leader in developing, manufacturing and commercializing immunobiotics that target diseases with significant unmet or underserved medical needs. Key elements of our strategy to achieve this goal are:

Maximize the commercial potential of BioThrax. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax. The potential label expansions and improvements for

BioThrax include an extension of shelf life, reductions in the number of required doses, addition of another method of administration and use as a post-exposure prophylaxis for anthrax infection in combination with antibiotic therapy.

Continue to develop a balanced portfolio of immunobiotic products. We seek to maintain a balanced product portfolio that includes both biodefense and commercial immunobiotic product candidates and both vaccines and therapeutics to diversify product development and commercialization risk. We use multiple technologies in our development programs, which we believe significantly reduces our risk in these activities. We expect that biodefense product candidates may generate revenues from product sales sooner than commercial product candidates because of Project BioShield, which allows the U.S. government to purchase biodefense products for the strategic national stockpile before they are approved by the FDA.

Focus on core capabilities in product development and manufacturing. We focus our efforts on immunobiotic product development and manufacturing, which we believe are our core capabilities. This approach enables us to avoid the expense and time entailed in early stage research activities and, we believe, reduces product development and commercialization risk. We seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. We believe that we have secured, and will be able to continue to secure, rights to a diverse product pipeline that targets diseases with significant unmet or underserved medical needs. We also believe that this approach may enable us to accelerate product development timelines through our preclinical and clinical development and regulatory expertise and manufacturing capabilities.

Build a large scale manufacturing infrastructure. To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We also own two buildings in Frederick, Maryland that we plan to build out as future manufacturing facilities. We are constructing our new facility in Lansing as a large scale commercial manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new Lansing facility in 2008. We are constructing this facility to accommodate production of up to 40 million doses of BioThrax per year on a single production line, which we could expand for production of up to 80 million doses per year through the addition of a second production line. In comparison, our current facility has a maximum production capacity of approximately nine million doses of BioThrax per year.

Selectively establish collaborations. 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 to access particular markets. We recently entered into a collaboration with Sanofi Pasteur for our meningitis B vaccine candidate as we believe that the value of this vaccine candidate may be maximized if it is sold in combination with other vaccines offered by Sanofi Pasteur. We are currently collaborating with HPA for the development of both a new botulinum toxoid vaccine, which we plan to use to develop our botulinum immune globulin candidate, and our recombinant bivalent botulinum vaccine candidate, which has given us access to HPA's technology and manufacturing capabilities.

Seek governmental and other third party grants and support. The biodefense immunobiotic product candidates that we are developing are of significant interest to the U.S. and potentially other governments. The CDC currently is independently conducting a clinical trial to evaluate whether as few as three doses of BioThrax, administered over six months, will confer adequate immune response over as long as 42 months. In addition, NIAID has completed an independent animal efficacy study of BioThrax in

combination with antibiotics as a post-exposure prophylaxis for anthrax infection. NIAID has awarded us grant funding for animal efficacy studies of our anthrax immune globulin candidate. We believe that some of our commercial immunobiotic product candidates that may benefit people in the developing world are of interest to charitable and philanthropic organizations. The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. We plan to encourage government entities and non-government and philanthropic organizations to continue to conduct studies of, and pursue other development efforts and provide development funding for, BioThrax and our product candidates.

Market opportunity

We focus on the biodefense and commercial markets for immunobiotics.

The biodefense market

The biodefense market for immunobiotics has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The letter attacks involved the delivery of mail contaminated with anthrax spores to government officials and members of the media in the United States. As a result of the letter attacks, 22 people became infected with anthrax, including 11 with inhalational anthrax, and five people died.

The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from procurement of countermeasures by HHS, the CDC and the DoD and development funding from NIAID and the DoD. The U.S. government is now the largest source of funding for academic institutions and biotechnology companies conducting biodefense basic research or developing novel vaccines and other immunobiotic therapeutics.

Department of Health and Human Services. In 2004, the Project BioShield Act became law. This statute provides $5.6 billion in appropriations over ten years and authorizes the procurement of countermeasures for biological, chemical, radiological and nuclear attacks. Pursuant to Project BioShield, HHS has begun to procure vaccines and other products for a strategic national stockpile. The strategic national stockpile is a national repository of medical assets and countermeasures designed to provide state and local public health agencies with medical supplies needed to treat those affected by terrorist attacks, natural disasters, industrial accidents and other public health emergencies, such as a flu epidemic. Materials from the strategic national stockpile were deployed following both the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. We expect that HHS will procure supplies of vaccines for the strategic national stockpile on an ongoing basis and replenish the stockpile as the existing inventories reach the end of their shelf lives.

Pursuant to Project BioShield, the CDC has categorized bioterrorism agents into three categories from A to C based on the perceived risk of the agent to national security. The highest risk category is category A. The six agents that the CDC has classified as category A are anthrax, botulism, plague, smallpox, tularemia and viral hemorrhagic fevers. The Secretary of HHS has directed most of the BioShield procurement efforts and funding to date to category A agents. Under Project BioShield, the Secretary of HHS can contract to purchase countermeasures for the strategic national stockpile prior to FDA approval of the countermeasure in specified circumstances. To be eligible for purchase under these provisions, the Secretary of HHS must

determine that there is sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years, even though the product has not completed clinical trials and has not yet been approved by the FDA. 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.

Members of Congress have proposed and may in the future propose legislation that expands the funding and coverage of Project BioShield. We believe that continued assessments of the threat that bioterrorism poses to the public health are likely to advance these legislative initiatives.

Centers for Disease Control. The U.S. Congress provides annual funding to the CDC for the procurement of medical assets and countermeasures for the strategic national stockpile. This appropriation funding supplements amounts available under Project BioShield for procurement of countermeasures. Congress provided funding to CDC of $525 million in fiscal year 2006 and $467 million in fiscal year 2005 for this purpose.

Department of Defense. The DoD procures biodefense immunobiotics that it administers primarily through the Military Vaccine Agency, or MilVax. MilVax administers various vaccination programs for military personnel, including vaccines for common infectious diseases, such as influenza, and vaccines to protect against specific bioterrorism threats, such as anthrax and smallpox. The DoD has included anthrax at the top of its biological threat list. The level of spending by the DoD for MilVax is a function of the size of the U.S. military and the approach of the DoD with respect to vaccine stockpile and use, particularly whether, and to what extent, the DoD mandates that members of the military participate in vaccination programs. Absent a Presidential waiver or the informed consent of the recipient, the DoD is required to use FDA approved products, if available, and not investigational products under development, in MilVax vaccination programs. The DoD provides development funding for biodefense vaccines through its Joint Vaccine Acquisition Program.

National Institute of Allergy and Infectious Diseases. Beginning with fiscal year 2003, the U.S. Congress added approximately $1.5 billion per year to the biodefense research funding budget for NIAID. In fiscal year 2004, NIAID awarded more than 700 research project grants for biodefense research. In fiscal year 2004, biodefense funding by NIAID totaled $1.6 billion, which was more than one-third of NIAID's total third party research funding budget.

There are also a number of potential additional customers for biodefense immunobiotics. These include:

- the U.S. Postal Service;
- foreign governments;
- state and local governments, which we expect will be interested in these products to protect first responders, such as police, fire and emergency medical personnel;
- multinational companies and non-governmental organizations; and
- hospitals.

Although there have been minimal sales to these customers to date, we believe that they may comprise an important component of the overall biodefense market in the future.

The commercial market

Vaccines have long been recognized as a safe and cost-effective method for preventing infection caused by various bacteria and viruses. Because of an increased emphasis on preventative medicine in industrialized countries, vaccines are now well recognized as an important part of public health management strategies. According to Frost & Sullivan, a market research organization, from 2002 to 2005, annual worldwide vaccine sales increased from $6.7 billion to $9.9 billion, a compound annual growth rate of approximately 14%. Frost & Sullivan estimates that the worldwide sales of vaccines will grow at a compound annual rate of approximately 10.5% from 2005 through 2012. As of 2005, Frost & Sullivan estimates that approximately two-thirds of global vaccine sales were attributable to pediatric vaccines. In addition, vaccines sold in developed markets represented approximately 80% of worldwide vaccine revenues. New vaccine technologies and a greater understanding of how disease-causing organisms, or pathogens, cause disease are leading to the introduction of new vaccine products. Moreover, while existing marketed vaccines generally are designed to prevent infections, new vaccine technologies have also led to a focus on the development of vaccines for therapeutic purposes. Potential therapeutic vaccines extend beyond infectious diseases to cancer, autoimmune diseases and allergies.

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. With respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or nongovernmental, charitable or philanthropic organizations fund the cost of vaccines. According to Frost & Sullivan, public purchases of vaccines, including for immunization programs and government stockpiles, account for approximately 90% of the total volume of worldwide vaccine sales. Although accounting for only 10% of the total volume of worldwide vaccine sales, private market purchases of vaccines accounted for approximately 60% of total worldwide vaccine sales revenues in 2005.

Scientific background

The immune system

The immune system provides protection against pathogens, such as bacteria and viruses, through immune responses that are generated by a type of white blood cells known as lymphocytes. Immune responses that depend on lymphocyte recognition of components of pathogens, called antigens, have two important characteristics. First, these immune responses are specific, which means that lymphocytes recognize particular antigens on pathogens. Second, these immune responses induce memory so that when the antigen is encountered again, the immune response is enhanced. Generally, there are two types of specific immunity: humoral immunity and cell mediated immunity. Humoral immunity is provided by proteins, known as antibodies or immune globulins, that are produced by lymphocytes. Antibodies are effective in dealing with pathogens before the pathogens enter cells. Cell mediated immunity is provided by lymphocytes that generally deal with threats from cells that are already infected with pathogens by directly killing infected cells or interacting with other immune cells to initiate the production of antibodies or activate cells that kill and eliminate infected cells.

Vaccines

A vaccine is normally given to a healthy person as a prophylaxis in order to generate immune responses that will protect against future infection and disease caused by pathogens. Following vaccination, the immune system’s memory of antigens presented by a vaccine allows for an immune response to be generated to a pathogen to provide protection against disease. Therapeutic vaccines also are being

developed to strengthen or modify the immune response in patients already infected with bacterial and viral pathogens to clear the pathogens from their bodies. Without treatment, these patients can be subject to recurring bouts of the disease.

There are three basic types of vaccines: live attenuated vaccines, inactivated whole cell vaccines and subunit vaccines. Live attenuated vaccines are made from weakened, or attenuated, viruses or bacteria that are designed to mimic some of the early stages of infection without causing disease. Inactivated whole cell vaccines are made by growing the infectious organism in culture media or mammalian cells and then inactivating the organisms. Subunit vaccines are derived from individual antigens that can be purified and used as vaccines. Culture filtrate vaccines are a type of subunit vaccine. These vaccines are based on components that are secreted by pathogens grown in a culture media and then purified by filtration of the culture media.

Live attenuated vaccines can produce stronger, longer lasting immunity than inactivated whole cell vaccines and often are effective after only a single dose. However, live attenuated vaccines are subject to safety concerns related to the risk that they may revert to the virulent form or cause disease in patients with weakened immune systems. Inactivated whole cell vaccines have been successfully developed for some pathogens, but large quantities of the infectious organism have to be grown to make the vaccine. This poses a safety risk for people involved in the manufacturing process and requires high levels of containment. Subunit vaccines generally produce fewer side effects than vaccines that use the whole organism, but often are not as immunogenic as inactivated whole cell or live attenuated vaccines. Adjuvants, which augment or enhance the immune responses to vaccine antigens, are often used in combination with weaker antigens, such as subunit vaccines.

Scientists have applied recombinant technology, which allows for the manipulation of the genetic material of pathogens, in the development of new live attenuated and subunit vaccines. For live attenuated vaccines, genes involved in virulence can be completely deleted from a pathogen so that the organism can no longer cause disease or revert to the virulent form. For subunit vaccines, the gene directing the production of the antigen can be isolated and moved into a harmless organism where it can be expressed at high levels and purified. In addition, scientists have used recombinant technology to develop vector systems to deliver multiple vaccine antigens from different disease-causing organisms in a single live attenuated vaccine by inserting genes coding for these antigens into the genetic material of the vector. Currently, the only recombinant vaccines approved by the FDA are those for the prevention of hepatitis B infection, including both stand-alone vaccines and combination vaccines that include the recombinant hepatitis B component. The only recombinant vaccines currently licensed by the European Medicines Agency for marketing in the European Union member states are several vaccines that contain recombinant hepatitis B and one vaccine that includes a recombinant cholera toxin B subunit. We believe that the primary application for recombinant technology in the vaccine field will be for the development of vaccines in situations in which other vaccine technologies have not been successful or in which recombinant technology permits vaccine production with a lower level of safety containment.

Immune globulins

Immune globulins are normally made by collecting plasma from individuals who have contracted or been vaccinated for a particular disease and whose plasma contains protective antibodies, known as IgG, generated by a humoral immune response to pathogen exposure or vaccination. These antibodies are isolated by fractionation of the plasma, purified and then administered intravenously to patients, providing an immediate protective effect. Because it normally takes several weeks to generate antibodies after vaccination, immune globulins are used in situations in which it is not possible to wait for active immunization to generate the protective immune response.

Products

The following table summarizes key information about our marketed product, BioThrax, and our biodefense and commercial immunobiotic product candidates. We utilize a wide array of technologies to develop and manufacture our marketed product and product candidates, including conventional and recombinant technologies. For each development program, we select and apply the technology that we believe is best suited to address the particular disease based on our evaluation of factors such as safety, efficacy, manufacturing requirements, regulatory pathway and cost. We currently hold all commercial rights to BioThrax and all of our immunobiotic product candidates, other than our recombinant bivalent botulinum vaccine, for which HPA has the non-exclusive right to make, use and sell to meet public health requirements in the United Kingdom, and our meningitis B vaccine candidate that we are developing in collaboration with Sanofi Pasteur. For more information about our agreements with HPA, see “Intellectual property and licenses — License agreements — HPA agreements.” For more information about our collaboration with Sanofi Pasteur, see “— Sanofi Pasteur collaboration.”

Immunobiotic	Therapeutic/ prophylactic	Stage of development	Status	Collaboration/ external relationship
Biodefense				
Anthrax				
BioThrax (anthrax vaccine adsorbed)	Prophylactic	FDA approved	Commercially marketed six dose regimen	
	Prophylactic	Post-approval label expansion	BLA supplement submitted for five dose regimen and intramuscular injection; CDC clinical trial ongoing for three dose regimen with a booster dose once every three years thereafter	CDC — independent clinical trial
	Prophylactic	Post-approval label expansion	Single dose syringe development program initiated	
BioThrax (anthrax vaccine adsorbed)*	Post-exposure prophylactic	Post-approval label expansion	Phase I clinical trial ongoing; two proof-of-concept animal studies completed for three dose regimen	
Next generation anthrax vaccine*	Pre-exposure and post-exposure prophylactic	Phase I and preclinical	Proposals submitted for three distinct product candidates in response to NIAID request for proposals	
Anthrax immune globulin*	Therapeutic	Preclinical	Plasma donor stimulation program ongoing; animal efficacy studies planned; plan to file IND in late 2006 or early 2007	NIAID — funding for animal efficacy studies in rabbits
Botulinum				
Recombinant bivalent botulinum vaccine*	Prophylactic	Preclinical	Proof-of-concept animal study completed	HPA — collaboration
Botulinum immune globulin*	Therapeutic	Preclinical	Proof-of-concept animal studies planned	HPA — collaboration for development of a new botulinum toxoid vaccine
Commercial				
Typhoid vaccine	Prophylactic	Phase II	Phase I clinical trial in Vietnam completed for a drinkable single dose regimen; plan to initiate Phase II clinical trial in Vietnam in the fourth quarter of 2006	Wellcome Trust — funding for Phase I and Phase II clinical trials in Vietnam
Hepatitis B therapeutic vaccine	Therapeutic	Phase II	Phase I clinical trial in the United Kingdom completed for a drinkable multiple dose regimen; clinical trial application approved in the United Kingdom for a Phase II clinical trial	
Group B streptococcus vaccine	Prophylactic	Phase I	One Phase I clinical trial in the United Kingdom completed; two additional Phase I clinical trials planned	
Chlamydia vaccine	Prophylactic	Preclinical	Proof-of-concept animal study completed	
Meningitis B vaccine	Prophylactic	Preclinical	Antigen identification ongoing	Sanofi Pasteur — collaboration

* We currently intend to rely on the FDA animal rule in seeking marketing approval for these product candidates. Under the animal rule, if human efficacy trials are not ethical or feasible, the FDA can approve drugs or biologics used to treat or prevent serious or life threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological or nuclear substances based on human clinical data demonstrating safety and immunogenicity and evidence of efficacy from appropriate non-clinical animal studies and any additional supporting data. For more information about the FDA animal rule, see "— Government regulation — Clinical trials."

No assessment of the safety or efficacy of our vaccine candidates can be considered definitive until all clinical trials needed to support a submission for marketing approval are completed. The results of our completed preclinical tests and Phase I clinical trials do not ensure that our planned later stage clinical trials for our vaccine candidates will be successful. A failure of one or more of our clinical trials can occur at any stage of testing.

Biodefense business

In our biodefense business, we are developing and commercializing immunobiotics for use against biological agents that are potential weapons of bioterrorism. Our marketed product, BioThrax, is the only vaccine approved by the FDA for the prevention of anthrax infection. In addition to BioThrax, our biodefense product portfolio includes three product candidates in preclinical development and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical development. We are developing all of our biodefense product candidates to address category A biological agents, which are the class of biological agents that the CDC has identified as the greatest possible threat to public health.

BioThrax (anthrax vaccine adsorbed)

Anthrax overview. Anthrax is a potentially fatal disease caused by the spore forming bacterium *Bacillus anthracis*. Anthrax bacteria are naturally occurring, and spores are found in soil throughout the world. Anthrax spores can withstand extreme heat, cold and drought for long periods without nutrients or air. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, referred to as cutaneous anthrax, or by ingestion or inhalation of the spores. Once inside the body, anthrax spores germinate into bacteria that then multiply. Anthrax bacteria secrete three toxin proteins, protective antigen, lethal factor and edema factor, which are individually non-toxic but can become highly toxic if allowed to interact on the surface of human or animal cells.

Cutaneous anthrax, although rare in the United States, is the most common type of naturally acquired anthrax. Cutaneous anthrax is typically acquired through contact with contaminated animals and animal products. The fatality rate for untreated cases of cutaneous anthrax is estimated to be approximately 20%.

Inhalational anthrax is the most lethal form of anthrax. We believe that aerosolized anthrax spores are the most likely method to be used in a potential anthrax bioterrorism attack. Inhalational anthrax has been reported to occur from one to 43 days after exposure to aerosolized spores. Initial symptoms of inhalational anthrax are non-specific and may include sore throat, mild fever, cough, achiness or weakness, lasting up to a few days. After a brief period of improvement, the release of anthrax toxins may cause an abrupt deterioration of the infected person, with the sudden onset of symptoms, including fever, respiratory failure as the lungs fill with fluids and shock. Hemorrhagic meningitis is common. Death often occurs within 24 hours of the onset of advanced respiratory complications. The fatality rate for inhalational anthrax is estimated to be between 45% and 90%, depending on whether aggressive, early treatment is provided.

To date, the principal customer for anthrax vaccines has been the U.S. government. Because of concerns regarding the use of anthrax spores as a biological weapon during the first Persian Gulf War, the DoD began administering BioThrax to military personnel in 1990. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we supplied over nine million doses of BioThrax through September 2006 to the DoD for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.7 million doses of BioThrax. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We expect to deliver to the DoD approximately 480,000 of these doses by December 2006, with the balance to be delivered by September 2007. In October 2006, the DoD announced that it is resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency-essential and

comparable civilian personnel. For personnel not deployed in high threat areas or no longer assigned designated special mission roles, vaccination will be on a voluntary basis.

In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of $123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of $120 million. We delivered approximately one million doses of BioThrax under this contract modification through September 2006. We delivered approximately 1.5 million doses of BioThrax to HHS in November 2006. We expect to deliver to HHS between 1.25 million and 1.75 million doses of BioThrax in December 2006, with the balance to be delivered in the first half of 2007 prior to expiration of the contract.

Following the October 2001 anthrax letter attacks, the CDC provided BioThrax under an investigational new drug application, or IND, protocol for administration on a voluntary basis to Capitol Hill employees and others who may have been exposed to anthrax. In addition, we have supplied small amounts of BioThrax directly to several foreign governments. It is our understanding that the DoD has sold BioThrax to the governments of a number of other foreign countries for the protection of military personnel. We believe that state and local governments and several foreign governments are significant potential customers for BioThrax. Our total revenues from BioThrax sales were $55.5 million in 2003, $81.0 million in 2004, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006.

Current treatments. The only FDA approved product for pre-exposure prophylaxis of anthrax infection is BioThrax. The only FDA approved products for post-exposure prophylaxis of anthrax infection are antibiotics, which are typically administered over a 60-day period. Antibiotics prevent anthrax disease by killing the anthrax bacteria before the bacteria can release anthrax toxins into the body. However, antibiotics are not effective against anthrax toxins after the toxins have been released into the body and do not kill anthrax spores that may remain in the body for extended periods after exposure. In addition, antibiotics may not be effective against antibiotic resistant strains of anthrax. Anthrax spores that remain in the body can potentially lead to infection following the end of antibiotic treatment. Infection also may occur if patients do not adhere to the prolonged course of antibiotic treatment or are not able to remain on antibiotics for extended periods of time. Because of these limitations, the CDC recommends administering BioThrax in combination with antibiotics under an IND with informed consent of the patient as a post-exposure prophylaxis for anthrax infection as an emergency public health intervention. While BioThrax is not currently approved by the FDA for post-exposure prophylaxis, as discussed below, we are actively pursuing a label expansion for this indication.

Description and benefits of BioThrax. BioThrax is the only FDA approved vaccine for the prevention of anthrax infection. It is approved by the FDA as a pre-exposure prophylaxis for use in adults who are at high risk of exposure to anthrax spores. BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of *Bacillus anthracis,* and contains no dead or live bacteria. BioThrax is administered by subcutaneous injection in three initial doses followed by three additional doses, with an annual booster dose recommended thereafter. The three initial doses are given two weeks apart followed by three additional doses given at six, 12 and 18 months following the first vaccination. BioThrax includes aluminum hydroxide, or alum, as an adjuvant.

The NIH originally approved the manufacture and sale of BioThrax by the Michigan Department of Public Health in 1970. In 1972, responsibility for approving biological products transferred from the NIH to the FDA. Following that transfer of responsibility, the FDA established procedures for reviewing the safety and efficacy of biological products, including BioThrax, that had been previously approved by the NIH. The FDA set out to categorize the products according to evidence of safety and effectiveness and determine if the products should remain approved and on the market. In December 1985, the FDA issued a proposed rule containing a

finding that BioThrax was safe and effective. However, the FDA did not finalize that proposed rule pursuant to applicable notice and comment requirements. In December 2005, based on a review of data from the study used to support the original marketing approval of BioThrax and other studies of the use of BioThrax in humans, including studies by the CDC and the DoD, the FDA issued a final order regarding BioThrax. In the final order, the FDA affirmed the approval of BioThrax and found, among other things, that:

- BioThrax is safe and effective;
- the study used to support the original marketing approval of BioThrax constituted a well controlled human efficacy study in which BioThrax was 92.5% effective in preventing inhalational and cutaneous anthrax;
- as reported by the Institute of Medicine, studies in humans and animal models support the conclusion that BioThrax is effective against anthrax strains that are dependent upon the anthrax toxin as a mechanism of virulence by all routes of exposure, including inhalation;
- periodic evaluations of reports in the vaccine adverse event reporting system database maintained by the CDC and the FDA confirm that BioThrax continues to be safe for its intended use; and
- as reported by an independent advisory panel to the FDA, CDC data suggest that BioThrax is fairly well tolerated with systemic reactions and severe local reactions being relatively rare.

In a study published in 2002, the Institute of Medicine, which is a component of The National Academy of Sciences and provides independent, unbiased, evidence-based advice on matters pertaining to public health, found that BioThrax is an effective vaccine for protection against anthrax, including inhalational anthrax, caused by any known or plausible engineered strains and that no convincing evidence exists that people face an increased risk of experiencing short-term life-threatening or permanently disabling adverse effects from BioThrax or developing any adverse effects from long-term use of BioThrax.

As with any pharmaceutical product, the use of vaccines carries a risk of adverse health effects that must be weighed against the expected health benefit of the product. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and 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 such adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. These 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.

BioThrax development activities. In its 2002 study, the Institute of Medicine recommended characteristics for the development of a new anthrax vaccine. Based on these recommendations, we are actively pursuing label expansions and improvements for BioThrax, including the following:

- *Extend shelf life.* In 2005, the FDA approved an extension of BioThrax shelf life from two to three years, which will allow BioThrax to be stockpiled for a longer period of time. We are conducting ongoing stability testing of BioThrax, and, depending on the outcome of these tests, we may apply for a further extension of BioThrax shelf life in late 2006.
- *Reduce doses for pre-exposure prophylaxis.* We have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. Our application is based on an interim analysis of data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, will confer adequate immune response over as long as 42 months. In April 2006, the FDA issued a complete response letter to our application, requesting clarification and requiring additional analysis of the data that we submitted. We are in the process of responding to this letter and

amending our application. If the final data from the CDC trial, which we expect at the end of 2007, are favorable, we plan to apply to the FDA in 2008 for approval of a three dose regimen of BioThrax for pre-exposure prophylaxis, with a booster dose once every three years thereafter.

- *Add second route of administration.* We have applied to the FDA to add a second route of administration of BioThrax to include intramuscular injection in addition to subcutaneous injection. We believe that intramuscular injection will result in fewer local reactions than subcutaneous injection.
- *Single dose syringe.* We believe that products that are administered in a single dose syringe are of significant interest to HHS for inclusion in the strategic national stockpile. As a result, we have initiated a development program to make BioThrax available in single dose syringes.

Post-exposure prophylaxis. We also plan to seek approval of BioThrax in combination with antibiotic therapy as a post-exposure prophylaxis for anthrax infection. We expect that we will use three doses of BioThrax given two weeks apart for this indication. In 2005, NIAID completed a proof-of-concept study of BioThrax in which rabbits infected with anthrax were treated with the antibiotic levofloxacin or with levofloxacin in combination with two doses of BioThrax in one of three dose amounts. One of the dose amounts tested was a dilution of BioThrax designed to elicit an immune response that is proportional to the effect of an undiluted dose in humans. This is referred to as a humanized dose. Only 44% of the rabbits treated with antibiotics alone survived, while 100% of the rabbits treated with either humanized doses or undiluted human doses of BioThrax in combination with levofloxacin survived. In the trial, there were statistically significant increases in survival rates for rabbits treated with all dose amounts of BioThrax in combination with the antibiotic compared to rabbits treated with levofloxacin alone. These results were consistent with an earlier animal test conducted by the U.S. Army Medical Research Institute of Infectious Diseases, or USAMRIID, involving undiluted human doses of BioThrax in combination with an antibiotic administered to nonhuman primates infected with anthrax.

To advance the development of BioThrax for this additional indication, we plan to conduct additional animal efficacy studies in accordance with the FDA animal rule. We plan to evaluate the effect of a humanized dose of BioThrax in combination with an antibiotic compared to the antibiotic alone in rabbits and nonhuman primates exposed by inhalation to anthrax spores. We plan to initiate the rabbit efficacy study in late 2006 and the nonhuman primate efficacy study in late 2007. The timing of our nonhuman primate efficacy study depends upon the successful development of a nonhuman primate model by NIAID. In September 2006, we initiated a Phase I clinical trial of BioThrax for this indication using three doses of BioThrax given two weeks apart. The purpose of this trial is to obtain additional immunogenicity data regarding BioThrax using the planned three dose regimen. Depending on the results of this ongoing clinical trial, the FDA could require us to conduct a second human immunogenicity clinical trial. Under the FDA animal rule, we believe that, if the results are favorable, the rabbit and nonhuman primate animal efficacy studies together with the human immungenicity clinical trial data would be sufficient to support the filing with the FDA of a biologics license application, or BLA, supplement for marketing approval of BioThrax for this indication.

Next generation anthrax vaccine

We are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine, featuring attributes such as self administration and a longer shelf life. In September 2006, we submitted three separate proposals in response to a request for proposals issued by NIAID in June 2006 for the advanced development and testing of next generation anthrax vaccine candidates. One of our proposals relates to BioThrax combined with VaxImmune. VaxImmune, a product of Coley Pharmaceuticals Group, is an adjuvant intended to enhance immune response. We are designing our product candidate to be administered by needle-free intramuscular injection.
The DoD's Defense Advanced Research Projects Agency, or DARPA, previously funded a double-blind Phase I clinical trial of this product candidate pursuant to a collaboration among DARPA, Coley Pharmaceuticals and us. This trial, which was completed in 2005 and

involved 69 healthy volunteers, was designed to evaluate the safety and immunogenicity of this product candidate compared to BioThrax alone and VaxImmune alone. In this trial, the product candidate was administered in three doses by intramuscular injection. The immunogenicity results from this trial were statistically significant.

The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. We determined the statistical significance of the trial results based on a widely used, conventional statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less represents statistical significance. Immune responses observed in a group of vaccine trial participants can be compared with those observed in other groups of trial participants or with an assumed response rate. Immunogenicity alone does not establish efficacy for purposes of regulatory approval. Immunogenicity data only provide indications of efficacy and are neither required nor sufficient to enable a product candidate to proceed to Phase II clinical development. Phase I clinical trials are required to establish the safety of a product candidate, not its immunogenicity, before Phase II clinical trials may begin.

The immunogenicity parameters for this trial were the mean peak antibody concentration in trial participants who received the product candidate as compared to trial participants who received BioThrax alone and the median time to achieve mean peak immune response. In this trial, the mean peak concentration of antibodies to anthrax protective antigen in participants who received the product candidate was approximately 6.3 times higher than in participants who received BioThrax alone. This result was statistically significant, with a p-value of less than 0.001. Participants who received BioThrax alone achieved a mean peak concentration of antibodies to anthrax protective antigen approximately 42.5 days after first injection. Participants who received the product candidate achieved this same mean antibody concentration approximately 21 days earlier. This result was statistically significant, with a p-value of less than 0.001. In this trial, there was a slightly higher frequency of moderate injection site reactions and systemic adverse events in the volunteers who received the product candidate as compared to volunteers who received BioThrax alone or VaxImmune alone. One volunteer withdrew from this trial because of an adverse event. There were no serious adverse events reported that the trial investigators considered related to the product candidate, BioThrax or VaxImmune.

The second proposal that we submitted to NIAID relates to a product candidate based on immunization with a gene encoding an anthrax protective antigen followed by a dose of BioThrax using a device that facilitates self administration. The third proposal contemplates the use of recombinant protective antigen combined with a novel adjuvant delivered by a device that facilitates self administration.

The NIAID request for proposals specified properties desirable for a biodefense vaccine to be stored in the strategic national stockpile, including the following:

- shelf life of three years or longer at room temperature;
- the ability to generate protective immune response in one or two doses; and
- the ability to be safely self administered or rapidly inoculated into large numbers of people.

The NIAID request stated that anthrax vaccine candidates should maintain a superior safety profile to BioThrax, contain a protective antigen that has been shown to be efficacious against anthrax spore challenge in animal models and have progressed through a proof-of-concept efficacy study in a relevant spore challenged animal model. NIAID is not obligated to make any award, and may decide not to make any award, for development funding pursuant to this request for proposals or otherwise.

Anthrax immune globulin

We are developing an anthrax immune globulin as a single dose intravenous therapeutic for treatment of patients with manifest symptoms of anthrax disease resulting from the release of anthrax toxins into the

body. If successfully developed, we expect our anthrax immune globulin therapeutic to be prescribed for administration in these circumstances either as a monotherapy or in conjunction with an antibiotic.

There are no approved products for the effective treatment of anthrax disease after anthrax toxins have been released into the body. Cangene, in collaboration with the CDC, is currently developing an anthrax immune globulin for use in these circumstances based on plasma collected from military personnel who have been vaccinated with BioThrax. In August 2004, HHS issued a request for proposals in which HHS indicated that it was seeking between 10,000 and 200,000 therapeutic courses of treatment of a product to treat inhalational anthrax disease. The products sought by HHS included monoclonal antibodies, polyclonal antibodies, including human immune globulin, and other protein therapeutic products. Pursuant to this request for proposals, HHS awarded a contract to Cangene in 2005 to supply anthrax immune globulin for preliminary testing for evaluation of efficacy as a post-exposure therapeutic for anthrax infection. In July 2006, HHS exercised an option under this contract for Cangene to supply 10,000 doses of anthrax immune globulin for the strategic national stockpile. This contract modification has a total value of approximately $143 million. Cangene has announced that it expects to deliver these doses of anthrax immune globulin to the strategic national stockpile beginning in late 2007 through the end of 2009. HHS also awarded a contract to Human Genome Sciences in 2005 to supply a monoclonal antibody to *Bacillus anthracis* for evaluation of efficacy as a post-exposure therapeutic for anthrax infection. In June 2006, HHS exercised an option under this contract for Human Genome Sciences to supply 20,000 treatment courses of this monoclonal antibody, referred to as ABthrax, for the strategic national stockpile. This contract modification has a total value of approximately $165 million. Human Genome Sciences has announced that it expects to deliver ABthrax to the strategic national stockpile in 2008. The FDA has granted ABthrax an orphan drug designation for the treatment of inhalational anthrax.

Our plan is to develop our anthrax immune globulin therapeutic using antibodies that are produced by healthy donors immunized with BioThrax. We recently completed a plasma donor stimulation program in which we collected plasma from our employees and military personnel who had been vaccinated with BioThrax. We are currently designing a civilian donor stimulation program. We have collected a sufficient amount of plasma to initiate manufacturing of the anthrax immune globulin under current good manufacturing practice, or cGMP, requirements using a validated and approved process. The manufacturing process entails fractionating the plasma and purifying the immune globulin. We have engaged Talecris Biotherapeutics, Inc. to perform the plasma fractionation and purification processes and contract filling for our anthrax immune globulin candidate at its FDA approved facilities. We expect that the anthrax immune globulin that we are manufacturing will be acceptable under the FDA's rules for use in both preclinical studies and human clinical trials. We have manufactured and filled the first full-scale lot of this product candidate under cGMP requirements at Talecris.

We plan to rely on the FDA animal rule in connection with the development of our anthrax immune globulin candidate. Specifically, we plan to conduct efficacy studies of this product candidate in infected rabbits and then infected nonhuman primates. Concurrently, we plan to file an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of our anthrax immune globulin candidate in healthy volunteers. We currently anticipate filing such an IND in late 2006 or early 2007. We believe that favorable data from these animal efficacy studies and the safety and pharmacokinetic clinical trial would be sufficient to support an application to the FDA for marketing approval. NIAID has provided us grant funding of up to $3.7 million for the studies designed to assess the tolerability, pharmacokinetics and efficacy of this product candidate in infected rabbits and the development and validation of product assays. We believe that our anthrax immune globulin would be eligible to be procured by HHS under Project BioShield for inclusion in the strategic national stockpile after we file an IND and prior to receiving marketing approval.

Recombinant bivalent botulinum vaccine

Disease overview. Botulism is a frequently fatal disease caused by botulinum toxins produced by the bacterium *Clostridium botulinum*. *Clostridium botulinum* is widely distributed in soil and aquatic environments throughout the world. Botulinum bacteria produce seven distinct serotypes, each of which elicits a distinct antibody response. Naturally occurring outbreaks of botulism in humans have been reported from exposure to four of the seven serotypes: A, B, E and F. Botulism normally occurs when an individual consumes contaminated food containing botulinum toxin. Once consumed, the toxin rapidly attacks nerve cells, resulting in paralysis of peripheral muscles, including the muscles involved in respiration. Botulism can also be contracted if botulinum bacteria contaminate wounds or colonize in the intestine of infants, which is referred to as infant botulism.

Botulinum toxins are among the most potent and dangerous of potential biological weapons. Exposure to very small quantities of botulinum toxin can cause the rapid onset of life threatening paralytic disease syndrome. It has been estimated that a single gram of toxin evenly dispersed and inhaled could kill more than one million people.

Market opportunity and current treatment. Because botulinum toxin is stable when purified and extremely potent when administered in very small quantities, it has the potential to be used as a biological weapon, either through deliberate contamination of food supply or drinking water or as an aerosol. As with anthrax vaccines, we believe that the U.S. government will be the principal customer for a botulinum vaccine, particularly in the near term. We believe that state and local governments, which we expect will be interested in a botulinum vaccine to protect first responders to a bioterrorism attack, and several foreign governments are significant potential customers for a botulinum vaccine.

The Michigan Department of Public Health first developed a pentavalent botulinum toxoid vaccine in the late 1960s and began manufacturing the pentavalent vaccine for use under an IND in 1969. This vaccine is called pentavalent because it addresses five serotypes of botulinum neurotoxin. Since 1989, the CDC and the DoD have distributed the pentavalent botulinum toxoid vaccine under this IND for vaccination of at risk laboratory workers and military personnel as an adjunct to other measures of protection. The pentavalent botulinum toxoid vaccine exhibited an acceptable safety profile in connection with the immunization of over 5,000 individuals with more than 21,000 doses of the vaccine. Approximately 90% of injections were followed by no, or mild, local reactions. Only 0.3% of injections were followed by severe local reactions. A total of 5.1% of injections were followed by reported systemic reactions. In connection with our acquisition of assets from the Michigan Biologic Products Institute in 1998, we acquired rights to the pentavalent vaccine, know-how relating to the development of the pentavalent vaccine and rights to a master botulinum cell bank, which provides starting materials for the pentavalent vaccine.

After more than 15 years of use, the supplies of pentavalent botulinum toxoid vaccine are dwindling and in need of replacement. In August 2003, HHS issued a pre-solicitation notice for the acquisition of up to ten million doses of a recombinant trivalent botulinum vaccine, which would address botulinum serotypes A, B and E. HHS was seeking a trivalent vaccine because botulinum serotype F is more difficult to produce under cGMP conditions and does not appear to represent the same level of threat as other serotypes of botulinum neurotoxin. We also believe that botulinum serotype E does not represent the same level of threat as serotypes A and B. Botulinum serotypes A and B are responsible for approximately 85% of all cases of botulism.

In November 1997, the DoD, through its Joint Vaccine Acquisition Program, awarded a contract for $322 million to DynPort Vaccine Company for the development of various biodefense vaccines. In April 2005, the DoD provided additional funding to DynPort for the continued development of a recombinant bivalent botulinum vaccine for protection against botulinum serotypes A and B.

Description and development status. We are developing a recombinant protein subunit bivalent botulinum vaccine for protection against botulinum serotypes A and B in collaboration with HPA. We hold an exclusive license from HPA to the recombinant technology that we are using in the development of our vaccine candidate. HPA is also providing us with process development and toxicology expertise, access to its facilities and specialized manufacturing capabilities. We are designing our vaccine candidate to be administered by intramuscular injection with an alum adjuvant in a three dose regimen. Our recombinant vaccine candidate is based on a fragment of the botulinum toxin that we have selected as an antigen because we believe it to be non-toxic and immunogenic. We are producing this recombinant antigen in an *E. coli* expression system. We believe that our technology will allow us to develop a stable product with possible cross-protection against a range of toxin subtypes and ease of formulation into a multivalent vaccine.

We have completed initial proof-of-concept studies of this vaccine candidate in mice for botulinum serotypes A and B. In these studies, the vaccine elicited antibodies and provided protection against challenge with the botulinum toxin. We plan to initiate additional proof-of-concept animal studies in mice for botulinum serotype E and then to evaluate the toxicity of the vaccine in other animal studies so that we will be in a position, if we determine to do so, to develop a recombinant trivalent botulinum vaccine instead of a recombinant bivalent botulinum vaccine.

We have established a small scale production process for botulinum serotypes A and B. We anticipate that we will be able to manufacture our recombinant vaccine in a cGMP facility that will not require the high level of containment that is required for the production of conventional, non-recombinant toxoid vaccines that involve cultivation of the disease-causing organism. We plan to rely on the FDA animal rule in connection with the development of our recombinant bivalent botulinum vaccine candidate.

Botulinum immune globulin

We are developing our botulinum immune globulin candidate in collaboration with HPA as an intravenous therapeutic for treatment of symptomatic botulinum exposure. Because of the rapid onset of symptoms following infection with botulinum toxin, prophylactic vaccines, which take several weeks to create an effective protective immune response, are not useful as post-exposure treatments for botulism. In addition, antibiotics are not effective post-exposure treatments since they work by killing the botulinum bacteria that produce the toxin, but do not act directly against the botulinum toxin.

We believe that an intravenous botulinum immune globulin has the potential to provide immediate protection from the effects of botulinum toxin. A third party's FDA approved botulinum immune globulin was tested in a five-year, randomized, double-blind, placebo controlled trial in 122 infants with infant botulism and a subsequent six-year, open-label study in 382 infants. In the placebo controlled trial, infants treated with the botulinum immune globulin had statistically significant reductions in the average length of hospital stay, duration of intensive care, duration of mechanical ventilation, duration of tube or intravenous feeding and hospital charges. In the open-label study, the early treatment of patients with infant botulism shortened the average length of stay significantly more than later treatment.

The only current recommended therapy for exposure to botulism consists of passive immunization with an immune globulin derived from equine plasma. The components of a previously approved trivalent equine immune globulin that contained antibodies against botulinum toxin types A, B, and E have been reformulated into an approved bivalent product and an investigational monovalent product. However, the equine immune globulin is subject to important shortcomings. First, because the human body recognizes the equine immune globulin as a foreign substance, its efficacy may be limited. In addition, the antibody immune response against the equine immune globulin can lead to potential severe side effects, including anaphylactic shock, if the equine immune globulin is administered more than once. To screen for

sensitivity to the equine immune globulin, patients are given small challenge doses of the equine immune globulin before receiving a full dose.

In June 2006, HHS awarded a five-year development and supply contract with a base value of $362 million to Cangene for a heptavalent botulinum immune globulin derived from equine plasma. The contract provides for the supply of 200,000 doses of a botulinum immune globulin for the strategic national stockpile. Cangene has announced that it expects to produce and deliver usable product to the strategic national stockpile from mid to late 2007. The contract also provides for optional task orders worth up to an extra $234 million, which may be awarded at the sole discretion of HHS. Cangene previously began development work on the project under a research and development contract with the CDC.

We plan to rely on the FDA animal rule in connection with the development of our botulinum immune globulin candidate. Specifically, we plan to conduct efficacy studies of this product candidate in an infected rodent population and then infected nonhuman primates. Concurrently, we expect to file an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of the botulinum immune globulin in healthy volunteers. We believe that favorable data from these animal efficacy studies and the safety and pharmacokinetic clinical trial would be sufficient to support an application to the FDA for marketing approval.

As the first step in the development of our botulinum immune globulin candidate, we are initiating production of a bivalent botulinum toxoid vaccine using botulinum serotype B derived from the starting material for the pentavalent vaccine developed by the Michigan Department of Public Health and serotype A from HPA. We are designing this botulinum toxoid vaccine to be administered by injection with an alum adjuvant. We anticipate that several doses will be needed to elicit a strong immune response. We are performing development activities at existing HPA facilities, which we expect may expedite production of clinical material for the vaccine. HPA is also providing us with process development and specialized manufacturing capabilities for the vaccine.

We plan to conduct a preclinical proof-of-concept study of this vaccine candidate in mice to confirm the suitability of the vaccine for further development. If the results of this proof-of-concept study are favorable, based on a demonstration of protective efficacy or an immune response associated with protection, we plan to file an IND to initiate a Phase I clinical trial to evaluate the safety of this vaccine in healthy volunteers. We expect that the Phase I clinical trial will provide data sufficient to support an acceptable dose for the vaccine and the optimal dosing schedule. If the results of the Phase I clinical trial are favorable, we intend to initiate a donor stimulation program in which we will immunize healthy volunteers with the vaccine and collect plasma for fractionation for the manufacture of our botulinum immune globulin candidate. We expect to rely on safety and immunogenicity data from the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan in the development of this bivalent botulinum toxoid vaccine. This data includes the results of a Phase II safety and immunogenicity clinical trial conducted by the DoD from July 1998 to May 2000, animal efficacy data and the extensive use of the pentavalent vaccine by the CDC in immunizing at risk laboratory personnel. As a result, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the bivalent botulinum toxoid vaccine before permitting us to initiate the donor stimulation program. However, the FDA has not approved our plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial for the botulinum toxoid vaccine and may not do so.

Our current plan is to develop the botulinum toxoid vaccine that we are using in the development of our botulinum immune globulin candidate through Phase I clinical trials. At that point, we expect to assess our future development plans based on the U.S. government’s interest in providing funding for the further development or procurement of this toxoid vaccine, either instead of or in addition to a recombinant botulinum vaccine, as a pre-exposure prophylaxis for botulinum toxin. We believe that this type of government funding may become available as there is currently no botulinum vaccine available

for the military or the strategic national stockpile. Moreover, we believe that the well-established nature of the manufacturing process for a toxoid vaccine, the availability of safety data from the pentavalent botulinum vaccine, our access to know-how from the development and manufacturing of the pentavalent botulinum vaccine by the State of Michigan and access to HPA technology would all facilitate our development of a bivalent botulinum toxoid vaccine.

Commercial business

In our commercial business, we are developing a range of commercial immunobiotic product candidates for use against infectious diseases with significant unmet or underserved medical needs.

Typhoid vaccine

Disease overview. Typhoid, also known as typhoid fever, is caused by infection with the bacterium *Salmonella typhi.* Typhoid is characterized by fever, headache, constipation, malaise, stomach pains, anorexia and myalgia. Severe cases of typhoid can result in confusion, delirium, intestinal perforation and death. Typhoid is transmitted by consuming contaminated food or drinks. Contamination usually results from poor hygiene and sanitation. Typhoid is often endemic in developing countries in which there is limited access to treated water supplies and sanitation.

Market opportunity and current treatment. According to the CDC, approximately 400 cases of typhoid are reported annually in the United States, of which approximately 70% are contracted abroad. An estimated 22 million cases of typhoid occur per year worldwide, resulting in approximately 200,000 deaths annually. The CDC recommends that all persons from the United States traveling to developing countries consider receiving a typhoid vaccination, with travelers to Asia, Africa and Latin America deemed to be especially at risk. U.S. military personnel deployed in these areas are also at risk of infection.

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in both the United States and Europe. The approved oral typhoid vaccine is available in liquid and capsule formulations. Both formulations require three to four doses to generate a protective immune response. The capsule formulation requires a booster every five years thereafter. The liquid formulation has been reported to provide 77% of recipients in clinical trials with protection three years after vaccination. The approved injectable vaccine requires only a single dose. However, it is poorly immunogenic in children, requires a booster dose every three years thereafter and was effective in only 55% to 75% of recipients in clinical trials. Both approved vaccines have good safety profiles with relatively few adverse events reported. Antibiotics are used to treat typhoid after infection and usually lead to recovery commencing within four days. Without antibiotic therapy, the CDC estimates that the mortality rate of a typhoid infection is as high as 20%.

Description and development status. We are developing a live attenuated typhoid vaccine that contains deletions in two genes of the *Salmonella typhi* bacterium designed to eliminate virulence. We have designed our vaccine candidate to be administered in a single drinkable dose prior to travel to countries where typhoid is endemic. We believe that, if approved, the method of administration of our vaccine candidate would provide a competitive advantage compared to both currently approved typhoid vaccines.

We have completed preclinical studies in which we assessed the immunogenicity and toxicity of our vaccine candidate, with the following results:

- In *in vitro* tests in which human cells were exposed to our vaccine candidate, the live attenuated bacteria contained in the vaccine did not multiply.

- In pharmacology studies in mice, our vaccine candidate was immunogenic and had higher relative immunogenicity when delivered subcutaneously than the currently approved oral typhoid vaccine.
- In safety and toxicity studies in mice, a strain of *Salmonella* that causes a disease similar to typhoid in mice, which contained deletions in the genes that are also deleted in our vaccine candidate, did not cause disease.

We also have completed the following clinical trials of our typhoid vaccine candidate in the United States and Europe:

- An open-label, non-placebo controlled, pilot study conducted in the United Kingdom in nine healthy adult volunteers. The purpose of this study was to evaluate the safety and immunogenicity of our vaccine candidate. In this study, our vaccine candidate was immunogenic, eliciting both cell mediated and humoral immunogenicity, and well tolerated.
- A double-blind, placebo controlled, single dose escalating Phase I clinical trial conducted in the United States in 60 healthy adult volunteers. The purpose of this trial was to evaluate the safety, tolerability and immunogenicity of three dose levels of our vaccine candidate. In this trial, our vaccine candidate was immunogenic and well tolerated at all dose levels. The immunogenicity parameter for this trial was the proportion of trial participants with an immune response to the product candidate on day seven after dosing or day 28 after dosing. To be considered adequately immunogenic, 50% of the participants receiving a vaccine dose had to satisfy the primary immunogenicity endpoint. We performed analyses on both an intent to treat and a per protocol basis. An intent to treat analysis is based on the participants who receive a dose of vaccine. A per protocol analysis is based on the participants who complete a trial and substantially comply with the trial protocol. In both the intent to treat population and the per protocol population, 100% of the trial participants in the highest dose group and 56% of the participants in the lowest dose group had an immune response on day seven or day 28. The immune response rate for the highest dose group was statistically significantly greater than the immune response rate for the lowest dose group. The p-value was 0.0068 in the intent to treat population and 0.0073 in the per protocol population.
- An open-label, non-placebo controlled, single dose Phase I clinical trial conducted in the United States in 32 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two different presentations of the vaccine candidate, one using bottled water and another using tap water. We vaccinated 16 subjects with each presentation. Because one subject who received the tap water presentation of the vaccine candidate was excluded from the trial results due to a lack of post-baseline immunology data, the tap water presentation data reflected data from only 15 subjects. The immunogenicity parameter for this trial was the proportion of trial participants with an immune response to *S. typhi* following administration of a single dose of the vaccine candidate. The immune response rate was 94% for the participants who received the bottled water presentation and 93% for the participants who received the tap water presentation. The response rate for both groups was statistically significantly higher than the assumed response rate of 50%. The p-value was 0.0005 for the participants who received the bottled water presentation and 0.0010 for the participants who received the tap water presentation. Because the two presentations were similarly immunogenic and both were well tolerated by trial participants, we selected the tap water presentation for further development based on its relative convenience.

In these three clinical trials, our vaccine candidate demonstrated immunogenicity response levels following a single drinkable dose similar to those seen with multiple doses of the currently approved oral vaccine. As a result of these trials, we were able to establish the dose and regimen for our vaccine candidate with a formulation that we believe is appropriate for commercialization.

We recently completed a single-blind, placebo controlled Phase I clinical trial of our vaccine candidate in Vietnam in 27 healthy adult volunteers using the dose and regimen established in our Phase I clinical trials in the United States. The Wellcome Trust provided funding for the trial. The purpose of the trial was to evaluate the safety and immunogenicity of the vaccine candidate in adults living in an endemic area. Based on initial data from this trial, the vaccine candidate met the criterion for immunogenicity, with approximately 68% of subjects who received the vaccine candidate mounting a humoral antibody response. The vaccine candidate was well tolerated by trial participants, with no serious adverse events reported. We are continuing to analyze the data from this trial.

The remainder of our planned clinical development program for this vaccine candidate consists of the following:

- *Phase II clinical trial.* In the fourth quarter of 2006, we plan to initiate a single-blind, placebo controlled Phase II clinical trial in Vietnamese children between five and 14 years of age. The Wellcome Trust has agreed to provide funding for this trial. The purpose of this trial will be to evaluate the safety and immunogenicity of our vaccine candidate. The trial design calls for 100 subjects to receive vaccine and 50 to receive placebo, with at least 70% of the subjects being between five and ten years of age. We will assess safety and immunogenicity up to 28 days after vaccination.
- *Disease surveillance study.* Concurrently with the planned Phase II clinical trial, we plan to conduct a disease surveillance study in the areas where we are considering conducting a Phase III clinical trial of our vaccine candidate in order to confirm that a sufficient number of subjects will be included in the Phase III trial.
- *Phase III clinical trial.* We plan to conduct a single-blind Phase III clinical trial in an area where typhoid is endemic. The purpose of this trial will be to evaluate the efficacy of our vaccine candidate in children who are likely to be exposed to the typhoid bacterium. We expect to undertake the primary analysis of the data from the trial after approximately one year, which, if the results are favorable, we plan to use to support the filing with the FDA of a BLA for marketing approval of our vaccine candidate. We plan to continue to monitor the incidence of typhoid in the trial participants for several years after vaccination.
- *Tolerability and immunogenicity study.* Concurrently with our Phase III clinical trial in an endemic area, we plan to conduct a Phase III clinical trial in the United States or Europe in healthy volunteers. The purpose of this trial will be to evaluate the safety and immunogenicity of our vaccine candidate to support marketing approval in the United Sates and Europe.

Since typhoid fever in Asia is largely a disease of children, we plan to conduct our Phase II and Phase III clinical trials in this age group. We plan to conduct our Phase II and Phase III clinical trials in endemic areas because there are no agreed immune correlates of efficacy for live attenuated typhoid vaccines and it is not practicable to demonstrate clinical efficacy in travelers from the United States or Europe due to the prohibitively large number of subjects that would be needed. The currently approved typhoid vaccines relied on similar clinical trials for regulatory approval.

We plan to seek additional grant funding for development of this product candidate.

Hepatitis B therapeutic vaccine

Disease overview. Hepatitis B is a highly infectious virus transmitted from person to person by contact with blood and bodily fluids. Most hepatitis B infections in adults result in acute hepatitis, with the immune system eventually clearing the infection. However, in approximately 8% to 10% of infected adults and a much larger proportion of infected children, the immune system fails to clear the virus,

resulting in immune tolerance of the virus and chronic infection. In addition, pregnant women suffering from hepatitis B can pass the infection on to their babies during childbirth. Babies born infected rarely clear the infection, with over 90% becoming chronically infected. According to the World Health Organization, approximately 25% of people with chronic hepatitis B infection develop serious liver disease, including cirrhosis and liver cancer.

Market opportunity and current treatment. Chronic infection with the hepatitis B virus is a global problem, with an estimated 350 million carriers worldwide. The World Health Organization estimates that approximately one million people per year worldwide die from complications of hepatitis B infection. Infection rates are highest in the developing world, posing an infection risk to travelers from industrialized countries. Infection is less common in the United States and Europe. In the United States, there are an estimated 1.2 million people with chronic hepatitis B infection, resulting in approximately 4,000 to 5,000 deaths annually.

Prophylactic vaccines based on recombinant protein subunit preparations are effective in preventing hepatitis B infection. Childhood vaccination with these vaccines is common in industrialized countries and in some of the developing world. Childhood immunization programs have reduced the number of carriers of chronic hepatitis B infection by up to 90% in parts of the world where hepatitis B is most common. In the United States, infection rates for acute hepatitis B have decreased by approximately 77% over the past 20 years. However, these existing vaccines have not proven to be effective in treating people with chronic hepatitis B infection. As a result, there remains a large number of people who are chronically infected with hepatitis B and require treatment to prevent the development of liver disease and reduce the risk of transmitting the infection to others.

There is no vaccine currently on the market that is licensed for therapeutic use for chronic hepatitis B infection. Currently available therapies for this patient population consist mainly of antiviral drugs and immunotherapies, such as interferons. However, these treatments are subject to a number of shortcomings. Both of these treatments can only be used in a subset of patients, and their efficacy is limited. In addition, the use of antiviral drugs may lead to the development of resistant forms of the virus and interferons have side effects that reduce patient compliance.

Description and development status. We are developing a live attenuated therapeutic vaccine for treatment of patients with chronic hepatitis B infection. We have designed our vaccine candidate to be administered in multiple drinkable doses over several months. It may require further booster doses. Because chronic carriers have weak cellular responses to the hepatitis B virus, they cannot clear the virus. Our vaccine candidate is intended to redirect the immune system to make strong cellular responses to a hepatitis B antigen known as hepatitis B core in chronic carriers, leading to suppression of viral replication and associated liver damage.

Our vaccine candidate uses our proprietary *spi*-VEC® oral delivery system technology to deliver hepatitis B core antigen to the human immune system. *Spi*-VEC is based on our live attenuated typhoid vaccine and employs recombinant technology to insert the gene for hepatitis B core into the live attenuated S*almonella* bacteria. The bacteria produce the antigen once inside the patient. Because we are relying on recombinant technology to insert the gene for hepatitis B core into a vector delivery system, we do not need to separately purify the vaccine.

We have completed a program of pharmacology and toxicity studies of our hepatitis B therapeutic vaccine candidate in animals. In mice that were administered our vaccine candidate, the hepatitis B core antigen was produced and immune responses were elicited against the antigen. In separate toxicity studies also conducted in mice, our vaccine candidate was non-toxic.

In February 2004, we completed an open-label, dose escalating Phase I clinical trial of our vaccine candidate in the United Kingdom in 30 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two dose levels of our vaccine candidate. In this trial, we administered the two doses of vaccine over a period of approximately two months. The primary immunogenicity parameter for this trial was the proportion of trial participants with an immune response to the product candidate on day 28 after dosing or day 84 after dosing. In this trial, 50% of the participants in the low dose group and 40% of the participants in the high dose group demonstrated an immune response on day 28 or day 84. The results in the low dose group reflect a confidence interval of 19.0% to 81.0%. The results in the high dose group reflect a confidence interval of 18.5% to 61.5%. These confidence intervals indicate a 95% likelihood that the true value is within the range specified. The secondary immunogenicity endpoint for this trial was the proportion of participants who demonstrated the type of immune response known to be important in promoting clearance of hepatitis B at any point during the trial. In this trial, 100% of the participants in the high dose group and 90% of the participants in the low dose group demonstrated such a response. We did not conduct a statistical analysis of the results from the secondary immunogenicity endpoint. The vaccine candidate was well tolerated by trial participants, with no serious adverse events reported.

In March 2006, the U.K. Medicines and Healthcare Products Regulatory Agency approved our clinical trial application, including a trial protocol to initiate a Phase II clinical trial of our vaccine candidate in trial participants chronically infected with hepatitis B. The protocol provides for a placebo controlled, randomized, dose escalating study to be conducted in the United Kingdom in 45 chronic carriers of hepatitis B. If necessary, we may expand the study to additional sites in Europe to increase the recruitment rate. The primary purpose of this trial will be to evaluate the safety and tolerability of six monthly doses of our vaccine candidate. The secondary purpose will be to investigate whether the vaccine candidate can reduce the hepatitis B viral DNA load, a recognized surrogate endpoint for treatment of hepatitis B using current therapeutics. We expect to begin dosing trial participants in the fourth quarter of 2006.

If the results of this Phase II clinical trial are favorable, we expect to submit an IND to the FDA to conduct one or more clinical trials of this vaccine candidate in the United States as may be appropriate. The IND must become effective before we can conduct any clinical trials in the United States.

Group B streptococcus vaccine

Disease overview. Group B streptococcus is a bacterium that causes illness in newborn babies, pregnant women, the elderly and adults with other illnesses, such as diabetes or liver disease. Group B streptococcus is the most common cause of sepsis and meningitis in newborns in the developed world and is a frequent cause of pneumonia in newborns. It affects more babies than any other newborn health problem. Group B streptococcus bacteria can cause bladder and womb infections in pregnant women that in turn lead to infection of the fetus and premature delivery and stillbirth. In pregnant women carrying the group B streptococcus bacteria, the baby may become infected either before or during birth.

In the United States, approximately half of all neonatal group B streptococcus infections occur in newborns less than seven days old and are categorized as “early onset disease.” Infections in babies between seven days and three months old are categorized as “late onset disease.” Early onset disease is often associated with complicated or premature deliveries and usually results in pneumonia and the blood infection septicemia in the baby. It is also associated with meningitis. Approximately 5% of babies with early onset disease die. A high number of survivors of early onset disease are left with significant permanent disabilities, including sight or hearing loss and mental retardation. The majority of late onset cases occur in the first month of life. Late onset disease usually results in meningitis. Up to 5% of babies

with late onset disease die. A high number of survivors of late onset disease are left with permanent disabilities, with up to one-third suffering long-term mental or physical handicaps.

Group B streptococcus infections in the elderly cause blood infections, skin or soft tissue infections and pneumonia.

Market opportunity and current treatment. The NIH has identified prevention of group B streptococcus infection in newborns as a major vaccine objective. Concern about the number of group B streptococcus neonatal infections prompted the CDC to recommend routine screening of pregnant women for group B streptococcus bacteria and preventative antibiotic treatment at the time of labor for women found to be infected. Screening of pregnant women for infection is recommended during weeks 35 to 37 of pregnancy. Approximately 10% to 30% of women are found to be carrying the bacterium as a normal component of the vaginal microflora. These women are offered intravenous antibiotics throughout their labor as a preventative measure. In the absence of antibiotic treatment, the CDC estimates that the risk is one in 200 of delivering a baby with group B streptococcus infection. While the level of group B streptococcus disease decreased in the United States from 1.7 cases per 1,000 live births in 1993 to 0.4 cases per 1,000 live births in 2002, the CDC projects that there are approximately 2,750 neonatal infections each year in the United States. In a study of 338 of these cases of neonatal infections, the death rate was approximately 6%. We expect the target market for our vaccine candidate to be women of childbearing age.

The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. However, this approach is invasive and only partially effective. In addition, antibiotics create the risk of possible adverse reactions and may lead to the development of antibiotic resistant strains of the disease. Direct vaccination of newborns is not effective because their immune system is too immature to respond to the vaccine. Antibiotics are used to treat babies after infection.

Approximately 17,500 cases of group B streptococcus infection occur each year in the U.S. population over one year of age, with most occurring in those over age 50. According to the CDC, the average death rates for invasive infections are approximately 8% to 10% for adults 18 to 64 years of age and 15% to 25% for adults 65 years of age and over. Antibiotics are used to treat infected individuals.

Description and development status. We are developing a recombinant protein subunit group B streptococcus vaccine initially for administration to women of childbearing age for protection of the fetus and newborn babies. We are designing our vaccine candidate to be administered by injection with an alum adjuvant in a three dose regimen. We expect that a booster dose may also be required. We anticipate that the vaccine will elicit an antibody response resulting in the production of antibody in the mother, which may then cross the placenta to protect the fetus and the newborn baby by passive immunity.

We have identified several novel surface associated proteins and are working on the development of three of these proteins as components of our vaccine candidate. We believe that a combination of proteins will be required to provide effective protection. We have completed preclinical studies in which we evaluated the safety and immunogenicity of our vaccine candidate, with the following results:

- In studies in rabbits and mice, the three protein components of our vaccine candidate were immunogenic.
- In a passive immunization study in which we administered rabbit antibody to rat pups, the rat pups were protected against challenge with disease.

- Antibodies elicited by one of the protein components of our vaccine candidate recognized a number of group B streptococcus types, indicating that the protein component has potential to generate immune responses with broad coverage.
- In a toxicology study in mice with one of the protein components of our vaccine candidate, the protein was non-toxic.

We have completed an open-label, dose escalating Phase I clinical trial of the first protein component of our vaccine candidate in the United Kingdom in 47 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of this protein as an individual recombinant protein. We adjuvanted the protein with alum and tested it at four different strengths, with two doses given 28 days apart. In this trial, the protein was immunogenic at all doses tested. We performed analyses on both an intent to treat and a per protocol basis. In both the intent to treat population and the per protocol population, the immune response rate was 83% at the lowest dose tested and 100% at the highest dose tested. The response rate for both the highest dose group and the lowest dose group was statistically significantly higher than the assumed response rate of 50%. For the lowest dose group, the p-value was 0.0386 in both the intent to treat population and the per protocol population. For the highest dose group, the p-value was 0.0039 in the intent to treat population and 0.0078 in the per protocol population. The vaccine candidate was well tolerated by trial participants at all dose levels tested, with no serious adverse events reported. None of the subjects withdrew due to an adverse event.

As the next steps in our development plan, we plan to initiate two additional Phase I clinical trials for the other two proposed protein components of our vaccine candidate. First, we plan to evaluate the safety and immunogenicity of the protein that we already have tested together with one of these other proteins in a Phase I clinical trial in healthy adults. If the results of that trial are favorable, we plan to evaluate the safety and immunogenicity of all three proteins together in a further Phase I clinical trial. If the results of these Phase I clinical trials are favorable, we expect to submit an IND to the FDA to conduct more advanced clinical trials in the United States. The IND must become effective before we can conduct any clinical trials in the United States.

We are in active discussions with NIH for NIH to provide clinical development support for this product candidate.

Chlamydia vaccine

Disease overview. Chlamydia is the most prevalent sexually transmitted disease in the world. It is caused by infection with the bacterium *Chlamydium trachomatis. Chlamydia trachomatis* can cause urogenital disorders such as uritheritis, cervicitis, pelvic inflammatory disease, ectopic pregnancy and infertility among females and is the leading cause of non-gonococcal uritheritis and epidemiditis in males. *Chlamydia trachomatis* also causes the ocular disease trachoma, which is a form of vesicular conjunctivitis. Trachoma is the leading cause of preventable blindness worldwide.

Market opportunity and current treatment. The World Health Organization estimates that approximately 92 million new cases of *Chlamydia trachomatis* infection occur annually worldwide, approximately four million of which occur in North America. *Chlamydia trachomatis* infections are the most commonly reported notifiable disease in the United States, with an estimated 2.8 million Americans becoming infected with *Chlamydia trachomatis* each year. Epidemiological studies indicate that in the United States, *Chlamydia trachomatis* infections are most prevalent among young sexually active individuals between the ages of 15 to 24 years of age. There is no vaccine currently on the market for *Chlamydia trachomatis*. However, screening tests and effective antibiotic treatments have been effective at containing *Chlamydia trachomatis* in the United States and Europe. Although *Chlamydia trachomatis* infection can be treated

with antibiotics, control measures based on antimicrobial treatment alone are difficult due to the incidence of infection, the percentage of asymptomatic infections and deficiencies in diagnosis.

Description and development status. We are developing a recombinant protein subunit chlamydia vaccine for all clinically relevant strains of *Chlamydia trachomatis*, including strains that cause ocular disease. We are designing our vaccine candidate to be administered by injection with a novel adjuvant in a three dose regimen. We are currently evaluating in license opportunities for the adjuvant. We have cloned our vaccine candidate and produced it in *E. coli*. In studies in mice, our vaccine candidate protected against both upper reproductive tract disease and lower reproductive tract infection induced by *Chlamydia trachomatis*. In addition, there was no evidence of infertility in the mice following treatment with our vaccine candidate.

Meningitis B vaccine

Disease overview. Meningococcal disease is a life threatening condition caused by infection with the bacterium *Neisseria meningitidis. Neisseria meningitidis* is classified into 12 groups based on differences in the surface coating of the bacterium that elicit distinct immune responses. According to the World Health Organization, group B is the most common cause of endemic meningitis in industrialized countries, accounting for 30% to 40% of cases in North America and 30% to 80% of cases in Europe. Meningococcal disease has a fatality rate of approximately 10%. The infection can develop very rapidly and cause death within 24 hours of the symptoms first becoming apparent. Children from six months to two years of age are at the highest risk of group B meningococcal infection, with teenagers also at enhanced risk.

Market opportunity and current treatment. The World Health Organization estimates that approximately 1.2 million cases of bacterial meningitis occur annually worldwide, resulting in approximately 135,000 deaths. The World Health Organization estimates that approximately 500,000 of these cases and 50,000 of these deaths are caused by the bacterium *Neisseria meningitidis*. In the United States, 2,333 cases of meningococcal disease were reported in 2001, with approximately one-third due to group B. In 2003, 1,756 cases of meningococcal disease were reported in the United States. Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Current meningitis B treatments include antibiotics and clinical support. The rapid progression of the infection means that antibiotic therapy can be ineffective in preventing serious morbidity and mortality.

Description and development status. We are developing a recombinant protein subunit meningitis B vaccine for babies, children and adolescents. We are designing our vaccine candidate to be administered by injection with an alum adjuvant in a two dose regimen for children under age five and a single dose regimen for children over age five. We do not expect that a booster dose will be required. We anticipate that the vaccine will consist of two or three protein antigens. We are currently evaluating a pool of 46 protein candidates in a number of preclinical studies. We are producing recombinant proteins in *E. coli.*

We have entered into a collaboration agreement with Sanofi Pasteur for this vaccine candidate.

Sanofi Pasteur collaboration

In May 2006, we entered into a license and co-development agreement effective April 1, 2006 with Sanofi Pasteur, the vaccines business of Sanofi-Aventis, pursuant to which we granted Sanofi Pasteur an exclusive, worldwide license to develop and commercialize a meningitis vaccine that contains program antigens evaluated and selected under the agreement. We retain the right and obligation to conduct development activities through Phase I clinical trials. Under specified circumstances, we also retain the right to exploit antigens that have been terminated from development under the agreement on an

exclusive basis and other specified antigens on a co-exclusive basis. Sanofi Pasteur has agreed to use commercially reasonable efforts to develop and commercialize a meningitis B vaccine in the United States, the European Union and other major market countries.

A steering committee made up of an equal number of representatives from us and Sanofi Pasteur oversees all development and commercialization activities under the agreement. The steering committee has the authority to make strategic decisions by unanimous vote relating to the development of a meningitis vaccine. Sanofi Pasteur has ultimate decision-making authority over matters that are not resolved at the steering committee and executive officer levels, but does not have the unilateral authority to amend the agreement or the development plan in a manner that would alter our obligations. In addition, Sanofi Pasteur has the right to make all strategic decisions relating to the development of any combination product and has sole discretion over the commercialization of any meningitis vaccine developed under the agreement.

Under the agreement, Sanofi Pasteur paid us an initial fee of €3 million. In addition, Sanofi Pasteur has agreed to pay all expenses incurred by us under the development program. We are also eligible to receive payments of up to a maximum of €73 million upon the achievement of specified research, development and commercialization milestones. Sanofi Pasteur has agreed to pay royalties to us based on net sales by Sanofi Pasteur, its affiliates and sublicensees of licensed products from the collaboration, including specified minimum royalties with respect to sales of any combination product. In addition, Sanofi Pasteur has agreed to pay us a portion of specified sublicense income received by Sanofi Pasteur or its affiliates.

The term of the agreement ends, on a country-by-country basis, upon the later of ten years from first commercial sale or the expiration of the last-to-expire patent covering a licensed product in such country. Sanofi Pasteur may terminate the agreement for convenience beginning April 1, 2007 upon six months' prior written notice. Sanofi Pasteur also may terminate the agreement upon any change of control involving us or as a result of our uncured material breach of the agreement or bankruptcy.

Facilities

The following table sets forth general information regarding our materially important facilities.

Location	Use	Segment	Approximate square feet	Owned/leased
Lansing, Michigan	Manufacturing operations facilities and office space	Biodefense	214,000	Owned
Frederick, Maryland	Future manufacturing facilities and office and laboratory space	Biodefense/ Commercial	290,000	Owned
Gaithersburg, Maryland	Office and laboratory space	Biodefense/ Commercial	36,000	Leases expire 2008
Rockville, Maryland	Office space	Biodefense/ Commercial	23,000	Lease expires 2016
Wokingham, England	Office and laboratory space	Commercial	16,000	Leases expire 2016

Lansing, Michigan. We own a multi-building campus on approximately 12.5 acres in Lansing, Michigan that includes facilities for bulk manufacturing of BioThrax, including fermentation, filtration and formulation, as well as for raw material storage and in-process and final product warehousing. The campus is secured through perimeter fencing, limited and controlled ingress and egress and 24 hour on-site security personnel. We acquired these facilities in 1998 from the Michigan Biologic Products Institute after the State of Michigan, with the concurrence of the DoD, suspended the production of BioThrax to renovate these manufacturing facilities. Following our acquisition of BioThrax, we completed

the facility renovations initiated by the State of Michigan. Our comprehensive renovations included the implementation of work plans to systematically validate the manufacturing process of BioThrax and improve our quality systems. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

In February 2006, we began construction of a new 50,000 square foot manufacturing facility on our Lansing campus. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We are constructing this new facility as a large scale commercial manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. Subject to regulatory approval, we expect that the new manufacturing facility will serve as our primary BioThrax manufacturing facility. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. Our plans assume that the FDA will not require us to complete a human bridging trial demonstrating that BioThrax manufactured at our new facility is bioequivalent to BioThrax manufactured at our existing facility. We currently expect to rely on nonclinical studies for these purposes. However, the FDA has not approved our plan to rely on nonclinical studies without conducting a human bridging trial and may not do so. If the FDA requires us to conduct a human bridging trial, the initiation of large scale manufacturing of BioThrax at our new facility will be delayed and we will incur additional unanticipated costs.

We are constructing this facility to accommodate production of up to 40 million doses of BioThrax per year on a single production line, which we could expand for production of up to 80 million doses per year through the addition of a second production line. In comparison, our current facility has a maximum production capacity of approximately nine million doses of BioThrax per year. In addition to construction of a new manufacturing facility, we recently commissioned a new pilot plant on our Lansing campus. Our Lansing facilities and substantially all of the other assets of our wholly owned subsidiary, Emergent BioDefense Operations Lansing Inc., other than accounts receivable under our DoD and HHS contracts, serve as collateral for our financing obligations for our facility expansion in Lansing. For more information, see “Management’s discussion and analysis of financial condition and results of operations — Liquidity and capital resources — Debt financing.”

Frederick, Maryland. We own two buildings of approximately 145,000 square feet each on a 15-acre site in Frederick, Maryland. We financed the purchase of these buildings with a forgivable loan from the Department of Business and Economic Development of the State of Maryland and mortgage loans from commercial lenders. These buildings serve as collateral for these financing obligations. For more information, see “Management’s discussion and analysis of financial condition and results of operations — Liquidity and capital resources — Debt financing.”

We are in the preliminary phase of establishing plans to build out this site for product development and a portion of our potential future product manufacturing requirements. Our preliminary plans contemplate that the site would be designed to provide laboratory space, product development and pilot plant production capabilities, full scale commercial manufacturing operations, warehouse and storage facilities, fill and finish operations and administrative office space. We expect that we will complete the build out of this site in several stages. Our preliminary plans contemplate a build out of one of the two buildings on this site to accommodate laboratory space, product development, pilot plant, initial product launch capabilities and administrative office space during 2008 and 2009. Our preliminary plans also contemplate that we will build out commercial manufacturing operations two to three years after establishing initial product launch capabilities.

Other. We lease two separate product development facilities. Our facility in Gaithersburg, Maryland of approximately 36,000 square feet contains a combination of laboratory and office space, including our current executive offices. We conduct product development programs at this site for both our biodefense and commercial product candidates. Our facility in Wokingham, England of approximately 16,000 square feet contains a combination of laboratory and office space. We conduct product development programs at this site primarily for our commercial product candidates. Our facility in Rockville, Maryland contains approximately 23,000 square feet of office space. We plan to relocate our executive offices to our Rockville facility in late 2006.

Manufacturing

We manufacture BioThrax at our facilities in Lansing, Michigan using well established vaccine manufacturing procedures. We currently rely on contract manufacturers and other third parties to manufacture the supplies of our immunobiotic product candidates that we require for preclinical and clinical development. We acquire these supplies on a purchase order basis. We anticipate that we will use our existing plant facilities in Michigan, including our recently commissioned pilot plant, and, when constructed and approved, our planned new plant facilities in Michigan and Maryland to support both continued process development and the manufacture of clinical supplies of our product candidates. However, we also expect that we will continue to use third parties for production of preclinical and clinical supplies of some of our product candidates. We believe that manufacturing our products and product candidates independently will provide us cost savings and greater control over the manufacturing and regulatory approval and oversight process, accelerate product development timelines and allow us to expand our base of manufacturing know-how that we can then apply to the development and manufacture of future product candidates.

Hollister-Stier Laboratories LLC performs the contract filling operation for BioThrax vials at its FDA approved facility located in Spokane, Washington. Hollister-Stier has agreed to meet all of our firm purchase orders for contract filling of BioThrax based on a good faith annual estimate that we provide prior to each calendar year. In addition, Hollister-Stier has agreed to accommodate fill requests in excess of our annual estimate subject to its available production capacity. Our contract with Hollister-Stier expires December 31, 2007. The contract also can be terminated by either party following an uncured material breach by the other party.

Talecris Biotherapeutics has agreed to perform plasma fractionation and purification and contract filling relating to the manufacture of our anthrax immune globulin candidate at its FDA approved facilities located in Melville, New York and Clayton, North Carolina. Subject to limited exceptions, we have agreed to obtain all of our anthrax immune globulin requirements exclusively from Talecris. While our agreement with Talecris remains in effect, Talecris has agreed not to market, sell or acquire any competing product that contains anthrax immune globulin as an active ingredient.

Talecris has agreed to perform plasma fractionation and purification and contract filling for the manufacture of our anthrax immune globulin candidate for preclinical or animal studies, for clinical use or for non-clinical testing required for clinical trials and for commercial sale. We have agreed to pay Talecris royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris under the contract.

Our contract with Talecris expires December 31, 2013 or five years following initiation of commercial manufacturing. We have the option to extend the term for an additional five-year period upon notice to Talecris at least 12 months prior to the expiration of the initial term. After three years following initiation of commercial manufacturing, either party may terminate the contract upon two years' advance notice. The contract can also be terminated by either party following an uncured material breach by the other party. We have the right to terminate the contract, under specified circumstances, if we discontinue our

production of anthrax immune globulin source plasma or the development of our anthrax immune globulin candidate.

We expect to engage one or more third parties to perform the plasma fractionation and purification processes and contract filling for our botulinum immune globulin candidate. We also 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 and contract fill and finish operations.

We rely on third parties for supplies and raw materials used for the production of BioThrax and our immunobiotic product candidates. We purchase these supplies and raw materials from various suppliers in quantities adequate to meet our needs. We believe that there are adequate alternative sources of supply available if any of our current suppliers were unable to meet our needs.

Marketing and sales

We currently market and sell BioThrax directly to the DoD and HHS with 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. We plan to expand our sales and marketing organization as we broaden our sales activities of biodefense products to state and local governments, which we expect will be interested in these products to protect first responders, such as police, fire and emergency medical personnel. We have established marketing and sales offices in Singapore and Munich, Germany to target sales of biodefense products to foreign governments. We have engaged third party marketing representatives to market BioThrax in the Middle East, Turkey, India, Australia and several Scandinavian countries in Europe.

We expect to establish a separate internal organization to market and sell commercial products for which we retain commercialization or co-commercialization rights. We anticipate that our internal marketing and sales organization will be complemented by selective co-promotion and other arrangements with leading pharmaceutical and biotechnology companies.

We generally expect to retain commercial rights for our product candidates that we successfully develop in situations in which we believe it is possible to access the market through a focused, specialized sales force. In particular, we believe that such a sales force could address commercial markets, such as the market for typhoid vaccines and other vaccines for travelers to developing countries, that overlap with markets for our biodefense products. 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 or product candidates or to access particular markets.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience, and resources provide us with competitive advantages, we face potential competition from many different sources, including commercial pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions.

GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Chiron generated approximately 85% of total vaccine revenues in 2005. The concentration of the industry reflects a number of factors, including:

- the need for significant, long-term investment in research and development;

- the importance of manufacturing capacity, capability and specialty know-how, such as techniques, processes and biological starting materials; and
- the high regulatory burden for prophylactic products, which generally are administered to healthy people.

These factors have created a significant barrier to entry into the vaccine industry.

Many of our competitors, including those named above, 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. These companies 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. Smaller or more focused companies, including VaxGen, Cangene, Human Genome Sciences, Acambis, Avant Immunotherapeutics and Avecia, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop. In addition, we may not be able to compete effectively if our products and product candidates do not satisfy government procurement requirements, particularly requirements of the U.S. government with respect to biodefense products.

Any immunobiotic product candidates 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.

BioThrax. Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face significant competition for the supply of this vaccine to the U.S. government. The NIAID Biodefense Research Agenda for CDC Category A Agents includes the development of an anthrax vaccine based on recombinant protective antigen. In September 2003, NIAID awarded joint three-year contracts totaling $151.6 million to VaxGen and Avecia to fund development of a recombinant protective antigen anthrax vaccine. In November 2004, HHS awarded VaxGen a contract with a value of $877.5 million to supply 75 million doses of recombinant protective antigen vaccine for the strategic national stockpile. Avecia submitted a competing proposal to supply vaccine for the strategic national stockpile, which HHS did not accept. The HHS procurement request was limited to a recombinant anthrax vaccine. Because BioThrax is not a recombinant vaccine, BioThrax was precluded from consideration under that procurement program.

VaxGen has not yet delivered any vaccine doses under its contract with HHS. In May 2006, VaxGen announced that HHS unilaterally modified its contract to provide its anthrax vaccine for the strategic national stockpile. The contract modification extends the deadlines by which VaxGen is required to complete various milestones, including deliveries, and imposes additional requirements for clinical and non-clinical studies to be completed prior to the initiation of vaccine deliveries to the strategic national stockpile. VaxGen announced that meeting the new requirements would delay deliveries to the strategic national stockpile to the end of 2007 at best or more likely into 2008. VaxGen is obligated under the modified contract to initiate deliveries no later than November 2008. In May 2006, an HHS official stated in Congressional testimony that delays in accelerated development programs are not unexpected or unprecedented and that HHS maintains a commitment to develop a next generation recombinant protective antigen anthrax vaccine.

HPA manufactures an anthrax vaccine for use by the government of the United Kingdom. In addition, other countries may have anthrax vaccines for use by or in development for their own internal purposes.

Other biodefense products. The competition for our biodefense immunobiotic product candidates includes the following:

- *Next generation anthrax vaccine.* We expect that NIAID will issue multiple contracts to fund future development and testing of a next generation anthrax vaccine pursuant to its request for proposals issued in June 2006. We face significant competition for NIAID funding from other companies that have responded to this NIAID request for proposals. If we continue to pursue the development of a next generation anthrax vaccine, we also expect that we will face significant competition for the supply of our product candidate to the U.S. government.
- *Anthrax immune globulin.* Cangene, in collaboration with the CDC, is currently developing an anthrax immune globulin using plasma collected from military personnel who have been vaccinated with BioThrax. In July 2006, HHS exercised an option under a modification to an existing development and supply contract for Cangene to supply 10,000 doses of anthrax immune globulin for the strategic national stockpile. In June 2006, HHS awarded a contract to Human Genome Sciences to supply 20,000 treatment courses of a monoclonal antibody to *Bacillus anthracis*, referred to as ABthrax, for the strategic national stockpile.
- *Recombinant bivalent botulinum vaccine.* DynPort Vaccine Company has a recombinant bivalent botulinum vaccine in Phase I clinical development with funding from the DoD.
- *Botulinum immune globulin.* The current recommended therapy for clinical symptoms of botulism following exposure consists of passive immunization with an immune globulin derived from equine plasma. In June 2006, HHS awarded a five-year development and supply contract to Cangene for a heptavalent botulinum immune globulin derived from equine plasma. The contract provides for the supply of 200,000 doses of a botulinum immune globulin for the strategic national stockpile.

BioThrax and our biodefense product candidates also face competition for government funding from other defensive measures, including medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures.

Commercial products. The competition for our commercial immunobiotic product candidates includes the following:

- *Typhoid vaccine.* One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the United States and Europe. In addition, combination vaccines are available for the prevention of hepatitis A and typhoid infections. Antibiotics typically are used to treat typhoid after infection. For more information, see “— Products — Commercial business — Typhoid vaccine.” We believe that Avant Immunotherapeutics Inc. has an oral, single dose, live attenuated typhoid vaccine candidate in Phase I clinical development with funding from NIAID.
- *Hepatitis B therapeutic vaccine.* There is no vaccine currently on the market that is licensed for therapeutic use for hepatitis B infection. Currently available therapies for this patient population consist mainly of antiviral drugs and immunotherapies, such as interferons. For more information, see “— Products — Commercial business — Hepatitis B therapeutic vaccine.” Several other companies have vaccine candidates in clinical development, including Enzo Biochem, Oxxon Therapeutics and Genencor International.
- *Group B streptococcus vaccine.* The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. A number of competitors have passive immune vaccines in preclinical development.

- *Chlamydia vaccine.* There is no vaccine currently on the market for chlamydia, and we are not aware of any competing chlamydia vaccine candidate in clinical development. Several competitors may have chlamydia vaccine candidates in preclinical development. Screening tests and effective antibiotic treatments have been effective at containing chlamydia in the United States and Europe.
- *Meningitis B vaccine.* Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Novartis markets a meningitis B vaccine in New Zealand to people under the age of 20 and is also developing a broad coverage protein subunit vaccine candidate. Current meningitis B treatment strategies include antibiotics and clinical support.

Intellectual property and licenses

Our success, particularly with respect to our commercial business, depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. U.S. patents generally have a term of 20 years from the date of nonprovisional filing. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of October 20, 2006, we owned or licensed a total of 20 U.S. patents and 44 U.S. patent applications relating to our biodefense and commercial product candidates described in this prospectus, as well as numerous foreign counterparts to many of these patents and patent applications. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations and methods of use.

We consider the patent rights that we have licensed from HPA relating to our recombinant bivalent botulinum vaccine candidate and our botulinum toxoid vaccine, which we plan to use in the development of our botulinum immune globulin candidate, to be most important to the protection of our biodefense product portfolio. These patents rights are described below under "— License agreements — HPA agreements."

We consider the following patents that we own or license to be most important to the protection of our vaccine candidates in our commercial business that are in clinical development.

- *Typhoid vaccine.* We hold five U.S. patents relating to our typhoid vaccine candidate. Some of these patents have claims to the composition of matter of the vaccine candidate and methods of use of attenuated *Salmonella typhi* bacteria as vaccines for the treatment and prevention of typhoid and for the delivery of vaccine antigens. In addition, we have two pending U.S. patent applications with claims to additional compositions and methods of therapy that are generally related to our typhoid vaccine candidate. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2015 and 2020. We hold 28 foreign counterparts to our issued U.S. patents relating to our typhoid vaccine candidate, including counterparts under the European Patent Convention and in Japan, that expire, and 34 foreign patent applications that, if issued, would expire, between 2015 and 2020.
- *Hepatitis B therapeutic vaccine.* Our hepatitis B therapeutic vaccine candidate uses our proprietary *spi*-VEC oral delivery system technology to deliver hepatitis B core antigen to the human immune system. *Spi*-VEC is based on our live attenuated typhoid vaccine candidate and employs recombinant technology to insert the gene for hepatitis B core into the live attenuated *Salmonella* bacteria. As a result, the patents relating to our typhoid vaccine candidate also protect our hepatitis B therapeutic vaccine candidate. We also hold one U.S. patent with claims to the use of attenuated *Salmonella* organisms for the delivery of hepatitis B vaccine antigens, which expires in 2019. In addition, we have

one pending U.S. patent application relating to our hepatitis B therapeutic vaccine candidate, which if issued also would expire in 2019. We have four foreign patent applications relating to our hepatitis B therapeutic vaccine candidate that, if issued, would expire in 2019.

- *Group B streptococcus vaccine.* We hold two U.S. patents relating to our group B streptococcus vaccine candidate with claims to the composition of matter of the vaccine candidate and methods of use for the prevention or treatment of infection caused by *Streptococcus agalactiae*. In addition, we have four pending U.S. patent applications with claims to additional compositions and methods of therapy relating to our group B streptococcus vaccine candidate. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2019 and 2022. We hold 19 foreign counterparts to our issued U.S. patents relating to our group B streptococcus vaccine candidate, including counterparts under the European Patent Convention and in Japan, that expire, and 40 foreign patent applications that, if issued, would expire, in 2019.
- *STM technology.* We jointly own with Imperial College Innovations Limited patents with claims to methods for the identification of virulence genes using our signature tagged mutagenesis, or STM, technology, which we used to identify and develop the gene mutations that form the basis of our typhoid vaccine and hepatitis B therapeutic vaccine candidates. We also jointly own with Imperial Innovations the composition of matter patents covering these gene mutations. We have exclusive rights, even as to Imperial Innovations, under these jointly owned patents in all fields of use, except in the field of diagnosis, prevention, treatment, or palliation of microbial diseases, disorders and infections in humans and animals where our rights are generally non-exclusive and are subject to existing license agreements with third parties. Because our typhoid vaccine and hepatitis B therapeutic vaccine candidates are outside of this non-exclusive field of use, we have exclusive rights with respect to these vaccine candidates. We exclusively own the composition of matter patents covering the specific combination of mutations employed in our typhoid vaccine and hepatitis B therapeutic vaccine candidates.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We also rely on trade secrets relating to manufacturing processes and product development to protect our business. Because we do not have patent protection for BioThrax, the label expansions and improvements that we are pursuing for BioThrax or our anthrax immune globulin candidate, our only intellectual property protection for BioThrax and our anthrax immune globulin candidate 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, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and

systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

License agreements

We are a party to a number of license agreements under which we license patents, patent applications, and other intellectual property. We enter into these agreements to augment our owned intellectual property. These agreements impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future. The only existing licenses that we consider to be material to our current product portfolio or development pipeline are our agreements with HPA, which are described below. We also have a license agreement with the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StMUGV, relating to a viral vector technology that we may use in the development of future product candidates, which is also described below.

HPA agreements. In November 2004, we entered into two separate license agreements with HPA for our botulinum toxoid vaccine and our recombinant bivalent botulinum vaccine candidate. Under the license agreements, we obtained the exclusive, worldwide right to develop, manufacture and commercialize pharmaceutical products that consist of botulinum toxoid components or recombinant botulinum toxin components for the prevention or treatment of illness in humans caused by exposure to the botulinum toxin, subject to HPA's non-exclusive right to make, use or sell recombinant botulinum products to meet public health requirements in the United Kingdom.

The licensed patent portfolio includes one U.S. patent with claims to the composition of matter of recombinant components of *Clostridium botulinum*, which expires in 2016. Additional composition of matter and method of use claims are pending in three U.S. patent applications, which if issued as patents also would expire in 2016. The licensed portfolio also includes seven foreign applications, which if issued would expire in 2016.

Under each license agreement, we are required to pay HPA royalties on sales of the licensed product by us, our affiliates or third party sublicensees in the major market countries of the United States, United Kingdom, France, Germany, Italy and Japan, and a separate royalty on sales of the licensed product by us and our affiliates in any other country.

Under each license agreement, we are generally obligated to use commercially reasonable efforts to respond to applicable solicitations or procurement proposals from, and to enter into contracts with, governmental agencies in each of the major market countries with respect to the licensed product. We may satisfy this obligation by filing an IND with respect to a licensed product by November 2009. If we fail to file an IND within that time period under either of the license agreements, we are obligated to pay HPA an annual fee until an IND has been filed.

In November 2004, we also entered into two separate development agreements with HPA pursuant to which HPA agreed to conduct specified tests, studies and other development activities with respect to the botulinum toxoid product and the recombinant botulinum product in accordance with mutually-agreed development plans. We have paid minimum contractual commitments of $1.0 million under each development agreement to compensate HPA for this development work. HPA also agreed to provide us with clinical supplies of the botulinum toxoid product and the recombinant botulinum product for clinical trials.

The term of each development agreement lasts until the development activities are completed. HPA may terminate each development agreement as a result of our uncured material breach or insolvency. Each of the development agreements automatically terminates if the applicable license agreement is terminated.

The term of each license agreement lasts until the expiration of all of our royalty obligations under the applicable license agreement. We are obligated to pay royalties under each license agreement, on a product-by-product and country-by-country basis, until the later of seven years from first commercial sale of the first licensed product in that country and the expiration of the last-to-expire licensed patent in that country. HPA may terminate each license agreement if we terminate the applicable development agreement without cause before we have paid, or if HPA terminates such development agreement due to our failure to pay, the minimum commitment amount set forth in such development agreement. In addition, HPA may terminate each license agreement as a result of our uncured material breach or insolvency.

MVAtor Platform Technology. In July 2006, in connection with our acquisition of ViVacs GmbH, a German limited liability company, we acquired a license agreement with StMUGV that provides us the non-exclusive, worldwide right to develop and produce viruses and viral products, including recombinant viral vectors, using the modified vaccinia Ankara virus, or MVA. Our MVAtor platform technology, which is based on these licensed rights, could potentially be used as a viral vector for delivery of multiple vaccine antigens for different disease-causing organisms, including influenza, using recombinant technology.

Under the license agreement, we are required to pay StMUGV:

- a percentage of the net revenue or license fees, as applicable, that we receive from products developed using MVA that are used for research or other purposes; and
- a percentage of the license fees that we receive from products developed using MVA that are licensed as starting material for the production of a smallpox vaccine.

The license agreement does not have a specified term. Each party may terminate the license agreement as a result of an uncured material breach by the other party. In addition, StMUGV may terminate the license agreement upon the insolvency or liquidation of our wholly owned subsidiary, Emergent Product Development GmbH, formerly ViVacs GmbH.

Government contracts

We have an ongoing BioThrax supply contract with the DoD, which purchases BioThrax for immunization of military personnel. In addition, we supply BioThrax to HHS for placement into the strategic national stockpile.

Department of Defense. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. We have completed delivery of all of the doses of BioThrax under our first contract with the DoD. In November 2003, we entered into a follow-on, second supply contract with the DoD. This second contract is referred to as an indefinite delivery/indefinite quantity contract. Under this contract, the DoD is obligated to acquire a minimum number of doses of BioThrax and has the right to acquire up to a maximum number of doses. We invoice the DoD for progress payments under the contract upon reaching pre-determined process stages in the manufacture of BioThrax. We amended this contract in October 2006. As amended, this contract provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We expect to deliver to the DoD approximately 480,000 of these doses by December 2006, with the balance to be delivered by September 2007. The DoD may submit additional orders under this contract through February 2007.

Department of Health and Human Services. In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of $123 million. We completed delivery of all five million doses of BioThrax by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of $120 million. We expect to complete delivery of all five million additional doses by the first half of 2007. Our contract with HHS does not provide for progress payments. We invoice HHS under the contract upon completing delivery of the specified doses of BioThrax.

U.S. government indemnification. Under our BioThrax contracts with the DoD and HHS, the U.S. government indemnifies 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 DoD for all costs incurred in defending these claims.

Safety Act and other statutory protections. In August 2006, the Department of Homeland Security approved our application under the 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 United States 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. We have successfully asserted the government contractor defense in product liability litigation in a federal district court in Michigan.

As part of the 2006 Defense Authorization Act, the U.S. Congress adopted the Public Readiness and Emergency Preparedness Act, which offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic and epidemic products and security countermeasures. The Public Readiness and Emergency Preparedness Act provides immunity, subject to limited exceptions, for claims arising out of, related to or resulting from the administration or use of a covered countermeasure.

Government regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements for the preclinical and clinical development, manufacture, distribution and marketing of pharmaceutical and biological products, including immunobiotics. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, recordkeeping, approval, advertising, sale, promotion, import, and export of our products and product candidates.

U.S. government regulation

In the United States, BioThrax and our product candidates are regulated by the FDA as biological products. Biologics are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, the regulations promulgated under the FDCA and the PHSA and other federal, state, and local statutes and regulations. Violations of regulatory requirements at any stage may result in various adverse consequences, including delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions, including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions or civil or criminal penalties.

The process required by the FDA under these laws before our product candidates may be marketed in the United States generally involves the following:

- preclinical laboratory and animal tests;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- completion of human clinical trials and other studies to establish the safety and efficacy of the proposed product for each intended use;
- FDA review of whether the facility in which the product is manufactured, processed, packed or held complies with cGMP requirements designed to assure the product's continued quality; and
- submission to the FDA and approval of an NDA in the case of a drug, or a BLA in the case of a biologic, containing preclinical and clinical data, proposed labeling and information to demonstrate that the product will be manufactured to appropriate standards of identity, purity and quality.

The research, development and approval process requires substantial time, effort and financial resources, and approvals may not be granted on a timely or commercially viable basis, if at all.

Preclinical studies

Preclinical studies include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess its potential safety and efficacy. We submit the results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND submission also contains clinical trial protocols, which describe the design of the proposed clinical trials. The IND becomes effective 30 days after the FDA receives the filing, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the preclinical trials or the design of the proposed clinical trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. In addition, an independent Institutional Review Board charged with protecting the welfare of human subjects involved in research at each medical center proposing to conduct the clinical trials must review and approve any clinical trial. Furthermore, study subjects must provide informed consent for their participation in the clinical trial.

Clinical trials

Human clinical trials are typically conducted in three sequential phases, which may overlap:

- In a Phase I clinical trial, the drug or biologic is initially administered into healthy human subjects or subjects with the target condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- In a Phase II clinical trial, the drug or biologic is administered to a limited subject population to identify possible adverse effects and safety risks, the efficacy of the product for specific targeted diseases and dosage tolerance and optimal dosage.
- A Phase III clinical trial is undertaken if a Phase II clinical trial demonstrates that a dosage range of the drug or biologic is effective and has an acceptable safety profile. In a Phase III clinical trial, the drug or biologic is administered to an expanded population, often at geographically dispersed clinical trial sites, to further evaluate dosage and clinical efficacy and to further test for safety.

U.S. law requires that trials to support approval for product marketing be “adequate and well controlled.” In general, this means that pivotal clinical trials typically must be prospective, randomized, blinded and controlled. The design of the clinical trials must be described in appropriate protocols submitted to the FDA and approved by an Institutional Review Board. Clinical trials typically compare the experimental product to either a placebo or, in some cases, a product already approved for the treatment of the applicable disease or condition. Trials must also be conducted in compliance with good clinical practice, or GCP, requirements.

In the case of product candidates that are intended to treat rare life-threatening diseases, such as infection caused by exposure to the anthrax toxin, conducting controlled clinical trials to determine efficacy may be unethical or infeasible. Under regulations issued by the FDA in 2002, often referred to as “the animal rule,” the FDA described the circumstances under which it will rely on evidence from studies in animals to provide substantial evidence of efficacy for products for which human efficacy studies are not ethical or feasible. The animal rule provides that, under these circumstances, approval of the product can be based on clinical data from trials in healthy subjects that demonstrate adequate safety and immunogenicity and efficacy data from adequate and well controlled animal studies. Among other requirements, the animal studies must establish that the biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, these studies add complexity and uncertainty to the testing and approval process. In addition, products approved under the animal rule are subject to additional regulation not normally required of other products. Additional regulation may include post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We may not successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or the Institutional Review Boards or the sponsor may prevent clinical trials from beginning or may place clinical trials on hold or terminate them at any point in this process if, among other reasons, they conclude that study subjects are being exposed to an unacceptable health risk.

Marketing approval

In the United States, the results of product development, preclinical studies and clinical trials must be submitted to the FDA for review and approval prior to marketing and commercial shipment of the product candidate. If the product is regulated as a drug, an NDA must be submitted and approved before

commercial marketing may begin. If the product is regulated as a biologic, a BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness and, in the case of a biologic, purity and potency of the product candidate from laboratory, animal and clinical testing, as well as data and information on the finished product, including manufacturing, product stability and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA or BLA and must be registered with the FDA. The FDA generally will not approve an application until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug or biological product and determines that the facility is in compliance with cGMP requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products.

Under applicable laws and FDA regulations, each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will "file" the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable.

The FDA may deny an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if additional clinical data is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. If the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan or otherwise limit the scope of any approval or post-approval, or limit labeling. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized. The FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies often takes many years and the actual time required may vary substantially, based upon the type, complexity and novelty of the product candidate. Government regulation may delay or prevent marketing of potential products for a considerable period of time or permanently and impose costly procedures upon our activities. The FDA or other regulatory agencies may not grant approval for any of our product candidates on a timely basis, or on a commercially viable basis, if at all. Success in preclinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific indications. Furthermore, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Ongoing regulation

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including:

- recordkeeping requirements;
- periodic reporting requirements;
- cGMP requirements related to all stages of manufacturing, testing, storage, packaging, labeling and distribution of finished dosage forms of the product;
- reporting of adverse experiences with the drug or biologic; and
- advertising and promotion restrictions.

The FDA's rules for advertising and promotion require in particular that we not promote our products for unapproved uses and that our promotion be fairly balanced and adequately substantiated. We must also submit appropriate new and supplemental applications and obtain FDA approval for some changes to the approved product, product labeling or manufacturing process.

Drug and biologics manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies. The cGMP requirements for biological products are extensive and require considerable time, resources, and ongoing investment to comply. The regulations require manufacturers to establish validated systems to ensure that products meet high standards of sterility, purity and potency. The requirements apply to all stages of the manufacturing process, including the synthesis, processing, sterilization, packaging, labeling, storage and shipment of the biological product. The regulations require investigation and correction of any deviations from cGMP and impose documentation requirements upon us and any third party manufacturers that we may decide to use. Manufacturing establishments are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner. We or our present or future suppliers may not be able to comply with cGMP and other FDA regulatory requirements.

In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. We, our collaborators or third party contract manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new 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;
- refusal to permit the import or export of products;

- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action in the United States or abroad. We and our product candidates are also subject to a variety of state laws and regulations in those states or localities where they are or will be marketed. Any applicable state or local regulations may hinder our ability to market our product candidates in those states or localities.

BioThrax lot release and FDA review

Because of the complex manufacturing processes for most biological products, the FDA requires that each product lot of an approved biologic, including vaccines, undergo thorough testing for purity, potency, identity and sterility. Before a lot of BioThrax can be used, we must submit a sample of the vaccine lot and a lot release protocol to the FDA. The lot release protocol documents reflect the results of our tests for potency, safety, sterility and any additional assays mandated by our BLA for BioThrax and a summary of relevant manufacturing details. The FDA reviews the manufacturing and testing information provided in the lot release protocol and may elect to perform confirmatory testing on lot samples that we submit. We cannot distribute a lot of BioThrax until the FDA releases it. The length of the FDA review process depends on a number of factors, including reviewer questions, license supplement approval, reviewer availability, and whether our internal testing of product samples is completed before or concurrently with FDA testing.

Biologics review for BioThrax

The NIH originally approved the manufacture and sale of BioThrax in 1970 pursuant to the regulatory process in effect at the time. In 1972, responsibility for approving biological products was transferred from the NIH to the FDA. Following that transfer of responsibility, the FDA established procedures for reviewing the safety, efficacy and labeling of biological products, including BioThrax, that had been approved by the NIH prior to July 1, 1972. Under the biologics review process, the FDA appointed advisory panels of independent experts to evaluate previously approved biologic products and to advise the FDA as to whether the products were safe, effective and not misbranded. After reviewing a particular panel's recommendation, the FDA publishes the panel's report, along with a proposed order recommending classification of the biological product into one of three categories: Category I, safe, effective and not misbranded; Category II, unsafe, ineffective or misbranded; or Category III, not within Category I or Category II because further studies are required. After a ninety-day comment period, the FDA reviews any comments and then publishes a final rule or order classifying the product at issue as Category I, II or III. Only after publishing a final order does the FDA then take action with respect to individual products. For example, if the biologics review determines that a specific product is not safe and effective, the FDA would initiate the process of revoking the approval for the product. Likewise, if further study is required before the status of a product can be determined, the sponsor would be required to come forward with additional data within prescribed time periods. The FDA completed the biologics review for BioThrax in 2005, classifying the product as Category I, safe, effective and not misbranded.

Regulation of immune globulin products

Products derived from humans, including our immune globulin candidates, are subject to additional regulation. The FDA regulates the screening and vaccination of human donors and the process of collecting source plasma. FDA regulations require that all donors be tested for suitability and provide informed consent prior to vaccination or collection of source plasma for the immune globulin. The vaccination and collection of source plasma may also be subject to Institutional Review Board approval or to an IND, depending on factors such as whether donors are to be vaccinated according to the vaccine's approved schedule. The FDA also regulates the process of testing, storage and processing of source plasma, which is used to manufacture immune globulin candidates for use in clinical trials and, after approval by the FDA, for commercial distribution.

Regulation related to bioterrorism counteragents and pandemic preparedness

Because some of our products or product candidates are intended for the treatment of diseases that may result from acts of bioterrorism or for pandemic preparedness, they may be subject to the specific requirements described below.

Project BioShield

The Project BioShield Act of 2004 provides expedited procedures for bioterrorism related procurement and awarding of research grants, making it easier for HHS to quickly commit funds to countermeasure projects. Project BioShield relaxes procedures under the Federal Acquisition Regulation for procuring up to $25 million of property or services used in performing, administering or supporting biomedical countermeasure research and development. In addition, if the Secretary of HHS deems that there is a pressing need, Project BioShield authorizes the Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts and cooperative agreements related to biomedical countermeasure research and development activity. This power is limited to awards of $1.5 million or less.

Under Project BioShield, the Secretary of HHS, with the concurrence of the Secretary of the Department of Homeland Security and upon the approval of the President, can contract to purchase unapproved countermeasures for the strategic national stockpile in specified circumstances. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the strategic national stockpile is paid on delivery of a substantial portion of the countermeasure. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there is sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. 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. To exercise this authority, the Secretary of HHS must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- the product may reasonably be believed to be effective in detecting, diagnosing, treating or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks;
- there is no adequate alternative to the product that is approved and available; and
- any other criteria prescribed in regulations are met.

Although this provision permits the Secretary of HHS to circumvent the FDA approval process, its use would be limited to rare circumstances. We cannot predict whether these authorities would be applicable to any of our current product candidates.

Safety Act

The Safety Act enacted by the U.S. Congress in 2002 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 United States 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 sales of BioThrax are subject to the protections of the Safety Act, our product candidates may not qualify for the protections of the Safety Act or the government contractor defense.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act enacted by the U.S. Congress in 2005 provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products," including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. In the declaration, the Secretary may recommend the manufacture, administration or use of one or more countermeasures. Once the Secretary issues a declaration invoking the immunity provisions of the Act for the specified countermeasures, immunity applies with regard to administration or use of those countermeasures during the effective period of the declaration and for the diseases specified in the declaration. However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. A declaration also triggers the establishment of a compensation program. If Congress funds the compensation program, persons injured by a qualified countermeasure must first seek compensation under the program before they may bring a suit alleging willful misconduct. We cannot predict whether our products or product candidates would fall within the provisions of this law, whether Congress would fund the relevant compensation program or if the necessary prerequisites for immunity would be triggered.

Foreign regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The actual time required to obtain clearance to market a product in a particular foreign jurisdiction may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product candidate and the specific requirements of that jurisdiction. The requirements governing the

conduct of clinical trials, marketing authorization, pricing and reimbursement vary from country to country.

In the European Union, our products are subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products has for many years been subject to the granting of marketing authorizations by regulatory agencies. European Union member states require both regulatory clearance and a favorable ethics committee opinion prior to the commencement of a clinical trial, whatever its phase. Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is currently mandatory for products developed by means of a biotechnological process, including recombinant DNA technology, the controlled expression of genes coding for biologically active proteins and monoclonal antibody methods, and new chemical entities for the treatment of acquired immune deficiency syndrome, cancer and neurodegenerative disorder or diabetes. Beginning in May 2008, the centralized procedure will be mandatory for products for the treatment of auto-immune diseases and other immune dysfunctions and viral diseases. The centralized process is optional for medicines that constitute a “significant therapeutic, scientific or technical innovation” or for which a centralized process is in the interest of patients.

The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and an assessment report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Unlike the United States, the European Union member states do not have separate rules or review procedures for biologics and vaccines. Regulators apply broadly consistent principles and standards when reviewing applications, although they accept that the nature of the efficacy data supporting a vaccine application is likely to differ from the data that would support applications for the majority of therapeutic products. However, there are special procedures for some types of vaccine products. For example, influenza vaccines are subject to accelerated review and approval each year, following the release by the World Health Organization of the annual influenza strains. European Union member states have the discretion to require that marketing authorization holders submit samples of live vaccines or other immunological products for examination and formal batch release by a government control laboratory prior to release onto the market.

Orphan drugs

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the United States. A vaccine also can receive these incentives if it is expected to be administered to fewer than 200,000 persons per year. Sponsors may request that the FDA grant a drug orphan designation prior to approval. Biologics may qualify for designation as an orphan drug.

Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity prevents FDA approval of applications by others for the same drug or biologic intended for use for the designated orphan disease or condition. The FDA may approve a

subsequent application from another person if the FDA determines that the application is for a different product or different use, or if the FDA determines that the subsequent product is clinically superior or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug or biologic to meet the public's need. The FDA also may approve another application for the same drug or biologic that has orphan exclusivity but for a different use, in which case the competing drug or biologic could be prescribed by physicians outside its FDA approval for the orphan use notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved.

The European Union operates an equivalent system to encourage the development and marketing of medicinal products for rare diseases. Applications for orphan designations are submitted to the European Medicines Agency and reviewed by a Committee on Orphan Medicinal Products, comprising representatives of the member states, patient groups and other persons. The final decision is made by the European Commission.

A product can be designated as an orphan drug if it is intended for either a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Community when the application is made or a life-threatening, seriously debilitating or serious and chronic condition in the European Community for which, without incentives, it is unlikely that the marketing of the product in the Community would generate sufficient return to justify the necessary investment. In either case, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

After a marketing authorization has been granted in the European Community for an orphan product, no similar product may be approved for a period of ten years. At the end of the fifth year, however, any member state can initiate proceedings to restrict that period to six years if it believes the criteria for orphan designation no longer apply, for example, because the prevalence of disease has increased or the manufacturer is earning an unreasonable profit. In addition, competitive products can be approved during the marketing exclusivity period if they are not similar to the original product or are safer, more effective or otherwise clinically superior to it.

None of our products or product candidates have been designated as orphan drugs.

Reimbursement and pricing controls

In many of the markets where we or our potential collaborators would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to reimbursement programs with varying price control mechanisms.

In the United States, there has been an increased focus on drug and biologic pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on specified drugs and biologics to enable them to be eligible for reimbursement under public health care programs such as Medicaid. Vaccines are generally exempt from these programs. Various states have adopted further mechanisms that seek to control drug and biologic prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. 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.

Public and private health care payors control costs and influence drug and biologic pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to particular products over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug or biologic that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses that are either approved by the FDA or that are supported by other appropriate evidence, such as published medical literature, and appear in a recognized compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

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 United States, pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. The CDC currently distributes pediatric grant funding on a discretionary basis under the Public Health Service Act. Federal and state governments purchase the majority of all pediatric vaccines produced in the United States, primarily through the Vaccine for Children Program implemented by the U.S. Congress in 1994. The Vaccine for Children Program is designed to help pay for vaccinations to disadvantaged children, including uninsured children, children on Medicaid and underinsured children who receive vaccinations at federally qualified health centers.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Regulations regarding government contracting

Our status as a government contractor in the United States and elsewhere means that we are also subject to various statutes and regulations, including the Federal Acquisition Regulation, which govern the procurement of goods and services by agencies of the United States and other countries. These governing statutes and regulations can impose stricter penalties than those normally applicable to commercial contracts, such as criminal and civil damages liability and suspension and debarment from future government contracting. In addition, pursuant to various statutes and regulations, our government contracts can be subject to unilateral termination or modification by the government for convenience in the United States and elsewhere, detailed auditing requirements, statutorily controlled pricing, sourcing and subcontracting restrictions and statutorily mandated processes for adjudicating contract disputes.

Vaccine Injury Compensation Program

Because the cost of vaccine related litigation had reduced significantly the number of manufacturers willing to sell childhood vaccines, the U.S. Congress enacted the National Childhood Vaccine Injury Act in 1986. The Vaccine Injury Compensation Program established under the Vaccine Injury Act is a no-fault compensation program funded by an excise tax on each dose of a covered vaccine and is designed to streamline the process of seeking compensation for those injured by childhood vaccines. The Vaccine Injury Act requires all individuals injured by a vaccine to go through the compensation program before pursuing other remedies. Although claimants can reject decisions issued under the compensation program and pursue subsequent legal action through the courts, the Vaccine Injury Act determines the circumstances under which a manufacturer may be found liable in a civil action. The Vaccine Injury Act may not protect us if our products or product candidates cause injury.

Hazardous materials and select agents

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 and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. 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.

In particular, this legislation and related regulations require that we:

- develop and implement biosafety, security and emergency response plans;
- restrict access to select agents and toxins;
- provide appropriate training to our employees for safety, security and emergency response;
- comply with strict requirements governing transfer of select agents and toxins;
- provide timely notice to the government of any theft, loss or release of a select agent or toxin; and
- maintain detailed records of information necessary to give a complete accounting of all activities related to select agents and toxins.

Other regulations

In the United States and elsewhere, the research, manufacturing, distribution, sale and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of HHS, such as the Office of Inspector General, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice and state and local governments. For example, sales, marketing and scientific and educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with

the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Outside the United States, advertising and promotion of medicinal products, along with associated commercial practices, are often subject to significant government regulation. We are subject to the Export Administration Regulations implemented by the Bureau of Industry and Security governing the export of BioThrax and technology for the development and use of pathogens and toxins in the development and manufacture of BioThrax and our product candidates. In connection with our international sales activity, we are also subject to export regulations and other sanctions imposed by the Office of Foreign Assets Control of the Department of the Treasury, the antiboycott provisions of the Export Administration Act and the Internal Revenue Code and the Foreign Corrupt Practices Act.

Litigation

BioThrax product liability litigation. On October 14, 2005, January 9, 2006 and January 17, 2006, we were named as a defendant in three federal lawsuits filed on behalf of three individuals 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 each of these three lawsuits claimed different injuries and sought varying amounts of damages. The first plaintiff alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million. The second plaintiff alleged that the vaccine caused Bell's palsy and other related conditions and requested damages in excess of $75,000. The third plaintiff alleged that the vaccine caused a condition that originally was diagnosed as encephalitis related to a gastrointestinal infection and caused him to fall into a coma for many weeks and requested damages in excess of $10 million.

We moved to dismiss these three lawsuits for lack of personal jurisdiction, or, in the alternative to transfer the lawsuits to federal court in Michigan. On October 27, 2006, one of these lawsuits was transferred to the U.S. District Court for the Western District of Michigan. On October 31, 2006, another of these lawsuits was dismissed for lack of jurisdiction. The plaintiff in this lawsuit is entitled to appeal the decision or refile the lawsuit in a court that can properly exercise personal jurisdiction. These lawsuits are in the preliminary stages of litigation, and we believe that we are entitled to indemnification under our contract with the DoD for legal fees and any damages that may result from these claims. In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four other lawsuits asserting similar claims brought by approximately 120 individuals. These four lawsuits had previously been consolidated in the Michigan District Court.

The District Court's ruling in the consolidated Michigan 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 United States 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. We intend to rely on similar defenses with respect to the substantive claims asserted in our pending lawsuits. We also expect

to rely on contractual indemnification provisions with the DoD and statutory protections to limit our potential liability resulting from the pending lawsuits.

MilVax 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. On October 27, 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. On February 9, 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. Although we are not a party to this lawsuit, if the District Court institutes another injunction or otherwise restricts the administration of BioThrax by the DoD, the amount of future purchases of BioThrax by the DoD could be limited. In October 2006, the DoD announced that it is resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency-essential and comparable civilian personnel.

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 United States 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 41 lawsuits pending in two jurisdictions: four in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines and immune globulins. 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. One plaintiff in a thimerosal lawsuit alleges that he was injured by immune globulin containing thimerosal. We previously manufactured human immune globulin that contained thimerosal. We no longer manufacture any products that contain thimerosal. We believe that our defense costs for these thimerosal lawsuits will be covered by applicable product liability insurance and have submitted a request for coverage to our carriers for defense costs incurred to date.

Personnel

As of October 20, 2006, we had 470 employees, including 123 employees engaged in product development, 243 employees engaged in manufacturing, six employees engaged in sales and marketing and 98 employees engaged in general and administrative activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

Management

Our executive officers and directors and their respective ages and positions as of October 20, 2006 are as follows:

Name	Age	Position
Fuad El-Hibri	48	President, Chief Executive Officer and Chairman of the Board of Directors
Edward J. Arcuri, Ph.D.	55	Executive Vice President and Chief Operating Officer
Robert G. Kramer, Sr.	49	President and Chief Executive Officer, Emergent BioDefense Operations Lansing Inc.
Steven N. Chatfield, Ph.D.	49	President, Emergent Product Development UK Limited, and Chief Scientific Officer
Daniel J. Abdun-Nabi	52	Senior Vice President Corporate Affairs, General Counsel and Secretary
Kyle W. Keese	44	Senior Vice President Marketing and Communications
Thomas K. Zink, M.D.	50	Senior Vice President and Chief Medical Officer
R. Don Elsey	53	Vice President Finance, Chief Financial Officer and Treasurer
Joe M. Allbaugh	55	Director
Zsolt Harsanyi, Ph.D.(1)(2)(3)	62	Director
Jerome M. Hauer	54	Director
Shahzad Malik, M.D.(1)(2)	39	Director
Ronald B. Richard(1)(2)(3)	50	Director
Louis W. Sullivan, M.D.	72	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

Fuad El-Hibri. Mr. El-Hibri has served as chief executive officer and as chairman of our board of directors since June 2004 and as president since March 2006. Mr. El-Hibri served as chief executive officer and chairman of the board of directors of BioPort Corporation from May 1998 until June 2004, when, as a result of our corporate reorganization, BioPort became a wholly owned subsidiary of Emergent. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc. Mr. El-Hibri served as chairman of Digicel Holdings, Ltd., a privately held telecommunications firm, from August 2000 to October 2006. He served as president of Digicel from August 2000 to February 2005. Mr. El-Hibri has served as chairman of East West Resources Corporation, a venture capital and financial consulting firm, since June 1990. He served as president of East West Resources from September 1990 to January 2004. Mr. El-Hibri is a member of the board of trustees of American University and a member of the board of directors of the International Biomedical Research Alliance, an academic joint venture among the NIH, Oxford University and Cambridge University. He also serves as chairman and treasurer of El-Hibri Charitable Foundation. Mr. El-Hibri received a master’s degree in public and private management from Yale University and a B.A. in economics from Stanford University.

Edward J. Arcuri, Ph.D. Dr. Arcuri has served as executive vice president and chief operating officer since January 2005. Dr. Arcuri served as senior vice president of manufacturing operations from September 2003 to January 2005 and senior vice president of vaccine manufacturing from January 2002 to September 2003 for MedImmune, Inc., a biotechnology company. Dr. Arcuri served as senior vice president, operations from May 1999 to January 2002, vice president, manufacturing from July 1999 to May 2000 and chief operating officer from May 2001 to January 2002 at Aviron, Inc., a biotechnology company, which was acquired by MedImmune in January 2002. Prior to joining Aviron, Dr. Arcuri served in various management positions at North American Vaccine, Inc., Merck & Co. and SmithKline Beecham Pharmaceuticals, formerly SmithKline & French Laboratories. Dr. Arcuri received both a Ph.D. and an M.S. in biology from Rensselaer Polytechnic Institute and a B.S. in biology from the State University of New York at Albany.

Robert G. Kramer, Sr. Mr. Kramer has served as president and chief executive officer of Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, since July 2004. Mr. Kramer served as chief financial officer of BioPort from February 1999 to August 2000, as chief operating officer of BioPort from September 2000 to June 2004 and as president of BioPort from October 2001 to June 2004. Prior to joining BioPort, Mr. Kramer served in various financial management positions at Pharmacia Corp., which was subsequently acquired by Pfizer Inc., and with subsidiaries of Northwest Industries. Mr. Kramer received an M.B.A. from Western Kentucky University and a B.S. in industrial management from Clemson University.

Steven N. Chatfield, Ph.D. Dr. Chatfield has served as chief scientific officer since January 2005 and as president of our wholly owned subsidiary, Emergent Product Development UK Limited, since June 2005. Dr. Chatfield served as development director and chief scientific officer of Microscience Limited, a U.K. biotechnology company, from March 1999 to December 2004. We acquired Microscience in June 2005. Prior to joining Microscience, Dr. Chatfield held various positions in the field of vaccine research and development, including director of biotechnology at Medeva plc, director of research at Evans Medical and several positions at Wellcome Biotechnology and the Wellcome Foundation. Dr. Chatfield received a Ph.D. from the Council for National Academic Awards in association with the University of Birmingham in the United Kingdom.

Daniel J. Abdun-Nabi. Mr. Abdun-Nabi has served as senior vice president corporate affairs, general counsel and secretary since December 2004. Mr. Abdun-Nabi served as vice president and general counsel from May 2004 to December 2004. Mr. Abdun-Nabi served as general counsel for IGEN International, Inc., a biotechnology company, and its successor BioVeris Corporation, from September 1999 to May 2004. Prior to joining IGEN, Mr. Abdun-Nabi served as senior vice president, legal affairs, general counsel and secretary of North American Vaccine, Inc. Mr. Abdun-Nabi received an L.L.M. in taxation from Georgetown University Law Center, a J.D. from the University of San Diego School of Law and a B.A. in political science from the University of Massachusetts, Amherst.

Kyle W. Keese. Mr. Keese has served as senior vice president marketing and communications since March 2006. Mr. Keese served as vice president of sales and marketing of Emergent from June 2004 to March 2006 and of BioPort Corporation from June 2003 to June 2004. Mr. Keese served as vice president, business development for Antex Biologics, Inc., a biotechnology company, from March 2001 to May 2003, when we acquired substantially all of the assets of Antex. Prior to joining Antex, Mr. Keese served in various business development, marketing and sales management positions at IGEN International and Abbott Laboratories and as an officer in the U.S. Navy. Mr. Keese received an M.B.A. from National University and a B.A. in mathematics and computer science from Tulane University.

Thomas K. Zink, M.D. Dr. Zink has served as senior vice president of medical affairs and chief medical officer since May 2006. Dr. Zink served as the director of immunization practices and scientific affairs of

GlaxoSmithKline Vaccines, USA, a subsidiary of GlaxoSmithKline plc**,** a pharmaceutical company, from September 1999 to November 2004. After leaving GlaxoSmithKline and prior to joining Emergent, Dr. Zink served as a pro bono consultant on issues of patient safety and consumer-driven healthcare. Prior to joining GlaxoSmithKline, Dr. Zink served as the medical director for Prudential HealthCare of Kansas City, Missouri Region and as the chief medical officer of the Medicare Peer Review Organization of the State of Missouri. Dr. Zink also spent over a decade as a practicing physician specializing in emergency medicine. Dr. Zink received his joint B.A./M.D. from the University of Missouri-Kansas City and holds a current medical license as a physician and surgeon in good standing.

R. Don Elsey. Mr. Elsey has served as chief financial officer since March 2006 and as vice president finance and treasurer since June 2005. Mr. Elsey served as the director of finance and administration at IGEN International, Inc., a biotechnology company, and its successor BioVeris Corporation, from April 2000 to June 2005. Prior to joining IGEN, Mr. Elsey served as director of finance at Applera, a genomics and sequencing company, and in several finance positions at International Business Machines, Inc. Mr. Elsey received an M.B.A. in finance and a B.A. in economics from Michigan State University. Mr. Elsey is a certified management accountant.

Joe M. Allbaugh. Mr. Allbaugh has served as a director since June 2006. Mr. Allbaugh has served as president of Ecosphere Systems, Inc., a subsidiary of Ecosphere Technologies, a technology company serving the homeland security, disaster response and defense markets, since September 2006. Mr. Allbaugh has served as president and chief executive officer of The Allbaugh Company, LLC, a corporate strategy and consulting services firm, since March 2003. Mr. Allbaugh served as director of the Federal Emergency Management Agency from February 2001 to March 2003. Previously, Mr. Allbaugh served as deputy secretary of transportation of the Oklahoma Department of Transportation and manager of a number of state and federal political campaigns. Mr. Allbaugh serves on the boards of directors of Citadel Security Software Inc., a publicly held enterprise security software company, and UltraStrip Systems, Inc., a publicly held technology company in the defense, homeland security and global ship repair markets. Mr. Allbaugh also serves on the board of advisors of Compressus Inc., a privately held software company. Mr. Allbaugh received a B.A. in political science from the Oklahoma State University.

Zsolt Harsanyi, Ph.D. Dr. Harsanyi has served as a director since August 2004. Dr. Harsanyi has served as chief executive officer and chairman of the board of directors of Exponential Biotherapies Inc., a private biotechnology company, since December 2004. Dr. Harsanyi served as president of Porton International plc, a pharmaceutical and vaccine company, from January 1983 to December 2004. Dr. Harsanyi was a founder of Dynport Vaccine Company LLC in September 1996. Prior to joining Porton International, Dr. Harsanyi was vice-president of corporate finance at E.F. Hutton, Inc. Previously, Dr. Harsanyi directed the first assessment of biotechnology for the U.S. Congress' Office of Technology Assessment, served as a consultant to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and was on the faculties of Microbiology and Genetics at Cornell Medical College. Dr. Harsanyi received a Ph.D. from Albert Einstein College of Medicine and a B.A. from Amherst College.

Jerome M. Hauer. Mr. Hauer has served as a director since June 2005. Mr. Hauer has served as chief executive officer at The Hauer Group, a consulting services firm, since March 2006. Mr. Hauer served as senior vice president and co-chair of the homeland security practice of Fleishman-Hillard Government Relations, a government relations service firm, from January 2005 to March 2006. Prior to joining Fleishman-Hillard, Mr. Hauer served as the director of Response to Disaster and Emergencies Institute and assistant professor at the George Washington University School of Public Health from November 2003 to December 2004. Mr. Hauer served as acting assistant secretary for public health emergency preparedness of HHS from June 2002 to November 2003 and as director of the office of public health preparedness of HHS from May 2002 to June 2002. He also served as managing director of the crisis and consequence management group at Kroll Associates, a risk consulting firm, from October 2000 to February 2002.

Mr. Hauer served as the first director of the New York City Mayor's Office of Emergency Management under Mayor Rudolph Giuliani. He also served as the director of Emergency Medical Services and Emergency Management as well as director of the Department of Fire and Buildings for the State of Indiana under Governor Evan Bayh. Mr. Hauer serves on the board of directors of Hollis Eden Pharmaceuticals, Inc., a publicly held pharmaceutical company. Mr. Hauer previously served as a member of the Health Advisory Board of the Johns Hopkins School of Public Health and as a member of the National Academy of Science's Institute of Medicine's Committee to Evaluate the R&D Needs for Improving Clinical Medical Response to Chemical or Biological Terrorism Incidents. Mr. Hauer received an M.H.S. in public health from Johns Hopkins University School of Hygiene and Public Health and a B.A. from New York University.

Shahzad Malik, M.D. Dr. Malik has served as a director since June 2005. Dr. Malik has served as a general partner of Advent Venture Partners, a venture capital firm, since April 1999. Prior to joining Advent Venture Partners, Dr. Malik spent two years at McKinsey & Company where he focused on healthcare and investment banking and six years as a practicing physician specializing in cardiology. Dr. Malik also serves on the board of directors for several private biotechnology companies. Dr. Malik received his M.D. from Cambridge University and an M.A. in physiological sciences from Oxford University.

Ronald B. Richard. Mr. Richard has served as a director since January 2005. Mr. Richard has served as the president and chief executive officer of the Cleveland Foundation, the nation's oldest community foundation, since June 2003. From August 2002 to February 2003, Mr. Richard served as president of Stem Cell Preservation, Inc., a start-up medical research company. After leaving Stem Cell Preservation and prior to joining Emergent, Mr. Richard served as a strategic business advisor for IGEN International, Inc., a biotechnology company. Mr. Richard served as chief operating officer of In-Q-Tel, a venture capital fund that provides technologies to the Central Intelligence Agency, from March 2001 to August 2002. Prior to joining In-Q-Tel, Mr. Richard served in various senior management positions at Matsushita Electric Industrial Co., a consumer electronics company. Mr. Richard is a former U.S. foreign service officer. He served in Osaka/Kobe, Japan and as a desk officer for North Korean, Greek and Turkish affairs at the U.S. Department of State in Washington, D.C. Mr. Richard previously served as chairman of the board of trustees of the International Biomedical Research Alliance, an academic joint venture among the NIH, Oxford University and Cambridge University. Mr. Richard received an M.A. in international relations from Johns Hopkins University School of Advanced International Studies and a B.A. in history from Washington University. He holds an honorary doctorate in humane letters from Notre Dame College.

Louis W. Sullivan, M.D. Dr. Sullivan has served as a director since June 2006. Dr. Sullivan has served as president emeritus of Morehouse School of Medicine since July 2002. Dr. Sullivan served as president of Morehouse School of Medicine from 1981 to 1989 and from 1993 to 2002. From 1989 to 1993, Dr. Sullivan was Secretary of HHS. Dr. Sullivan also serves on the boards of directors of United Therapeutics Corporation, BioSante Pharmaceuticals, Inhibitex, Inc. and Henry Schein, Inc., publicly traded biotechnology companies. He is a founder and chairman of Medical Education for South African Blacks, Inc., a trustee of Morehouse School of Medicine and Africare and a director of the National Center on Addiction and Substance Abuse at Columbia University. Dr. Sullivan recently retired from the boards of directors of Bristol-Myers Squibb Company, 3-M Corporation, Georgia Pacific Corporation, Cigna Corporation and Equifax, Inc. Dr. Sullivan received his M.D. from Boston University and a B.S. from Morehouse College.

Board composition and election of directors

Our board of directors is currently authorized to have and currently has seven members. Upon completion of this offering, our board of directors will be divided into three classes, each of whose members will serve for staggered three-year terms:

- Mr. El-Hibri, Mr. Hauer and Mr. Richard will serve as class I directors, and their terms will expire at our 2007 annual meeting;
- Dr. Harsanyi and Dr. Sullivan will serve as class II directors, and their terms will expire at our 2008 annual meeting; and
- Mr. Allbaugh and Dr. Malik will serve as class III directors, and their terms will expire at our 2009 annual meeting.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

Until the fifth anniversary of the completion of this offering, any change in the number of directors serving on our board and the appointment and removal of the chairman of our board will require the vote of at least 75% of the directors then in office. Our directors may be removed from office only for cause and only by the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote. Mr. El-Hibri, through his ownership interests in our common stock and voting arrangements among our significant stockholders, will be able to control the election of directors following this offering. See “Description of capital stock — Anti-takeover effects of Delaware law and our certificate of incorporation and by-laws.”

Under the rules of the New York Stock Exchange, a director will only qualify as “independent” if our board of directors affirmatively determines that he has no material relationship with us, either directly or as a partner, stockholder or officer of an organization that has a relationship with us. Our board of directors has established guidelines to assist it in determining whether a director has a material relationship with us. Under these guidelines, a director is not considered to have a material relationship with us if he is independent under Section 303A.02(b) of the NYSE Listed Company Manual, even if he:

- is an executive officer of another company which is indebted to us, or to which we are indebted, unless the total amount of either company’s indebtedness to the other is more than one percent of the total consolidated assets of the company he serves as an executive officer; or
- serves as an officer, director or trustee of a tax exempt organization to which we make contributions, unless our discretionary charitable contributions to the organization are more than the greater of $1 million or 2% of that organization’s consolidated gross revenues. Our matching of employee charitable contributions would not be included in the amount of our contributions for this purpose.

In addition, ownership of a significant amount of our stock, by itself, does not constitute a material relationship.

For relationships not covered by the guidelines set forth above, the determination of whether a material relationship exists is made by the other members of the board of directors who are independent.

Applying the guidelines described above, our board of directors has affirmatively determined that the following directors are independent: Mr. Allbaugh, Dr. Harsanyi, Dr. Malik, Mr. Richard and Dr. Sullivan. We refer to these directors as our “independent directors.” There are no family relationships among any of our directors or executive officers.

In October 2006, Mr. Hauer was hospitalized with a serious, unexpected medical condition from which he is beginning to recover. We cannot determine when, or if, Mr. Hauer will be able or willing to resume active participation as a member of our board of directors.

Board committees

Audit committee

The members of our audit committee are Dr. Harsanyi, Dr. Malik and Mr. Richard. Dr. Harsanyi chairs the committee. Our audit committee assists our board of directors in its oversight of our accounting and financial reporting processes and the integrity of our financial statements, our compliance with legal and regulatory requirements, the audits of our financial statements and the qualifications, independence and performance of our independent registered public accounting firm.

Upon the completion of this offering, our audit committee's responsibilities will include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from our independent registered public accounting firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- establishing procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management; and
- preparing the audit committee report required by Securities and Exchange Commission rules.

All audit services to be provided to us and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Dr. Harsanyi and Dr. Malik qualify as "audit committee financial experts." We believe that the composition of our audit committee meets the requirements for independence under current New York Stock Exchange and Securities and Exchange Commission rules and regulations.

Compensation committee

The members of our compensation committee are Dr. Harsanyi, Dr. Malik and Mr. Richard. Mr. Richard chairs the committee. Our compensation committee assists the board of directors in the discharge of its responsibilities relating to the compensation of our executive officers and establishing and maintaining broad-based employee benefit plans and programs.

Upon the completion of this offering, our compensation committee's responsibilities will include:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of our chief executive officer;

- determining the compensation of our chief executive officer;
- reviewing and approving, or making recommendations to the board of directors with respect to, the compensation of our other executive officers;
- overseeing the evaluation of the performance of our senior executives;
- overseeing and administering our broad-based compensation programs and our cash and equity incentive plans;
- reviewing and making recommendations to the board of directors with respect to director compensation; and
- preparing the compensation committee report required by Securities and Exchange Commission rules.

Nominating and corporate governance committee

The members of our nominating and corporate governance committee are Dr. Harsanyi and Mr. Richard. Dr. Harsanyi chairs the committee.

Upon the completion of this offering, our nominating and corporate governance committee's responsibilities will include:

- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors or to fill vacancies and to be appointed to each of the board's committees;
- overseeing an annual review by the board of directors with respect to management succession planning;
- developing and recommending to the board of directors corporate governance principles and guidelines; and
- overseeing an annual evaluation of the board of directors.

Compensation committee interlocks and insider participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee has ever been our employee.

Director compensation

Under our director compensation program, we pay each of our non-employee directors an annual retainer of $20,000 for service as a director. Each non-employee director also receives a fee for each board and committee meeting attended. The board meeting fee is $1,500 for attendance in person and $500 for attendance by telephone. The audit committee meeting fee is $1,500 for attendance in person and $500 for attendance by telephone. The compensation committee meeting fee is $1,000 for attendance in person and $300 for attendance by telephone. The nominating and corporate governance committee meeting fee is $1,000 for attendance in person and $300 for attendance by telephone. Each member of our audit committee receives an additional annual retainer of $5,000. Each member of our

compensation committee receives an additional annual retainer of $3,000. Each member of our nominating and corporate governance committee receives an annual retainer of $3,000. We reimburse our non-employee directors for out-of-pocket expenses incurred in connection with attending our board and committee meetings.

Under the director compensation program, we have granted a non-qualified option to purchase 43,156 shares of our class B common stock to each of our independent directors, unless the director's appointment was pursuant to any transaction or other arrangement requiring such appointment, and to each of our non-employee directors who does not qualify as an independent director if our board of directors determined that the option grant was necessary to attract such non-employee director to join the board. These options vest over three years and expire ten years from the date of grant, subject to the director's continued service as a director. Upon a change in control, as defined in each director stock option agreement, we will have the option to purchase and redeem all the options owned by the director, or held for the benefit of the director, for a purchase price equal to the difference between the option exercise price and the fair market value. In the event we exercise such repurchase option, any unvested options will be deemed fully vested on the day preceding the date of repurchase.

We have granted the following non-qualified stock options to our independent and non-employee directors:

- On December 1, 2004, we granted a stock option to purchase 43,156 shares at an exercise price of $2.74 per share to Dr. Harsanyi.
- On January 26, 2005, we granted a stock option to purchase 43,156 shares at an exercise price of $2.74 per share to Mr. Richard.
- On June 15, 2005, we granted a stock option to purchase 43,156 shares at an exercise price of $3.50 per share to Mr. Hauer.
- On June 30, 2006, we granted a stock option to purchase 43,156 shares at an exercise price of $10.28 per share to Dr. Sullivan.
- On June 30, 2006, we granted a stock option to purchase 43,156 shares at an exercise price of $10.28 per share to Mr. Allbaugh.

Following the completion of this offering, pursuant to automatic option grants to non-employee directors under our 2006 stock incentive plan, we will grant each of our non-employee directors a nonstatutory option to purchase:

- 21,600 shares of common stock upon commencement of service on our board of directors;
- 14,400 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director after the annual meeting and has served on our board of directors for at least six months; and
- if the non-employee director is serving as the chair of one or more committees of our board of directors, an additional 7,200 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director after the annual meeting and has served on our board of directors for at least six months.

See "— Stock option and other compensation plans — 2006 stock incentive plan" for additional information regarding option grants to non-employee directors under our 2006 stock incentive plan.

Executive compensation

The following table sets forth a summary of the compensation paid or accrued during the year ended December 31, 2005 to our chief executive officer and to our four most highly compensated executive officers other than our chief executive officer who were serving as executive officers as of December 31, 2005. We refer to these individuals as our named executive officers.

Summary compensation table

Name and principal position	Annual compensation			Long-term compensation	All other compensation
	Salary	Bonus	Other annual compensation	Shares underlying options	
Fuad El-Hibri President, Chief Executive Officer and Chairman of the Board of Directors	$ 490,818	$ 237,215	$ —	215,782	$ 7,000(1)
Edward J. Arcuri, Ph.D. Executive Vice President and Chief Operating Officer	280,192	94,517	—	115,083	—
Robert G. Kramer, Sr. President and Chief Executive Officer, Emergent BioDefense Operations Lansing Inc.	371,192	140,816	—	115,083	7,000(1)
Steven N. Chatfield, Ph.D. President, Emergent Product Development UK Limited and Chief Scientific Officer	225,162	82,250	38,752(2)	57,542	—
Daniel J. Abdun-Nabi Senior Vice President Corporate Affairs, General Counsel and Secretary	272,631	110,400	—	—	7,000(1)

(1) Represents the value of our contributions on behalf of the named executive officer to our 401(k) savings plan.

(2) Represents a relocation payment of $15,000 and a living allowance of $23,752.

Stock option grants

The following table sets forth information regarding grants of stock options to purchase shares of our common stock to our named executive officers during the year ended December 31, 2005. Immediately prior to the completion of this offering, each outstanding option to purchase shares of our class B common stock automatically will become an option to purchase an equal number of shares of our common stock.

Potential realizable values are calculated using the initial public offering price of $12.50 per share and assuming that the market price appreciates from this price at the indicated rate for the entire term of each option and that each option is exercised and sold on the last day of its term at the assumed appreciated price. The assumed 5% and 10% rates of stock price appreciation are required by the rules of the Securities and Exchange Commission and do not represent our estimate or projection of the future price of our common stock. Actual gains, if any, on stock option exercises depend on the future performance of our common stock and the date on which the options are exercised.

Option grants in last fiscal year

Name	Number of shares underlying options granted	Percentage of total options granted to employees in fiscal year	Exercise price per share	Expiration date	Potential realizable value at assumed annual rates of stock price appreciation for option term(1)	
					5% ($)	10% ($)
Fuad El-Hibri	215,782(2)	30.0%	$ 3.50	5/25/10	$ 2,687,245	$ 3,588,751
Edward J. Arcuri, Ph.D.	115,083(3)	16.0	2.74	2/9/10	1,520,651	2,001,452
Robert G. Kramer, Sr.	115,083(2)	16.0	3.50	5/25/10	1,433,188	1,913,989
Steven N. Chatfield, Ph.D.	57,542(3)	8.0	2.74	2/9/10	760,332	1,000,735
Daniel J. Abdun-Nabi	—	—	—	—	—	—

(1) The dollar amounts under these columns are the result of calculations at rates set by the Securities and Exchange Commission and, therefore, are not intended to forecast possible future appreciation, if any, in the price of the underlying common stock.

(2) These options vest in three annual installments, with 40% of the original number of shares having vested on December 31, 2005 and 30% of the original number of shares vesting on each of December 31, 2006 and December 31, 2007.

(3) These options vest in three equal annual installments beginning on December 31, 2005.

Option exercises and year-end option values

The following table sets forth information regarding the number of shares of our common stock issued upon option exercises by our named executive officers during the year ended December 31, 2005 and the value realized by our named executive officers. In addition, the table sets forth information regarding the number and value of unexercised options held by our named executive officers at December 31, 2005. There was no public trading market for our common stock as of December 31, 2005. Accordingly, as permitted by the rules of the Securities and Exchange Commission, we have calculated the value of unexercised in-the-money options at December 31, 2005 assuming that the fair market value of our

common stock as of December 31, 2005 was equal to the initial public offering price of $12.50 per share, less the aggregate exercise price.

Aggregated option exercises in last fiscal year and fiscal year-end option values

Name	Number of shares acquired on exercise	Value realized	Number of securities underlying unexercised options at December 31, 2005		Value of unexercised in-the-money options at December 31, 2005	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Fuad El-Hibri	—	—	86,312	129,470	$ 776,808	$ 1,165,230
Edward J. Arcuri, Ph.D.	—	—	38,361	76,722	374,403	748,807
Robert G. Kramer, Sr.	—	—	513,561	69,050	6,211,644	621,450
Steven N. Chatfield, Ph.D.	—	—	19,181	38,361	187,207	374,403
Daniel J. Abdun-Nabi	—	—	74,516	31,936	727,276	311,695

Employment agreement with Steven Chatfield, Ph.D.

In September 2006, our wholly owned subsidiary, Emergent Product Development UK Limited, formerly Emergent Europe Limited, entered into an employment contract with Dr. Chatfield to serve as president of Emergent Product Development UK. Under this agreement, Dr. Chatfield is entitled to an annual base salary of £149,914, which may be reviewed annually in the discretion of Emergent Product Development UK. Dr. Chatfield is also eligible to participate in any bonus plan established by Emergent Product Development UK from time to time. Under the agreement, Emergent Product Development UK agreed to contribute 10% of Dr. Chatfield's salary, which amount will be capped at Inland Revenue Limits, in equal monthly installments to a qualified pension plan, subject to Dr. Chatfield making monthly contributions to the qualified pension plan in an amount equal to 2.5% of his salary. Either party may terminate the agreement upon not less than six months' prior written notice. Emergent Product Development UK may terminate Dr. Chatfield's employment without prior notice for conduct amounting to gross misconduct or any other equivalent conduct or performance issues. Emergent Product Development UK may terminate Dr. Chatfield's employment for cause, as defined in the agreement, upon providing the statutory minimum period of notice required under English law. Subject to any contrary provision of applicable law, Dr. Chatfield's employment will end automatically without the need for notice of termination at the end of the month in which Dr. Chatfield reaches the age of 65.

Under the agreement, Dr. Chatfield is entitled to protections substantially similar to those in our severance plan and termination protection program, except Dr. Chatfield is not entitled to a gross-up payment with respect to applicable taxes in the circumstances provided in the severance plan and termination protection program. See "— Severance plan and termination protection program" for additional information about our severance plan and termination protection program. If Emergent Product Development UK terminates Dr. Chatfield's employment without cause, as defined in the agreement, then Dr. Chatfield is entitled to 75% of his annual base salary and continued eligibility for employee benefits for a period of nine months following the date of termination. Dr. Chatfield is entitled to 100% of his annual base salary and continued eligibility for employee benefits for a period of 12 months following the date of termination of his employment under the circumstances described in the

severance plan and termination protection program in connection with a change of control, as defined in the agreement.

Under the terms of a prior employment contract with us, which has been superseded in all other respects, Dr. Chatfield remains subject to the following noncompetition obligations. Dr. Chatfield is prohibited from competing with us during the term of his employment and for a period thereafter of not less than six months and not more than 12 months as may be required by us, provided that we notify Dr. Chatfield in writing not less than three months prior to expiration of employment or any severance pay period, or in the event of termination by us for cause, at the time of termination, and that we continue to pay Dr. Chatfield 50% of his base salary in effect at termination during the additional period. Dr. Chatfield is also prohibited, during his term of employment and for a period of six months after termination of employment, from inducing or soliciting our employees, including any employees who left our employ within the previous six months, to leave our employ or inducing or soliciting customers, clients or business partners to reduce their relationship or breach their agreements with us. Dr. Chatfield is also bound by the terms of Emergent Product Development UK's standard non-disclosure, invention and assignment agreement.

Dr. Chatfield currently serves as our chief scientific officer pursuant to a letter agreement dated July 11, 2006.

Severance plan and termination protection program

In May 2006, our board of directors approved a severance plan and termination protection program effective April 1, 2006 for the benefit of employees with the title of chief executive officer, president, executive vice president, senior vice president or vice president who have been designated to participate in the severance plan by our board of directors or, with the authorization of our board of directors, by our chief executive officer. Our chief executive officer may designate the greater of 7% of the total number of our employees or 35 employees to be participants in the severance plan at any particular time, on the basis of name, title, function or compensation level. Our chief executive officer will at all times be a participant under the severance plan and shall have no less favorable rights under the severance plan than any other participant. Each of our executive officers based in the United States is currently a participant in the severance plan.

The severance plan is effective through December 31, 2009. Commencing on December 31, 2009, and on December 31 of each year thereafter, the severance plan will automatically extend for additional one-year periods unless we provide 90 days' prior written notice that the term will not be extended.

If during the term of the severance plan, we terminate a participant's employment without cause, as defined in the severance plan, then the participant will be entitled to:

- any unpaid base salary and accrued paid time-off through the date of termination;
- a pro rata target annual bonus in respect of the year of termination;
- any bonus earned but unpaid as of the date of termination for any previously completed year;
- reimbursement for any unreimbursed expenses incurred by the participant prior to the date of termination;
- an amount equal to a specified percentage of the participant's annual base salary;
- employee and fringe benefits and perquisites, if any, to which the participant may be entitled as of the date of termination under our relevant plans, policies and programs; and

- continued eligibility for the participant and his or her eligible dependents to receive employee benefits, for a stated period following the participant's date of termination, except when the provision of employee benefits would result in a duplication of benefits provided by any subsequent employer.

The following table sets forth the percentage of base salary and the stated period for continued employee benefits that each of our executive officers who participates in the plan is entitled if we terminate the executive officer's employment without cause.

Name	Percentage of annual base salary	Stated period for continued employee benefits
Fuad El-Hibri	150%	18 months
Robert G. Kramer, Sr.	100	12 months
Edward J. Arcuri, Ph.D.	100	12 months
Daniel J. Abdun-Nabi	100	12 months
Kyle W. Keese	100	12 months
Thomas K. Zink, M.D.	75	9 months
R. Don Elsey	75	9 months

We may pay any amount under the severance plan, in our sole and absolute discretion, either in a single lump sum amount within 30 days following termination or in equal monthly installments over the same stated period during which we have agreed to provide continued employee benefits to the terminated employee.

As a condition to payment of any amounts under the severance plan, the participant is required:

- for the same stated period during which we have agreed to provide continued employee benefits to the terminated employee, not to:
  - induce, counsel, advise, solicit or encourage our employees to leave our employ or to accept employment with any other person or entity,
  - induce, counsel, advise, solicit or encourage any person who we employed within six months prior to that time to accept employment with any person or entity besides us or hire or engage that person as an independent contractor,
  - solicit, interfere with or endeavor to cause any of our customers, clients or business partners to cease or reduce its relationship with us or induce any such customer, client or business partner to breach any agreement that such customer, client or business partner may have with us, and
  - engage in or have a financial interest in any business competing with us within any state, region or locality in which we are then doing business or marketing products;
- upon reasonable notice and at our expense, to cooperate fully with any reasonable request that may be made by us in connection with any investigation, litigation or other similar activity to which we are or may be a party or may otherwise be involved and for which the participant may have relevant information; and

- to sign and deliver a suitable waiver and release under which the participant will release and discharge us from and on account of any and all claims that relate to or arise out of our employment relationship.

In connection with our implementation of the severance plan, in August 2006, we agreed to the following modifications and clarifications to Mr. El-Hibri's contractual obligations and duties:

- Mr. El-Hibri's service as chairman of Digicel Holdings, which service terminated in October 2006, and his service as chairman of East West Resources, general manager of Intervac, L.L.C. and Intervac Management, L.L.C., a member of the board of trustees of American University, a member of the board of directors of the International Biomedical Research Alliance and director and treasurer of El-Hibri Charitable Foundation and his management of his personal investments at levels of time and attention comparable to those that Mr. El-Hibri provided to such entities within the preceding twelve months, do not violate his contractual obligations to us or interfere with his ability to perform his duties to us;
- it is not a violation of Mr. El-Hibri's contractual obligations to us if he pursues a business transaction or opportunity where such transaction or opportunity was first presented to Mr. El-Hibri in his capacity as an officer or director of the entities listed above or where such transaction or opportunity was first presented to us and our board of directors declined to pursue such transaction or opportunity; and
- with respect to three employees who, at Mr. El-Hibri's invitation, left their employment with East West Resources to accept employment with us, it is not a violation of Mr. El-Hibri's non-solicitation agreement to induce, counsel, advise, solicit or encourage, or attempt to induce, counsel, advise, solicit or encourage those employees to return to employment with East West Resources.

If during the term of the severance plan, we terminate a participant's employment with cause, then the participant will not be entitled to receive any compensation, benefits or rights under the severance plan, and any stock options or other equity participation benefits vested on or prior to the date of the termination, but not yet exercised, will immediately terminate.

If during the term of the severance plan, we terminate a participant's employment without cause or a participant resigns for good reason, as defined in the severance plan, in each case within 18 months following a change of control, as defined in the severance plan, or we terminate a participant's employment prior to a change of control, which subsequently occurs, at the request of a party involved in the change of control, or otherwise in connection with or in anticipation of a change of control, then the participant will be entitled to:

- a lump sum amount, payable within 30 days following the date of termination, equal to the sum of:
  - any unpaid base salary and accrued paid time-off through the date of termination,
  - a pro rata target annual bonus in respect of the year of termination,
  - any bonus earned but unpaid as of the date of termination for any previously completed year,
  - any unreimbursed expenses incurred by the participant prior to the date of termination, and
  - an amount equal to a specified percentage of the sum of the participant's base salary and the greater of the annual bonus that was paid to the participant in respect of the most recently completed year or the maximum annual bonus that could have been paid to the participant under an established bonus plan for the most recently completed year;

- employee and fringe benefits and perquisites, if any, to which the participant may be entitled as of the date of termination of employment under our relevant plans, policies and programs;
- any unvested stock options held by the participant that are outstanding on the date of termination will become fully vested as of that date, and the period, during which any stock options held by the participant that are outstanding on that date may be exercised, shall be extended to a date that is the later of the 15th day of the third month following the termination date, or December 31 of the calendar year in which the stock option would otherwise have expired if the exercise period had not been extended, but not beyond the final date the stock option could have been exercised if the participant's employment had not terminated, in each case based on the term of the option at the original grant date;
- continued eligibility for the participant and his or her eligible dependents to receive employee benefits, for a stated period following the participant's date of termination, except when the provision of employee benefits would result in a duplication of benefits provided by any subsequent employer;
- a gross-up payment with respect to applicable taxes on any payment to the participant;
- the retention for the maximum period permitted by applicable law of all rights the participant has to indemnification from us immediately prior to the change of control and the continuation throughout the period of any applicable statute of limitations of any director's and officer's liability insurance covering the participant immediately prior to the change of control; and
- the advancement to the participant of all costs and expenses, including attorney's fees and disbursements, incurred by the participant in connection with any legal proceedings that relate to the termination of employment or the interpretation or enforcement of any provision of the severance plan, for which the participant will have no obligation to reimburse us if the participant prevails in the proceeding with respect to at least one material issue or the proceeding is settled.

The following table sets forth the percentage of base salary and the stated period for continued employee benefits that each of our executive officers who participates in the plan is entitled under the circumstances described above in connection with a change of control.

Name	Percentage of annual base salary	Stated period for continued employee benefits
Fuad El-Hibri	250%	30 months
Robert G. Kramer, Sr.	200	24 months
Edward J. Arcuri, Ph.D.	200	24 months
Daniel J. Abdun-Nabi	150	18 months
Kyle W. Keese	100	12 months
Thomas K. Zink, M.D.	75	9 months
R. Don Elsey	75	9 months

Our chief executive officer may designate up to two participants for whom any reason for resigning within the 30-day period following the first anniversary of a change of control shall also constitute good reason. Mr. El-Hibri has been designated as a participant to receive this benefit.

All payments under the severance plan will be reduced by any applicable taxes required by applicable law to be paid or withheld by us. All payments and benefits provided under the severance plan are intended to either comply with or be exempt from Section 409A of the Internal Revenue Code. If at the time a participant's employment is terminated, the participant is a specified employee within the meaning of

Section 409A(a)(2)(B)(ii), then any payments to the participant that constitute non-qualified deferred compensation within the meaning of Section 409A will be delayed by a period of six months. All such payments that would have been made to the participant during the six-month period will be made in a lump sum in the seventh month following the date of termination, and all remaining payments will commence in the seventh month following the date of termination.

Our board of directors or any committee thereof designated by our board of directors is authorized to administer the plan and has authority to adopt, amend and repeal the administrative rules, guidelines and practices relating to the severance plan as it deems advisable.

Limitation of liability and indemnification

Our certificate of incorporation that will be in effect upon the completion of this offering limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the General Corporation Law of Delaware. Our certificate of incorporation provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of their duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for voting or assenting to unlawful payments of dividends or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act or failure to act, or any cause of action, suit or claim that would accrue or arise prior to any amendment or repeal or adoption of an inconsistent provision. If the General Corporation Law of Delaware is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the General Corporation Law of Delaware.

In addition, our certificate of incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to limited exceptions.

We have entered into agreements to indemnify our directors and executive officers. These agreements, among other things, provide that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as our director, officer, manager, employee, agent or representative and advance expenses, including attorneys' fees, to these individuals in connection with legal proceedings, subject to limited exceptions. The indemnification agreements also establish the procedures that will apply in the event a director or officer makes a claim for indemnification.

Stock option and other compensation plans

Employee stock option plan

Our employee stock option plan was adopted by our board of directors and approved by our stockholders on June 30, 2004 and amended and restated on January 26, 2005. We refer to this

employee stock option plan, as amended and restated, as our employee stock option plan. Our employee stock option plan became effective on the date that our board of directors adopted the plan. We assumed all options outstanding under the BioPort Corporation employee stock option plan as of June 30, 2004 and granted option holders replacement stock options to purchase an equal number of shares of our class B common stock under our employee stock option plan. Under our employee stock option plan, the exercise period for options under the BioPort Corporation employee stock option plan that would have otherwise expired on June 30, 2004 was extended to June 30, 2007. For incentive stock options, the extension of the exercise period caused the options to be considered non-qualified stock options after June 30, 2004. Under our employee stock option plan, 3,596,375 shares of our class B common stock are reserved for issuance. Our board of directors has authorized our compensation committee to administer our employee stock option plan. Immediately prior to the completion of this offering, each outstanding option to purchase shares of our class B common stock automatically will become an option to purchase an equal number of shares of our common stock, with no other changes to the option.

If a merger or other reorganization event occurs, options granted under our employee stock option plan may be substituted or assumed. In the event of our merger, consolidation or combination with or into another corporation, other than a merger, consolidation or combination in which we are the surviving corporation and which does not result in any reclassification or other change in the number of outstanding shares of our common stock, each option holder will have the right after the merger, consolidation or combination and during the term of the option to receive upon exercise of the option, for each share of common stock as to which the option could be exercised, the kind and amount of shares of the surviving or new corporation, cash, securities, evidence of indebtedness, other property or any combination which would have been received upon the merger, consolidation or combination by the holder of a share of common stock immediately prior to the merger, consolidation or combination. Upon the occurrence of a change in control, as defined in our employee stock option plan, we have the option to purchase and redeem from any option holder all the options owned by the option holder for a purchase price equal to the difference between the option exercise price and the fair market value of the common stock. In the event that we exercise our right to repurchase the options, any unvested options will be deemed fully vested on the day preceding the date we exercise our repurchase option. We may exercise this option at any time during the six-month period following the date of change in control or such longer period of time as is reasonable.

Under our employee stock option plan, no award may be granted under the plan after June 30, 2009, unless the plan is terminated sooner. Our board of directors may amend, suspend or discontinue the employee stock option plan at any time, except that stockholder approval will be required for any revision that would increase the number of shares reserved for issuance under the plan, or otherwise as required to comply with applicable law or stock market requirements. No amendment may materially impair any rights or materially increase any obligations of an option holder under an outstanding option without the consent of the option holder.

As of October 20, 2006, options to purchase 3,109,932 shares of our class B common stock at a weighted average exercise price of $2.54 were outstanding under our employee stock option plan, options to purchase 229,275 shares of class B common stock have been exercised and options to purchase 411,505 shares of class B common stock have been forfeited. After the effective date of our 2006 stock incentive plan, which is described below, we will grant no additional options under our employee stock option plan.

2006 stock incentive plan

Our 2006 stock incentive plan was adopted by our board of directors on October 25, 2006 and approved by our stockholders on October 27, 2006. The 2006 stock incentive plan will become effective immediately prior to the completion of this offering. The 2006 stock incentive plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock unit awards. Our 2006 stock incentive plan provides that 503,500 shares of common stock, plus the number of shares of common stock reserved for issuance under our existing employee stock option plan that remain available for grant immediately prior to the completion of this offering, will be reserved for issuance under the 2006 stock incentive plan immediately following this offering.

In addition, our 2006 stock incentive plan contains an "evergreen provision" that allows for increases in the number of shares available for issuance under our 2006 stock incentive plan on the first day of the first and third quarter of each year from 2007 though 2009. Each semi-annual increase in the number of shares will be equal to the lowest of a specified number of shares, a specified percentage of the aggregate number of shares outstanding and an amount determined by our board of directors. The following table sets forth the maximum specified number of shares and maximum specified percentage of outstanding shares for each semi-annual increase in the number of shares.

	Maximum specified number of shares	Maximum specified percentage of outstanding shares
First Quarter of 2007	428,700	1.5%
Third Quarter of 2007	463,200	1.5
First Quarter of 2008	926,400	3.0
Third Quarter of 2008	466,100	1.5
First Quarter of 2009	937,900	3.0
Third Quarter of 2009	471,800	1.5

Our employees, officers, directors, consultants and advisors are eligible to receive awards under our 2006 stock incentive plan. Incentive stock options may only be granted to our employees. The maximum number of shares of common stock with respect to which awards may be granted to any participant under the plan is 287,700 per fiscal year.

In accordance with the terms of the 2006 stock incentive plan, our board of directors has authorized our compensation committee to administer the plan. Our compensation committee selects the recipients of awards and determines:

- the number of shares of common stock covered by options and the dates upon which the options become exercisable;
- the exercise price of options, which may not be less than 100% of the fair market value of the stock on the date of grant;
- the duration of options, which may not be in excess of 10 years;
- the method of payment of the exercise price; and

- the number of shares of common stock subject to any stock appreciation right, restricted stock, restricted stock units or other stock-unit awards and the terms and conditions of such awards, including conditions for exercise, repurchase, issue price and repurchase price.

If our board of directors delegates authority to an executive officer, the executive officer has the power to make awards to all of our employees, except to executive officers. Our board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards and the maximum number of shares subject to awards that such executive officer may make.

Our 2006 stock incentive plan provides for an automatic grant of options to non-employee directors as follows:

- 21,600 shares of common stock, upon the commencement of service on our board of directors;
- 14,400 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director after the annual meeting and has served on our board of directors for at least six months; and
- if the non-employee director is serving as the chair of one or more committees of our board of directors, an additional 7,200 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director after the annual meeting and has served on our board of directors for at least six months.

Automatic option grants to directors will:

- have an exercise price equal to the closing sale price of the common stock on the New York Stock Exchange, the Nasdaq Stock Market or the national securities exchange on which the common stock is then traded on the trading date immediately prior to the date of grant, or the fair market value of the common stock on such date as determined by our board of directors, if the common stock is not then traded on the New York Stock Exchange, the Nasdaq Stock Market or on a national securities exchange;
- vest in three equal annual installments beginning on the anniversary of the date of grant provided that the individual is serving on our board of directors on such date, or, with respect to annual grants, on the date which is one business day prior to the date of our next annual meeting, if earlier, provided that no additional vesting will take place after the individual ceases to serve as a director and that our board of directors may provide for accelerated vesting in the case of death, disability, attainment of mandatory retirement age or retirement following at least 10 years of service;
- expire on the earlier of 10 years from the date of grant or three months following cessation of service on our board of directors; and
- contain other terms and conditions as our board of directors determines.

Our board of directors may increase or decrease the number of shares subject to automatic option grants to directors.

If a merger or other reorganization event occurs, our board of directors will provide that all of our outstanding options are to be assumed or substituted by the successor corporation. If the merger or reorganization event also constitutes a change in control event, as defined under our 2006 stock incentive plan, the assumed or substituted options will become immediately exercisable in full if on or prior to the first anniversary of the reorganization event an option holder’s employment with us or our succeeding corporation is terminated by the option holder for good reason or is terminated by us or the

succeeding corporation without cause, each as defined in our 2006 stock incentive plan. In the event the succeeding corporation does not agree to assume, or substitute for, outstanding options, then our board of directors will provide that all unexercised options will become exercisable in full prior to the completion of the merger or other reorganization event and that these options will terminate immediately prior to the completion of the merger or other reorganization event if not previously exercised. Our board of directors may also provide for a cash out of the value of any outstanding options. In addition, upon the occurrence of a change in control event that does not also constitute a reorganization event under our 2006 stock incentive plan, each option will continue to vest according to its original vesting schedule, except that an option will become immediately exercisable in full if on or prior to the first anniversary of the change in control event an option holder's employment with us or our succeeding corporation is terminated by the option holder for good reason or is terminated by us or our succeeding corporation without cause.

No award may be granted under the 2006 stock incentive plan after December 31, 2009, but the vesting and effectiveness of awards granted before that date may extend beyond that date. Our board of directors may amend, suspend or terminate the 2006 stock incentive plan at any time, except that stockholder approval will be required for any revision that would materially increase the number of shares reserved for issuance, expand the types of awards available under the plan, materially modify plan eligibility requirements, extend the term of the plan or materially modify the method of determining the exercise price of options granted under the plan, or otherwise as required to comply with applicable law or stock market requirements.

401(k) retirement plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution savings plan under Section 401(k) of the Internal Revenue Code. Substantially all of our employees are eligible to participate. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, equal to $15,000 in 2006, and have the amount of the reduction contributed to the 401(k) plan. We are permitted to match employees' 401(k) plan contributions. For the year ended December 31, 2005, we have elected to match 50% of the first 6% of the eligible employees' contributions to the 401(k) plan.

Rule 10b5-1 trading plans

We expect that many of our executive officers and directors will adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The officer or director may amend or terminate the plan in some circumstances. Our executive officers and directors may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information. Under the terms of the lock-up agreements that our executive officers and directors have signed with the underwriters for this offering, our executive officers and directors can enter into Rule 10b5-1 trading plans during the 180-day lock-up period, provided that such plan does not provide for any transfers of common stock during the lock-up period or any extension thereof pursuant to the lock-up agreement.

Certain relationships and related party transactions

Since January 1, 2003, we have engaged in the following transactions with our executive officers, directors and holders of more than 5% of our voting securities, and affiliates of our executive officers, directors and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Corporate reorganization

On June 30, 2004, we completed a corporate reorganization in which:

- Emergent BioSolutions Inc., a newly formed Delaware corporation, issued 18,666,479 shares of class A common stock to stockholders of BioPort Corporation in exchange for 18,017,994 shares of BioPort class A common stock and 648,485 shares of BioPort class B common stock;
- we repurchased and retired all other issued and outstanding shares of BioPort class B common stock; and
- we assumed all outstanding stock options to purchase BioPort class B common stock and granted option holders replacement stock options to purchase an equal number of shares of our class B common stock under our employee stock option plan.

As a result of this reorganization, BioPort became a wholly owned subsidiary of Emergent. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc.

Issuance of class A common stock

The following table sets forth the number of shares of our class A common stock that we issued to the former stockholders of BioPort in our corporate reorganization.

Name	Number of shares of class A common stock
Intervac, L.L.C.	8,314,819
BioPharm, L.L.C.	4,065,043
Michigan Biologic Products, Inc.	1,934,849
Biovac, L.L.C.	1,599,155
Biologika, L.L.C.	1,375,084
Intervac Management, L.L.C.	719,275
ARPI, L.L.C.	658,254

Intervac, BioPharm, Michigan Biologic Products, Biovac, Biologika, Intervac Management and ARPI are parties to a voting agreement dated June 30, 2004. We refer to these stockholders collectively as the voting group. Under the voting agreement, each stockholder in the voting group has agreed to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any matter as directed by a majority in interest of the voting group as measured by the aggregate percentage of ownership of our capital stock. Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, has the power to direct the voting of a majority in interest of the voting group. As a result, Mr. El-Hibri is considered the beneficial owner of all of the shares held by Intervac, BioPharm,

Michigan Biologic Products, Biovac, Biologika, Intervac Management and ARPI. See “Principal and selling stockholders” for additional information regarding the beneficial ownership of our common stock.

Grant of options to purchase class B common stock

The following table sets forth the number of shares of our class B common stock underlying options that we granted under our employee stock option plan to our executive officers and directors contemporaneously with our corporate reorganization.

Name	Number of shares of class B common stock underlying options granted
Robert G. Kramer, Sr.	467,528
Daniel J. Abdun-Nabi	106,452
Kyle W. Keese	43,156

Special cash dividend

On June 15, 2005, our board of directors declared a special cash dividend to the holders of our outstanding shares of common stock in an aggregate amount of approximately $5.4 million. Our board of directors declared this special dividend in order to distribute the net proceeds of a payment that we received as a result of the settlement of litigation that we initiated against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. We filed the lawsuit in 2002 in an effort to clarify intellectual property rights and recover royalties that we asserted were owed under a series of agreements regarding the development of botulinum toxin products. We paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. The following table sets forth the amount of the special cash dividend that we paid to our 5% stockholders and their affiliates.

Name		Amount of special cash dividend
Intervac, L.L.C.	$	2,402,864
BioPharm, L.L.C.		1,174,739
Michigan Biologic Products, Inc.		559,144
Biovac, L.L.C.		462,133
Biologika, L.L.C.		397,380
Intervac Management, L.L.C.		207,860
ARPI, L.L.C.		190,226

See “Principal and selling stockholders” for additional information regarding the beneficial ownership of our common stock.

Microscience acquisition

On June 23, 2005, we acquired all of the outstanding shares of capital stock of Microscience Limited from Microscience Investments Limited, formerly Microscience Holdings plc, in exchange for

3,636,801 shares of our class A common stock. We subsequently renamed Microscience Limited as Emergent Product Development UK Limited.

Registration rights

Upon the completion of this offering, holders of 22,303,280 shares of our common stock as of October 20, 2006 will have the right to require us to register these shares of common stock under the Securities Act, under specified circumstances. In connection with our acquisition of Microscience Limited, we granted to Microscience Investments registration rights with respect to the shares of our common stock that we issued to Microscience Investments in the acquisition. We also have granted registration rights with respect to shares of our common stock to the holders of our previously existing class A common stock, in addition to Microscience Investments. The following table sets forth the number of shares of our common stock subject to these registration rights that are held by our 5% stockholders and their affiliates.

Name	Number of shares of common stock
Intervac, L.L.C.	8,314,819
BioPharm, L.L.C.	4,065,043
Microscience Investments Limited	3,636,801
Michigan Biologic Products, Inc.	1,934,849
Biovac, L.L.C.	1,599,155
Biologika, L.L.C.	1,375,084
Intervac Management, L.L.C.	719,275
ARPI, L.L.C.	658,254

See “Description of capital stock — Registration rights” for additional information regarding these registration rights. See “Principal and selling stockholders” for additional information regarding the beneficial ownership of our common stock.

Consulting agreements

In January 2005, we entered into an agreement with Fleishman-Hillard Inc. under which Fleishman-Hillard provided us government relations, strategic consulting and communication services. Jerome Hauer, a member of our board of directors, was a senior vice president of Fleishman-Hillard until March 2006. Under the agreement, we have agreed to pay Fleishman-Hillard $20,000 per month for its services. The monthly fee increased to $30,000 per month in March 2005. We paid Fleishman-Hillard $342,663 in 2005 and $87,059 in the three months ended March 31, 2006 for these services. The agreement terminated on March 31, 2006.

In March 2006, we entered into an agreement with The Hauer Group under which The Hauer Group provides us strategic consulting and domestic marketing advice. Jerome Hauer is the chief executive officer of The Hauer Group. Mr. Hauer and his wife are the sole owners of The Hauer Group. Under the terms of the agreement, we agreed to pay The Hauer Group $15,000 per month for its services. The agreement expires on March 31, 2007.

In November 2004, we entered into a consulting services agreement with Yasmine Gibellini to provide public relations services. Ms. Gibellini is the sister of Fuad El-Hibri, our president, chief executive officer

and chairman of our board of directors. Under the agreement, we agreed to pay Ms. Gibellini $220 per hour for a maximum of 20 hours per week, as needed, for her services, the total of which was not to exceed $60,000, and reimburse her reasonable out-of-pocket expenses. The agreement expired in June 2005. In March 2005, we entered into a separate consulting agreement with Ms. Gibellini to provide sales and marketing services. We agreed to pay Ms. Gibellini $700 per day for a time commitment of approximately two to three days per week, as needed, for her services, the total of which was not to exceed $60,000, and reimburse her reasonable out-of-pocket expenses. In addition, we agreed to pay Ms. Gibellini a sales commission equal to 4% of BioThrax net sales, not to exceed $2.00 per dose, from contracts to any customer in which Ms. Gibellini had direct involvement. The agreement terminated on August 31, 2005. We paid Ms. Gibellini $39,353 in 2005 and $25,200 in 2006 under these agreements.

From September 2004 through November 2004, we retained Louis W. Sullivan, M.D., a member of our board of directors, to provide consulting services for a fixed fee of $25,000 per month.

Agreements with Intergen N.V.

In November 1997, Emergent BioDefense Operations entered into a marketing agreement, which was amended and restated in January 2000, with Intergen N.V. Yasmine Gibellini, the chairperson of Intergen N.V., is the sister of Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors. Ibrahim El-Hibri, the president of Intergen, is the father of Fuad El-Hibri. Ibrahim El-Hibri and his wife are the sole stockholders of Intergen. Under the agreement, Intergen is the sole and exclusive marketing representative for BioThrax and any other biodefense vaccine that Emergent BioDefense Operations becomes licensed to manufacture or sell in countries in the Middle East and North Africa, except Israel and those countries to which export is prohibited by the U.S. government. Under the agreement, we agreed to pay Intergen a fee equal to 40% of the gross sales in these countries. We have not paid Intergen any fee under the agreement. The term of the agreement is scheduled to expire in November 2007. The agreement will automatically extend for an additional five years if Emergent BioDefense Operations achieves $5.0 million of sales in the territory during the initial three-year term of the agreement.

In January 2000, Emergent BioDefense Operations entered into a termination and settlement agreement with Intergen. Under the agreement, Emergent BioDefense Operations is obligated to pay Intergen a $70,000 settlement payment when it receives more than $3.0 million pursuant to a contract for sale of anthrax vaccine to a party other than the U.S. government. The settlement payment is in consideration for Intergen’s agreement to terminate a consulting agreement entered into between the parties in November 1997 and reduce the scope of its rights under the marketing agreement described above. This settlement payment has not yet become due and has not been paid.

Agreements with East West Resources Corporation

In January 2004, Emergent BioDefense Operations entered into a consulting agreement with East West Resources Corporation under which East West Resources provided financial analysis, business modeling and corporate and business development consulting services. Fuad El-Hibri is the chairman of East West Resources and was president of East West Resources from September 1990 to January 2004. Fuad El-Hibri and his wife are the sole stockholders of East West Resources. The agreement terminated in September 2005. We paid East West Resources $180,000 in 2004 and $135,000 in 2005 under the agreement.

In January 2004, Emergent BioDefense Operations entered into an amended and restated sublease and office services agreement with East West Resources under which East West Resources leased us office

space in Rockville, Maryland and provided us administrative, transportation and logistics support. Under the agreement, we agreed to pay East West Resources monthly rent of $10,707. The monthly rent increased by 3% each year. In September 2004, we terminated in part the agreement with respect to the lease of office space for a settlement fee of $69,687, an amount equal to eight months' rent, including the 3% escalation fee, but excluding the portion of monthly rent applicable to transportation and logistics support. We paid East West Resources $120,000 in 2003, $173,647 in 2004, $33,750 in 2005 and $19,741 in the nine months ended September 30, 2006 under the agreement. The agreement expired on July 31, 2006.

In August 2006, we entered into a services agreement with East West Resources under which East West Resources agreed to provide us transportation and logistics support. Under the agreement, we agreed to pay East West Resources a fee of $2,450 per month and reimburse fees and expenses associated with these services. We paid East West Resources $5,482 in the nine months ended September 30, 2006 under the agreement. The term of the agreement ends on July 31, 2007. The agreement will automatically extend for additional successive terms of one year unless terminated by either party with at least 60 days' notice. Under the agreement, the monthly fee increases by 3% each year upon extension of the term.

Airplane charter from Simba LLC

From time to time from March 2004 until April 2006, we chartered a private airplane for business purposes from Simba LLC. Fuad El-Hibri and his wife hold 100% of the ownership interests in Simba. Mr. El-Hibri also is the managing member of Simba. Simba sold the airplane in May 2006. The plane was managed and chartered by Frederick Aviation and was available for charter by the general public. We paid Simba $32,148 in 2004, $33,999 in 2005 and $13,283 in 2006 for charter fees and reimbursement of costs. Frederick Aviation provided us with a discount of $300 per hour from its commercial charter rate. In all other respects, the fees and expenses that we paid to Simba were equivalent to fees charged to third parties for charter flights.

Employee relationships

Mauro Gibellini, a brother-in-law of Fuad El-Hibri, is our vice president corporate planning and business development. In addition, Mauro Gibellini and his wife, Yasmine Gibellini, as tenants by the entirety, hold 100% of the ownership interests in Biologika, L.L.C., one of our 5% stockholders, and have the power to dispose of all shares of our capital stock held by Biologika. We paid total cash compensation to Mr. Gibellini of $228,994 in 2003 and $320,765 in 2004. We paid total cash compensation to Mr. Gibellini of $278,969 for 2005, including an annual bonus for 2005 paid in 2006. Mr. Gibellini's current annual base salary is $195,624. He is also eligible for an annual bonus for 2006. Mr. Gibellini is a participant in our severance plan and termination protection program. As of October 20, 2006, we have granted Mr. Gibellini options to purchase 71,927 shares of our class B common stock at a weighted average exercise price of $1.68 per share.

Mark Grunenwald, a brother-in-law of Fuad El-Hibri, is our manager of information systems. We paid total cash compensation to Mr. Grunenwald of $1,115 in 2003 and $63,282 in 2004. We paid total cash compensation to Mr. Grunenwald of $69,337 for 2005, including an annual bonus for 2005 paid in 2006. Mr. Grunenwald's current annual base salary is $74,000. He is also eligible for an annual bonus for 2006.

Robert Myers, who serves as senior policy and science advisor and director of Emergent BioDefense Operations, is also the President of Michigan Biologic Products, Inc., one of our 5% stockholders, and has the power to direct the disposition of all shares of our capital stock held by Michigan Biologic Products.

We paid total cash compensation to Dr. Myers of $492,351 in 2003, $258,369 in 2004 and $270,055 in 2005. In June 2005, Emergent BioDefense Operations entered into an employment agreement with Dr. Myers in his role as senior policy and science advisor to Emergent BioDefense Operations. Under this employment agreement, Dr. Myers is entitled to an annual base salary of $180,000 and an annual bonus of $15,000. The employment agreement terminates upon the completion of this offering. Upon the completion of this offering, Dr. Myers is entitled to the following termination benefits:

- payment of any previously unpaid base salary and accrued paid time off and other benefits through the date of termination;
- payment of any unpaid, pro-rated bonus through the date of termination; and
- a lump sum payment in the amount of $100,000, less applicable withholding and related taxes.

As of October 20, 2006, we have granted Dr. Myers options to purchase 459,196 shares of our common stock at an exercise price of $0.09 per share.

Executive compensation

See “Management — Executive compensation” and “Management — Stock option grants” for additional information regarding compensation of our executive officers.

Director compensation

See “Management — Director compensation” for a discussion of options granted and other compensation to our non-employee directors.

Severance plan and termination protection program

Our executive officers participate in our severance plan and termination protection program. See “Management — Severance plan and termination protection program” for additional information regarding these arrangements.

Indemnification agreements

We have entered into an indemnification agreement with each of our executive officers and directors. See “Management — Limitation of liability and indemnification” for additional information regarding these agreements.

Principal and selling stockholders

The following table sets forth information with respect to the beneficial ownership of our common stock as of October 20, 2006 by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The information in the following table assumes that our previously existing class A common stock has been reclassified as common stock and all previously outstanding shares of class B common stock have been converted into shares of common stock prior to the completion of this offering. The column entitled “Percentage of shares beneficially owned before offering” is based on 22,420,404 shares of our common stock outstanding as of October 20, 2006. The column entitled “Percentage of shares beneficially owned after offering” is based on shares of our common stock to be outstanding immediately after the completion of this offering, including the 5,000,000 shares of common stock that we are selling in this offering. The underwriters have an option to purchase up to 750,000 additional shares of our common stock to cover over-allotments, including 480,000 shares from the selling stockholders. For more information regarding the shares that may be sold by the selling stockholders, see “— Selling stockholders” below. No other stockholder is participating in the offering.

Beneficial ownership is determined in accordance with the rules and regulations of the Securities and Exchange Commission and includes voting or investment power with respect to our common stock. In computing the number of shares of common stock beneficially owned and percentage ownership, shares subject to options held by a person are deemed to be outstanding and beneficially owned by that person if the options are currently exercisable or exercisable within 60 days of October 20, 2006. Shares subject to options are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o Emergent BioSolutions Inc., 300 Professional Drive, Suite 250, Gaithersburg, Maryland 20879.

Name of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
Executive officers and directors			
Fuad El-Hibri(1)	22,389,592	99.5%	81.4%
Edward J. Arcuri, Ph.D.(2)	38,361	*	*
Robert G. Kramer, Sr.(3)	513,561	2.2	1.8
Steven N. Chatfield, Ph.D.(4)	19,181	*	*
Daniel J. Abdun-Nabi(5)	74,516	*	*
Joe M. Allbaugh	—	—	—
Zsolt Harsanyi, Ph.D.(6)	28,770	*	*
Jerome M. Hauer(7)	14,385	*	*
Shahzad Malik, M.D.	—	—	—
Ronald B. Richard(8)	14,385	*	*
Louis W. Sullivan, M.D.	—	—	—
All executive officers and directors as a group (14 persons)(9)	23,128,714	99.5	81.9
5% stockholders			
Stockholder voting group under voting agreement dated June 30, 2004(10)	22,303,280	99.5	81.3
Microscience Investments Limited(11)	3,636,801	16.2	13.3
Robert Myers, D.V.M.(12)	2,394,045	10.5	8.6
Mauro and Yasmine Gibellini(13)	1,447,011	6.4	5.3

* Less than 1%.

(1) Consists of the following shares of our common stock:

- 8,314,819 shares held by Intervac, L.L.C.;
- 4,065,043 shares held by BioPharm, L.L.C.;
- 1,934,849 shares held by Michigan Biologic Products, Inc.;
- 1,599,155 shares held by Biovac, L.L.C.;
- 1,375,084 shares held by Biologika, L.L.C.;
- 719,275 shares held by Intervac Management, L.L.C.;
- 658,254 shares held by ARPI, L.L.C.;
- 3,636,801 shares held by Microscience Investments Limited; and
- 86,312 shares subject to stock options held by Mr. El-Hibri exercisable within 60 days of October 20, 2006.

If the underwriters exercise their over-allotment option in full, Mr. El-Hibri will beneficially own 21,909,592 shares of our common stock after this offering, or 78.9% of our outstanding common stock, consisting of the following shares of our common stock:

- 8,014,819 shares held by Intervac, L.L.C.;

• 4,065,043 shares held by BioPharm, L.L.C.;
• 1,844,849 shares held by Michigan Biologic Products, Inc.;
• 1,599,155 shares held by Biovac, L.L.C.;
• 1,315,084 shares held by Biologika, L.L.C.;
• 719,275 shares held by Intervac Management, L.L.C.;
• 628,254 shares held by ARPI, L.L.C.;
• 3,636,801 shares held by Microscience Investments Limited; and
• 86,312 shares subject to stock options held by Mr. El-Hibri exercisable within 60 days of October 20, 2006.

Robert Myers has the power to direct the disposition of all shares of our capital stock held by Michigan Biologic Products.

Mauro and Yasmine Gibellini, as tenants by the entirety, have the power to dispose of all shares of our capital stock held by Biologika.

Janice Mugrditchian has the power to dispose of all shares of our capital stock held by ARPI.

The holders of series B preferred ordinary shares of Microscience Investments have the power to dispose of all shares of our capital stock held by Microscience Investments and share the power to vote these shares with BioPharm, L.L.C. These series B shareholders do not have any agreement to act together with respect to the disposition of any shares of our capital stock.

For more information regarding the beneficial ownership of these shares, see "— Stockholder arrangements" below.

(2) Consists of 38,361 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(3) Consists of 513,561 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(4) Consists of 19,181 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(5) Consists of 74,516 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(6) Consists of 28,770 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(7) Consists of 14,385 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(8) Consists of 14,385 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(9) Includes 825,434 shares of common stock subject to stock options exercisable within 60 days of October 20, 2006.
(10) Consists of the following shares of our common stock:
• 8,314,819 shares held by Intervac, L.L.C.;
• 4,065,043 shares held by BioPharm, L.L.C.;
• 1,934,849 shares held by Michigan Biologic Products, Inc.;

• 1,599,155 shares held by Biovac, L.L.C.;

• 1,375,084 shares held by Biologika, L.L.C.;

• 719,275 shares held by Intervac Management, L.L.C.;

• 658,254 shares held by ARPI, L.L.C.; and

• 3,636,801 shares held by Microscience Investments Limited.

If the underwriters exercise their over-allotment option in full, these stockholders will beneficially own 21,823,280 shares of our common stock after this offering, or 78.8% of our outstanding common stock, consisting of the following shares of our common stock:

• 8,014,819 shares held by Intervac, L.L.C.;

• 4,065,043 shares held by BioPharm, L.L.C.;

• 1,844,849 shares held by Michigan Biologic Products, Inc.;

• 1,599,155 shares held by Biovac, L.L.C.;

• 1,315,084 shares held by Biologika, L.L.C.;

• 719,275 shares held by Intervac Management, L.L.C.;

• 628,254 shares held by ARPI, L.L.C.; and

• 3,636,801 shares held by Microscience Investments Limited.

Intervac, BioPharm, Michigan Biologic Products, Biovac, Biologika, Intervac Management and ARPI are parties to a voting agreement dated June 30, 2004. BioPharm also is a party to separate voting agreements with Michigan Biologic Products, Biologika and Microscience Investments.

Robert Myers has the power to direct the disposition of all shares of our capital stock held by Michigan Biologic Products.

Mauro and Yasmine Gibellini, as tenants by the entirety, have the power to dispose of all shares of our capital stock held by Biologika.

Janice Mugrditchian has the power to dispose of all shares of our capital stock held by ARPI.

The holders of series B preferred ordinary shares of Microscience Investments have the power to dispose of all shares of our capital stock held by Microscience Investments. These series B shareholders do not have any agreement to act together with respect to the disposition of any shares of our capital stock.

For more information regarding the beneficial ownership of these shares, see “— Stockholder arrangements” below.

(11) The holders of series B preferred ordinary shares of Microscience Investments have the power to dispose of all shares of our capital stock held by Microscience Investments and share the power to vote these shares with BioPharm, L.L.C. Investment funds affiliated with Apax Funds Nominees Limited, Advent Private Equity Funds, JP Morgan Partners LLC and The Merlin Biosciences Funds are the holders of the Microscience Investments series B preferred ordinary shares. No holder or group of affiliated holders of series B preferred ordinary shares of Microscience Investments alone has the power to direct the disposition of the shares of our capital stock held by Microscience Investments. In addition, these series B shareholders do not have any agreement to act together with respect to the disposition of any shares of our capital stock. Microscience Investments is a party to a voting agreement with BioPharm. For more information regarding this voting agreement, see “— Stockholder arrangements” below.

(12) Consists of the following shares of our common stock:

• 1,934,849 shares held by Michigan Biologic Products, Inc.; and

• 459,196 shares subject to stock options held by Dr. Myers exercisable within 60 days of October 20, 2006.

If the underwriters exercise their over-allotment option in full, Dr. Myers will beneficially own 2,304,045 shares of our common stock after this offering, or 8.2% of our outstanding common stock, consisting of the following shares of our common stock:

• 1,844,849 shares held by Michigan Biologic Products, Inc.; and

• 459,196 shares subject to stock options held by Dr. Myers exercisable within 60 days of October 20, 2006.

Dr. Myers has the power to direct the disposition of all shares of our capital stock held by Michigan Biologic Products. Mr. El-Hibri has the power to direct the voting of all shares of our capital stock held by Michigan Biologic Products. For more information regarding the beneficial ownership of these shares, see "— Stockholder arrangements" below.

(13) Consists of the following shares of our common stock:

• 1,375,084 shares held by Biologika, L.L.C.; and

• 71,927 shares subject to stock options held by Mr. Gibellini exercisable within 60 days of October 20, 2006.

If the underwriters exercise their over-allotment option in full, Mr. and Mrs. Gibellini will beneficially own 1,387,011 shares of our common stock after this offering, or 5.2% of our outstanding common stock, consisting of the following shares of our common stock:

• 1,315,084 shares held by Biologika, L.L.C.; and

• 71,927 shares subject to stock options held by Mr. Gibellini exercisable within 60 days of October 20, 2006.

Mr. and Mrs. Gibellini, as tenants by the entirety, have the power to dispose of all shares of our capital stock held by Biologika. Mr. El-Hibri has the power to direct the voting of all shares of our capital stock held by Biologika. For more information regarding the beneficial ownership of these shares, see "— Stockholder arrangements" below.

Selling stockholders

The stockholders listed in the following table have granted an option to the underwriters to purchase up to an aggregate of 480,000 additional shares of our common stock to cover over-allotments. The following table sets forth for each selling stockholder the number of shares of our common stock subject to the over-allotment option.

Name	Number of shares of common stock
Intervac, L.L.C.	300,000
Michigan Biologic Products, Inc.	90,000
Biologika, L.L.C.	60,000
ARPI, L.L.C.	30,000
Total	480,000

Stockholder arrangements

Our principal stockholders are parties to voting agreements that result in Mr. El-Hibri having the power to direct the voting of all shares of our capital stock owned by the stockholders who are party to these voting agreements. A description of these voting agreements and additional information regarding the beneficial ownership of the shares held by our principal stockholders are set forth below.

Voting agreement dated June 30, 2004

Intervac, BioPharm, Michigan Biologic Products, Biovac, Biologika, Intervac Management and ARPI are parties to a voting agreement dated June 30, 2004. We refer to these stockholders collectively as the voting group. Under the voting agreement, each stockholder in the voting group has agreed to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any matter as directed by a majority in interest of the voting group as measured by the aggregate percentage of ownership of our capital stock. As described below, Mr. El-Hibri has the power to direct the voting of a majority in interest of the voting group. In addition, under the voting agreement, each stockholder in the voting group has appointed Mr. El-Hibri, in his capacity as the general manager of Intervac, as proxy to vote the shares of our capital stock in the manner provided in the voting agreement. The voting agreement automatically terminates on June 30, 2014. Under the voting agreement, any person to whom any stockholder in the voting group transfers any shares of our capital stock must agree to be bound by the terms of the voting agreement, other than as a result of a transfer pursuant to an effective registration statement filed with the Securities and Exchange Commission under the Securities Act or pursuant to Rule 144 under the Securities Act.

Intervac, L.L.C.

Mr. El-Hibri is the general manager of Intervac and in that capacity has the power to vote and dispose of all shares of our capital stock held by Intervac. The board of executive directors of Intervac, consisting of William J. Crowe, Jr., Mr. El-Hibri and Nancy El-Hibri, supervises the management of the company and has the power to remove the general manager. Nancy El-Hibri is the wife of Mr. El-Hibri. A majority of the executive directors of Intervac is required to decide any matter on which the board of executive directors may take action, including the removal of the general manager. Any member of the board of executive directors may be removed by members of Intervac holding more than 50% of the aggregate ownership interests in Intervac. Mr. El-Hibri and his wife, as tenants by the entirety, hold 32.5% of the ownership interests in Intervac. Under a voting agreement with the William J. Crowe, Jr. Revocable Living Trust, Mr. El-Hibri has the power to vote an additional 18.0% of the ownership interests in Intervac on any matter. As a result, Mr. El-Hibri has the power to direct the voting of more than 50% of the aggregate ownership interests in Intervac. The voting agreement between Mr. El-Hibri and the William J. Crowe, Jr. Revocable Living Trust automatically terminates on October 21, 2010.

BioPharm, L.L.C.

Mr. El-Hibri is the holder of more than 50% of the class B ownership units of BioPharm and in that capacity has the power to direct the voting and disposition of all shares of our capital stock held by BioPharm.

Michigan Biologic Products, Inc.

Michigan Biologic Products has agreed, pursuant to a separate voting agreement with BioPharm, to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any

matter in the same manner and to the same extent as BioPharm. As a result, Mr. El-Hibri has the power to direct the voting of all shares of our capital stock held by Michigan Biologic Products. The voting agreement automatically terminates on June 30, 2014. Under the voting agreement, any person to whom Michigan Biologic Products transfers any shares of our capital stock must agree to be bound by the terms of the voting agreement, other than as a result of a transfer in a brokers' transaction or directly with a market maker, subject to BioPharm's right to purchase at fair market value the shares that Michigan Biologic Products proposes to sell. Robert Myers, the president of Michigan Biologic Products, who also serves as senior science and policy advisor and director of our wholly owned subsidiary, Emergent BioDefense Operations Lansing Inc., has the power to direct the disposition of all shares of our capital stock held by Michigan Biologic Products.

Biovac, L.L.C.

Mr. El-Hibri and his wife, as tenants by the entirety, hold 89.2% of the ownership interests in Biovac and have the power to vote and dispose of all shares of our capital stock held by Biovac.

Biologika, L.L.C.

Biologika has agreed, pursuant to a separate voting agreement with BioPharm, to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any matter in the same manner and to the same extent as BioPharm. As a result, Mr. El-Hibri has the power to direct the voting of all shares of our capital stock held by Biologika. The voting agreement automatically terminates on June 30, 2014. Under the voting agreement, any person to whom Biologika transfers any shares of our capital stock must agree to be bound by the terms of the voting agreement, other than as a result of a transfer in a brokers' transaction or directly with a market maker, subject to BioPharm's right to purchase at fair market value the shares that Biologika proposes to sell. Mauro Gibellini and Yasmine Gibellini, as tenants by the entirety, hold 100% of the ownership interests in Biologika and have the power to dispose of all shares of our capital stock held by Biologika. Yasmine Gibellini is the sister of Mr. El-Hibri. Mauro Gibellini is the brother-in-law of Mr. El-Hibri.

Intervac Management, L.L.C.

Mr. El-Hibri is the general manager of Intervac Management and in that capacity has the power to vote and dispose of all shares of our capital stock held by Intervac Management. Mr. El-Hibri is appointed as general manager pursuant to the terms of the operating agreement of Intervac Management, which may only be amended with the unanimous consent of the members of Intervac Management. Mr. El-Hibri and his wife, as tenants by the entirety, hold 31.1% of the ownership interests in Intervac Management.

ARPI, L.L.C.

Janice Mugrditchian holds 100% of the ownership interests in ARPI and has the power to vote and dispose of all shares of our capital stock held by ARPI.

Microscience Investments Limited

Microscience Investments has agreed, pursuant to a separate voting agreement with BioPharm, to vote all shares of our common stock owned by it for and against and abstain from voting with respect to any proposal in the same manner and to the same extent as BioPharm. The voting agreement automatically terminates upon the conclusion of our first annual meeting of stockholders following the completion of this offering.

Description of capital stock

The following description of our capital stock and provisions of our restated certificate of incorporation, which we refer to as our certificate of incorporation, and our amended and restated by-laws, which we refer to as our by-laws, are summaries and are qualified by reference to the certificate of incorporation and the by-laws that will be in effect upon completion of this offering. We have filed copies of these documents with the Securities and Exchange Commission as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur prior to and upon completion of this offering.

Upon the completion of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, $0.001 par value per share, and 15,000,000 shares of preferred stock, $0.001 par value per share.

As of October 20, 2006, we had issued and outstanding 22,303,280 shares of class A common stock and 117,124 shares of class B common stock, held by 34 stockholders of record. As of October 20, 2006, we also had outstanding options to purchase 3,109,932 shares of class B common stock at a weighted average exercise price of $2.54 per share.

Prior to the completion of this offering:

- our class A common stock will be reclassified as common stock and each outstanding share of our class B common stock will be converted into one share of common stock; and
- each outstanding option to purchase shares of our class B common stock will automatically become an option to purchase an equal number of shares of common stock at the same exercise price per share.

Common stock

The holders of our common stock are entitled to one vote per share with respect to each matter presented to our stockholders on which the holders of common stock are entitled to vote and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive ratably all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred stock

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

Authorizing our board of directors to issue preferred stock and determine its rights and preferences has the effect of eliminating delays associated with a stockholder vote on specific issuances. The issuance of preferred stock or of rights to purchase preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Currently, we have no shares of preferred stock outstanding. Our board of directors has authorized 100,000 shares of series A junior participating preferred stock for issuance under our stockholder rights plan. See "— Stockholder rights plan" below. We have no current plans to issue any preferred stock other than as may be provided for by the stockholder rights plan.

Options

Upon the completion of this offering, based on options outstanding as of October 20, 2006, we will have outstanding options to purchase an aggregate of 3,109,932 shares of our common stock at a weighted average exercise price of $2.54 per share.

Anti-takeover effects of Delaware law and our certificate of incorporation and by-laws

Our certificate of incorporation and by-laws and Delaware law contain provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Immediately prior to this offering, Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, was the beneficial owner of 99.5% of our outstanding common stock. Immediately following this offering, Mr. El-Hibri will be the beneficial owner of 81.4% of our outstanding common stock, or 78.9% of our outstanding common stock if the underwriters exercise their over-allotment option in full. As a result, Mr. El-Hibri will be able to control the election of the members of our board of directors following this offering. In addition, some of the provisions summarized below may further enhance Mr. El-Hibri's control of our corporate affairs for at least the next several years, including control of our board of directors. This control could discourage others from initiating a potential merger, takeover or other change of control transaction that other stockholders may view as beneficial.

Number of directors

Subject to the rights of holders of any series of preferred stock to elect directors, our board of directors will establish the number of directors. Until the fifth anniversary of the completion of this offering, any change in the number of directors will require the affirmative vote of at least 75% of the directors then in office.

Staggered board; removal of directors

Our certificate of incorporation and our by-laws divide our directors into three classes with staggered three-year terms. Our directors may be removed from office only for cause and only by the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote.

Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by the affirmative vote of a majority of our directors present at a meeting duly held at which a quorum is present.

The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Appointment and removal of chairman of the board

Until the fifth anniversary of the completion of this offering, the appointment and removal of the chairman of our board of directors will require the affirmative vote of at least 75% of our directors then in office. Mr. El-Hibri currently serves as the chairman of our board of directors.

Stockholder action by written consent; special meetings

Our certificate of incorporation and our by-laws provide that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Our certificate of incorporation and our by-laws also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our board of directors, our chairman of the board or our president.

Advance notice requirements

Following the second anniversary of the completion of this offering, our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to the board of directors. Following the second anniversary of the completion of this offering, stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Delaware business combination statute

We are subject to Section 203 of the General Corporation Law of Delaware. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders.

Super-majority voting

The General Corporation Law of Delaware provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Until the second anniversary of the completion of this offering, 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 provisions of our certificate of incorporation described in this section entitled "Anti-takeover effects of Delaware law and our certificate of incorporation and by-laws." Following the second anniversary of the completion of this offering, 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 these provisions of our certificate of incorporation. Until the second anniversary of the completion of this offering, 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 the second anniversary of the completion of this offering, 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.

Stockholder rights plan

In connection with this offering, we are entering into a rights agreement pursuant to which we will issue to our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, will entitle the registered 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. We are entering into the rights agreement with American Stock Transfer & Trust Company, as rights agent.

The following description is a summary of the material terms of our stockholder rights plan. It does not restate these terms in their entirety. We urge you to read our stockholder rights plan because it, and not this description, defines its terms and provisions. We have filed a form of the rights agreement that establishes our stockholder rights plan as an exhibit to our registration statement of which this prospectus forms a part.

Rights. Each share of common stock will have attached to it one right. Initially, the rights are not exercisable and are attached to all certificates representing outstanding shares of our common stock, and we will not distribute separate rights certificates. The rights will only be exercisable under limited circumstances specified in the rights agreement when there has been a distribution of the rights and the rights are no longer redeemable by us.

The rights will expire at the close of business on the tenth anniversary of the date the rights plan was adopted, unless we redeem or exchange them earlier as described below.

Prior to the rights distribution date. Prior to the rights distribution date:

- the rights are evidenced by our common stock certificates and will be transferred with and only with such common stock certificates; and
- the surrender for transfer of any certificates of our common stock will also constitute the transfer of the rights associated with our common stock represented by such certificate.

Rights distribution date. The rights will separate from our common stock, and a rights distribution date will occur, upon the earlier of the following events:

- 10 business days following the later of (1) a public announcement that a person or group, other than an exempted person, has acquired, or obtained the right to acquire beneficial ownership of 15% or more of the outstanding shares of our common stock or (2) the first date on which one of our executive officers has actual knowledge of such an event; and
- 10 business days following the start of a tender offer or exchange offer that would result in a person or group, other than an exempted person, beneficially owning 15% or more of the outstanding shares of our common stock.

The distribution date may be deferred by our board of directors and some inadvertent actions will not trigger the occurrence of the rights distribution date. In addition, a rights distribution date will not occur as a result of the ownership of our stock by the following exempted persons:

- Fuad El-Hibri and his wife, Nancy El-Hibri, and any entity controlled by Fuad El-Hibri or Nancy El-Hibri;
- Microscience Investments Limited, unless and until such time as Microscience Investments, together with its affiliates and associates, directly or indirectly, becomes the beneficial owner of any additional shares of common stock, except under certain specified circumstances, and disregarding any shares Microscience Investments is or becomes the beneficial owner of solely as a result of the fact that it is a party to any of the voting agreements described under “Principal and selling stockholders — Stockholder arrangements;” and
- each other holder of our common stock immediately prior to this offering to the extent such person’s beneficial ownership exceeds 15% solely as a result of the fact that the person is a party to any of the voting agreements described under “Principal and selling stockholders — Stockholder arrangements.”

As soon as practicable after the rights distribution date, separate rights certificates will be mailed to the holders of record of our common stock as of the close of business on the rights distribution date. From and after the rights distribution date, the separate rights certificates alone will represent the rights. All shares of our common stock issued prior to the rights distribution date, including shares of common stock issued in this offering, will be issued with rights. Shares of our common stock issued after the rights distribution date in connection with specified employee benefit plans or upon conversion of specified securities will be issued with rights. Except as otherwise determined by our board of directors, no other shares of our common stock issued after the rights distribution date will be issued with rights.

Flip-in event. If a person or group, other than an exempted person, becomes the beneficial owner of 15% or more of the outstanding shares of our common stock, except as described below, each holder of a right will thereafter have the right to receive, upon exercise, a number of shares of our common stock, or, in some circumstances, cash, property or other securities of ours, which equals the exercise price of the right divided by one-half of the current market price of our common stock on the date the acquisition occurs. However, following the acquisition:

- rights will not be exercisable until the rights are no longer redeemable by us as set forth below; and
- all rights that are, or were, under the circumstances specified in the rights agreement, beneficially owned by any acquiring person will be null and void.

The event set forth in this paragraph is referred to as a flip-in event. A flip-in event would not occur if there is an offer for all of our outstanding shares of common stock that at least 75% of our board of directors determines is fair to our stockholders and in their best interests.

Flip-over event. If at any time after a person or group, other than an exempted person, has become the beneficial owner of 15% or more of the outstanding shares of our common stock:

- we are acquired in a merger or other business combination transaction in which we are not the surviving corporation;
- we are the surviving entity in a merger of other business combination transaction but our common stock is changed or exchanged for stock or securities of any other person or for cash or any other property; or
- more than 50% of our assets or earning power is sold or transferred,

then each holder of a right, except rights which previously have been voided as set forth above, shall thereafter have the right to receive, upon exercise, that number of shares of common stock of the acquiring company which equals the exercise price of the right divided by one-half of the current market price of that company's common stock at the date of the occurrence of the event. The event described in this paragraph is referred to as a flip-over event. A flip-over event does not arise if the merger or other transaction follows an offer for all of our outstanding shares of common stock that at least 75% of our board of directors determines is fair to our stockholders and in their best interests.

Exchange of rights. At any time after a flip-in event, when no person owns a majority of our common stock, our board of directors may exchange the rights, other than rights owned by the acquiring person that have become void, in whole or in part, at an exchange ratio of one share of our common stock, or one one-thousandth of a share of series A preferred stock, or of a share of a class or series of preferred stock having equivalent rights, preferences and privileges, per right.

Adjustments. The purchase price of the rights, and the number of securities purchasable, are subject to adjustment from time to time to prevent dilution. The number of rights associated with each share of common stock is also subject to adjustment in the event of stock splits, subdivisions, consolidations or combinations of our common stock that occur prior to the rights distribution date.

Series A junior participating preferred stock. Series A preferred stock purchasable upon exercise of the rights will not be redeemable. Each share of series A preferred stock will be entitled to receive when, as and if declared by our board of directors, a minimum preferential quarterly dividend payment of $10 per share or, if greater, an aggregate dividend of 1,000 times the dividend declared per share of our common stock. In the event of liquidation, the holders of the series A preferred stock will be entitled to a minimum preferential liquidation payment of $1,000 per share, plus accrued and unpaid dividends, and will be entitled to an aggregate payment of 1,000 times the payment made per share of our common stock. Each share of series A preferred stock will have 1,000 votes, voting together with our common stock. In the event of any merger, consolidation or other transaction in which our common stock is changed or exchanged, each share of series A preferred stock will be entitled to receive 1,000 times the amount received per share of our common stock. These rights are protected by customary antidilution provisions.

Because of the nature of the series A preferred stock's dividend, liquidation and voting rights, the value of one one-thousandth of a share of series A preferred stock purchasable upon exercise of each right should approximate the value of one share of common stock.

Redemption of rights. At any time until ten business days following the date of a public announcement that a person or group, other than an exempted person, has acquired or obtained the right to acquire beneficial ownership of 15% or more of the outstanding shares of our common stock, or such later date upon which one of our executive officers first has actual knowledge of such event or such later date as

our board of directors may determine, we may redeem the rights in whole, but not in part, at a price of $0.001 per right, payable in cash or stock. Immediately upon the redemption of the rights or such earlier time as established by our board of directors, the rights will terminate and the only right of the holders of rights will be to receive the redemption price.

Status of rights holder and tax effects. Until a right is exercised, the holder of the right, as such, will have no rights as a stockholder of ours, including no right to vote or to receive dividends. Although the distribution of the rights should not be taxable to stockholders or to us, stockholders may, depending upon the circumstances, recognize taxable income in the event that the rights become exercisable for our common stock, or other consideration, or for common stock of the acquiring company as described above.

Board's authority to amend. Our board of directors may amend any provision of the rights agreement, other than the redemption price, prior to the date on which the rights are no longer redeemable. Once the rights are no longer redeemable, our board's authority to amend the rights agreement is limited to correcting ambiguities or defective or inconsistent provisions in a manner that does not adversely affect the interest of holders of rights.

Effects of the rights. The rights are intended to protect our stockholders in the event of an unfair or coercive offer to acquire our company and to provide our board of directors with adequate time to evaluate unsolicited offers. The rights may have anti-takeover effects. The rights will cause substantial dilution to a person or group that attempts to acquire us without conditioning the offer on a substantial number of rights being acquired. The rights, however, should not affect any prospective offeror willing to make an offer at a fair price and otherwise in the best interests of us and our stockholders, as determined by our board of directors. The rights should not interfere with any merger or other business combination approved by our board of directors.

Registration rights

Upon the completion of this offering, holders of 22,303,280 shares of our common stock as of October 20, 2006 will have the right to require us to register these shares of common stock under the Securities Act under specified circumstances, including any additional shares issued or distributed by way of a dividend, stock split or other distribution in respect of these shares.

In connection with our acquisition of Microscience, we granted to Microscience Investments registration rights with respect to the shares of our common stock that we issued to Microscience Investments in the acquisition. We also have granted registration rights with respect to shares of our common stock to the holders of our previously existing class A common stock, in addition to Microscience Investments.

Registration rights held by Microscience Investments may be transferred to the following parties if they become holders of the shares covered by the registration rights: APAX Funds Nominees Limited, The Merlin BioSciences Funds, The Merlin Fund L.P., Advent Private Equity Funds, JPMorgan Partners LLC, Merlin Equity Limited, or any subsidiary, affiliate, parent or general partner of any of these parties.

Demand registration rights

Subject to specified limitations and to the lock-up agreements with the underwriters for this offering, holders of these registrations rights may, beginning 90 days after this offering, require that we register all or part of our common stock subject to the registration rights for sale under the Securities Act. These holders may demand registration of our common stock so long as the offering price to the public of the shares requested to be registered is at least $25,000,000. We are required to effect only one demand

registration, subject to specified exceptions for each of Microscience and the holders of our previously existing class A common stock.

Incidental registration rights

If, after the completion of this offering, we propose to register any of our common stock under the Securities Act, subject to specified exceptions, either for our own account or for the account of other security holders, holders of registration rights are entitled to notice of the registration and to include shares of common stock subject to the registration rights in the registered offering.

Limitations and expenses

With specified exceptions, the right to include shares in a registration is subject to the right of underwriters for the offering to limit the number of shares included in the offering. We are required to pay one-half of all fees, costs and expenses of any demand registration, other than underwriting discounts and commissions.

Transfer agent and registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

New York Stock Exchange

Our common stock has been authorized for listing on the New York Stock Exchange under the symbol “EBS.”

Shares eligible for future sale

Prior to this offering, there has been no market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of common stock, including shares issued upon exercise of outstanding options or in the public market after this offering, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities. Our common stock has been authorized for listing on the New York Stock Exchange under the symbol “EBS.”

Upon the completion of this offering, we will have outstanding 27,420,404 shares of common stock, after giving effect to the issuance of 5,000,000 shares of common stock in this offering.

Of the shares to be outstanding after the completion of this offering, the 5,000,000 shares of common stock sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining shares of our common stock are “restricted securities” under Rule 144. Substantially all of these restricted securities will be subject to the 180-day lock-up period described below.

After the 180-day lock-up period, these restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act.

Rule 144

In general and subject to the lock-up agreements described below, under Rule 144, beginning 90 days after the date of this prospectus, a person who has beneficially owned shares of our common stock for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 274,204 shares immediately after this offering; and
- the average weekly trading volume in our common stock on the New York Stock Exchange during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. Beginning 90 days after the date of this prospectus, 46,885 shares of our common stock outstanding as of October 20, 2006 will be eligible for sale under Rule 144. Upon expiration of the 180-day lock-up period described below, an additional 22,318,281 shares of our common stock outstanding as of October 20, 2006 will be eligible for sale under Rule 144, including shares eligible for resale under Rule 144(k) as described below. We cannot estimate the number of shares of common stock that our existing stockholders will elect to sell under Rule 144.

Rule 144(k)

Subject to the lock-up agreements described below, shares of our common stock eligible for sale under Rule 144(k) may be sold immediately upon the completion of this offering. In general, under Rule 144(k),

a person may sell shares of common stock acquired from us immediately upon the completion of this offering, without regard to manner of sale, the availability of public information about us or volume, if:

- the person is not our affiliate and has not been our affiliate at any time during the three months preceding the sale; and
- the person has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate.

Immediately upon the completion of this offering, 10,069 shares of our common stock outstanding as of October 20, 2006 will be eligible for sale under Rule 144(k). Upon expiration of the 180-day lock-up period described below, 13,232 shares of common stock outstanding as of October 20, 2006 will be eligible for sale under Rule 144(k).

Rule 701

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell those shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with the various restrictions, including the public information, holding period and volume limitation restrictions, contained in Rule 144. Beginning 90 days after the date of this prospectus, 117,124 shares of our common stock outstanding as of October 20, 2006 will be eligible for sale in accordance with Rule 701.

Lock-up agreements

The holders of substantially all of our currently outstanding capital stock have agreed that, without the prior written consent of J.P. Morgan Securities Inc., they will not, during the period ending 180 days after the date of this prospectus, subject to exceptions specified in the lock-up agreements, offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock. Further, these holders have agreed that, during this period, they will not make any demand for, or exercise any right with respect to, the registration of our common stock or any security convertible into or exercisable or exchangeable for our common stock. The 180-day lock-up period may be extended under specified circumstances. The lock-up restrictions, specified exceptions and the circumstances under which the 180-day lock-up period may be extended are described in more detail under “Underwriting.”

Registration rights

Subject to the lock-up agreements described above, upon the completion of this offering, holders of 22,303,280 shares of our common stock outstanding as of October 20, 2006 will have the right to require us to register these shares of common stock under the Securities Act under specified circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See “Description of capital stock—Registration rights” for additional information regarding these registration rights.

Stock options

As of October 20, 2006, we had outstanding options to purchase 3,109,932 shares of class B common stock, of which options to purchase 2,303,105 shares of class B common stock were vested as of October 20, 2006. As of October 20, 2006, options to purchase 2,628,982 shares of common stock will be vested and eligible for sale within 180 days after the date of this prospectus, subject to any lock-up agreements applicable to these shares. Immediately prior to the completion of this offering, each of these options automatically will become an option to purchase an equal number of shares of our common stock. Promptly following this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares subject to outstanding options and options and other awards issuable pursuant to our employee stock option plan and 2006 stock incentive plan. See “Management—Stock option and other compensation plans” for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities Inc., Cowen and Company, LLC and HSBC Securities (USA) Inc. are acting as representatives of the underwriters. We and the selling stockholders have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the initial public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities Inc.	2,500,000
Cowen and Company, LLC	1,625,000
HSBC Securities (USA) Inc.	875,000
Total	5,000,000

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.53 per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $0.10 per share from the initial public offering price. After the initial public offering of the shares, the offering price and other selling terms may be changed by the underwriters. The representatives have advised us that the underwriters do not intend to confirm discretionary sales in excess of 5% of the shares of common stock offered in this offering.

The underwriters have an option to purchase up to 480,000 additional shares of common stock from the selling stockholders and up to 270,000 additional shares of common stock from us to cover sales of shares by the underwriters that exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this over-allotment option. If any shares are purchased with this over-allotment option, the underwriters will purchase shares first from the selling stockholders and then from us, in each case, in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the initial public offering price per share of common stock less the amount paid by the underwriters to us and the selling stockholders per share of common stock. The underwriting fee is $0.875 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

Underwriting discounts and commissions	Without over-allotment exercise	With full over-allotment exercise
Per share	$ 0.875	$ 0.875
Total	$ 4,375,000	$ 5,031,250

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $3,450,000. Substantially all of these expenses are payable by us.

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed, with limited exceptions, that we will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, without the prior written consent of J.P. Morgan Securities Inc. for a period of 180 days after the date of this prospectus. Notwithstanding the foregoing, if (1) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to us occurs; or (2) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period, the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event. Notwithstanding the restrictions described above, we are permitted to issue up to an aggregate of 1,370,000 shares of our common stock or securities convertible into or exercisable or exchangeable for common stock in connection with transactions with unaffiliated third parties that involve commercial relationships, including joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements, or in connection with specified acquisition transactions. The recipients of the common stock or securities issued in connection with such transactions will be bound by the terms of the stockholder lock-up described below.

Our directors and executive officers and substantially all of our stockholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities Inc., (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise. Notwithstanding the foregoing, if (1) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to us occurs; or (2) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period, the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

The restrictions imposed by these lock-up agreements will not apply to the transfer or disposition of shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (1) as a bona fide gift, (2) to any trust for the direct or indirect benefit of the stockholder or the immediate family of the stockholder in a transaction not involving a disposition for value, (3) to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by the stockholder or the immediate family of the stockholder in a transaction

not involving a disposition for value, (4) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the stockholder, (5) as a distribution to partners, members or stockholders of the stockholder in a transaction not involving a disposition for value or (6) to any affiliate of the stockholder or any investment fund or other entity controlled or managed by the stockholder in a transaction not involving a disposition for value; provided that the transferee, distributee or donee agrees in writing to be bound by the terms of the lock-up agreement to the same extent as if a party thereto; and, provided further that, in the case of (3), (5) and (6) above, no filing pursuant to Section 16(a) of the Exchange Act, reporting a reduction in the beneficial ownership of common stock shall be required or shall be voluntarily made in connection with such transfer, other than a filing on a Form 5 made after the expiration of the 180-day restricted period or any extension thereof pursuant to the lock-up agreement. In addition, the restrictions imposed by the lock-up agreement do not apply to the sale of common stock by the stockholder pursuant to the underwriting agreement. Furthermore, notwithstanding the restrictions imposed by the lock-up agreement, the stockholder may, without the prior written consent of J.P. Morgan Securities Inc., (1) exercise an option to purchase shares of common stock granted under any stock incentive plan or stock purchase plan, (2) establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of common stock, provided that such plan does not provide for any transfers of common stock during the 180-day restricted period or any extension thereof pursuant to the lock-up agreement and (3) transfer shares of common stock acquired in this offering or on the open market following this offering.

We and the selling stockholders have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Our common stock has been approved for listing on the New York Stock Exchange under the symbol “EBS.”

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ over-allotment option referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the over-allotment option. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the New York Stock Exchange, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors, including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock, or that the shares of common stock will trade in the public market at or above the initial public offering price.

J.P. Morgan Partners, LLC, an affiliate of J.P. Morgan Securities Inc., through its ownership of various entities, owns approximately 10.9% of the voting securities of Microscience Investments Limited, which owns 16.2% of our common stock prior to this offering. Because J.P. Morgan Securities Inc. may be deemed an affiliate under the National Association of Securities Dealers, Inc.'s Conduct Rules, or the NASD Rules, as a result of J.P. Morgan Partners, LLC's ownership of more than 10% of the voting securities of Microscience Investments Limited, J.P. Morgan Securities Inc. may be deemed to have a "conflict of interest" with us under Rule 2720 of the NASD Rules. When an NASD member with a conflict of interest participates as an underwriter in a public offering, the NASD Rules require that the initial public offering price can be no higher than that recommended by a "qualified independent underwriter," as defined by the NASD Rules. In accordance with Rule 2720 of the NASD Rules, Cowen and Company, LLC has assumed the responsibility of acting as qualified independent underwriter. In this role, Cowen and Company, LLC has performed a due diligence investigation and reviewed and participated in the preparation of the registration statement, of which this prospectus is a part.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. HSBC Realty Credit Corporation, an affiliate of HSBC Securities (USA) Inc., is the lender under a mortgage loan for $8.5 million that we entered into in April 2006 in connection with the purchase of a building in Frederick, Maryland, a term loan for $10.0 million that we entered into in August 2006 to finance a portion of the costs of our facility expansion in Lansing, Michigan and a revolving line of credit for up to $5.0 million that we entered into in August 2006. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of

customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Notices to foreign investors

This prospectus may only be communicated or caused to be communicated in the United Kingdom to persons:

(a) authorised to carry on a regulated activity, or Authorised Persons, under the Financial Services and Markets Act of 2000, or FSMA;

(b) having professional experience in matters relating to investments and qualifying as investment professionals under article 19 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order;

(c) qualifying as high net worth persons under article 49 of the Order; or

(d) to whom investments or investment activity of the kind described in this prospectus may lawfully be made available.

This prospectus will only be available to the categories of persons in the United Kingdom described above and no one falling outside such categories is entitled to rely on, and they must not act on, any information in this prospectus. The communication of this prospectus to any person in the United Kingdom falling outside the categories described above is unauthorised and may contravene FSMA. Any individual who is in any doubt about the investment to which this prospectus relates should consult an Authorised Person specialising in advising on investments of this kind. By receiving this document you are deemed to represent and warrant to us and the underwriters that you fall within the categories of persons described above. Persons who do not fall within one of the categories of persons described above should not take any action on the basis of this prospectus and should not act or rely on it. Any individual who is in doubt about the investment to which this prospectus relates should consult an authorised person specialising in advising on investments of this kind.

No approved prospectus relating to the matters referred to in this prospectus has been made available to the public in the United Kingdom and, accordingly, the common stock may not be, and will not be, offered in the United Kingdom except to qualified investors under section 86 of FSMA or except in circumstances which would not result in an offer to the public in the United Kingdom within the meaning of FSMA. No approved prospectus will be registered and published in any other member state of the European Economic Area and common stock will only be offered or sold in any such member state in circumstances which do not require the publication of a prospectus pursuant to the provisions of the Prospectus Directive.

No prospectus will be approved by any member state of the European Economic Area which has implemented the Prospectus Directive, or Relevant Member State, and no prospectus will be registered or published in any Relevant Member State. Applications will be accepted and common stock will be issued to investors in the Relevant Member States only in circumstances which do not require the publication of a prospectus pursuant to the Prospectus Directive including:

(i) at any time to legal entities which are authorised or regulated to operate in the financial markets or, if not so authorised or regulated, whose corporate purpose is solely to invest in securities;

(ii) at any time to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year, (2) a total balance sheet of more than €43 million and (3) an annual turnover of more than €50 million, as shown in its last annual or consolidated accounts; or

(iii) at any time in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

No prospectus pursuant to the German Securities Prospectus Act will be filed with the German Federal Financial Supervisory Authority. Consequently the common stock must not be distributed within Germany by way of a public offer, public advertisement or in any similar manner. Applications will only be accepted and common stock will be issued to investors in Germany only in circumstances which do not require the publication of a prospectus pursuant to the German Securities Prospectus Act:

(i) at any time to legal entities which are authorised or regulated to operate in the financial markets or, if not so authorised or regulated, whose corporate purpose is solely to invest in securities pursuant to Section 2 no. 6 lit. a of the German Securities Prospectus Act;

(ii) at any time to a corporate entity which has two or more of (1) an average of at least 250 employees during the last financial year, (2) a total balance sheet of more than €43 million and (3) an annual turnover of more than €50 million, as shown in its last annual or consolidated accounts; or

(iii) at any time in any other circumstances which do not require the publication by us of a prospectus pursuant to Section 3 of the German Securities Prospectus Act.

This prospectus and any other document relating to the common stock, as well as information and statements contained therein, may not be supplied to the public in Germany or used in connection with any offer for subscription of the common stock to the public in Germany or any other means of public marketing. This prospectus and any other related information is strictly private and confidential. It must not be provided to any person or entity other than the original recipient, and may not be reproduced or used for any other purpose.

The common stock has not been registered with the Commissione Nazionale per le Società e la Borsa, or CONSOB, pursuant to Italian securities legislation and, accordingly, the common stock cannot be offered or sold, and shall not be offered or sold in the Republic of Italy in a solicitation to the public at large, and that sales of the common stock in the Republic of Italy shall only be negotiated on an individual basis with “Professional Investors”, as defined under Article 31, paragraph 2, of CONSOB Regulation no. 11522 of 1 July 1998, as amended, and effected in compliance with the requirements of Articles 94 and seq. of Legislative Decree no. 58 of 24 February 1998, as amended, and CONSOB Regulation no. 11971 of 14 May 1999, as amended, and shall in any event be effected in accordance with all Italian securities, tax and exchange control and other applicable laws and regulations.

This prospectus does not constitute an issue prospectus pursuant to Art. 652a of the Swiss Code of Obligations. The common stock will not be listed on the SWX Swiss Exchange and, therefore, the prospectus may not comply with the disclosure standards of the listing rules of the SWX Swiss Exchange. Accordingly, the common stock may not be offered to the public in or from Switzerland, but only to a selected and limited circle of investors which do not subscribe to the common stock with a view to distribution. The investors will be individually approached by the underwriters from time to time.

This prospectus is personal to each offeree and does not constitute an offer to any other person. The prospectus may only be used by those persons to whom it has been handed out in connection with the offer described therein and may neither directly nor indirectly be distributed or made available to other persons without express consent of the issuer. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland.

Legal matters

The validity of the common stock offered hereby is being passed upon by Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C. Thelen Reid & Priest LLP, Washington, D.C., is acting as counsel to the selling stockholders in connection with this offering. Dechert LLP, Philadelphia, Pennsylvania is acting as counsel for the underwriters in connection with this offering.

Experts

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2004 and 2005, and for each of the three years in the period ended December 31, 2005, as set forth in their report. We have included our consolidated financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Ernst & Young LLP, London, England, independent auditors, has audited the financial statements of Emergent Product Development UK Limited for each of the two years in the period ended December 31, 2004, as set forth in their report. We have included these financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Where you can find more information

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract or any other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract or other documents filed as an exhibit to the registration statement. Each of theses statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the Securities and Exchange Commission's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for more information about the operation of the Securities and Exchange Commission's public reference room. In addition, the Securities and Exchange Commission maintains an Internet website, which is located at http://www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the Securities and Exchange Commission. You may access the registration statement of which this prospectus is a part at the Securities and Exchange Commission's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the Securities and Exchange Commission.

This prospectus includes statistical data that were obtained from industry publications. These industry publications generally indicate that the authors of these publications have obtained information from sources believed to be reliable but do not guarantee the accuracy and completeness of their information. While we believe these industry publications to be reliable, we have not independently verified their data.

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Emergent BioSolutions Inc. and subsidiaries

Report of independent registered public accounting firm

The Board of Directors and Stockholders
Emergent BioSolutions Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2004 and 2005, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Emergent BioSolutions Inc. and Subsidiaries at December 31, 2004 and 2005, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

May 23, 2006,
except as to Note 17, as to which the date is
October 27, 2006
McLean, VA

Emergent BioSolutions Inc. and subsidiaries
Consolidated balance sheets

(in thousands, except share and per share data)	December 31, 2004	December 31, 2005	As of September 30, 2006 (unaudited)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 6,821	$ 36,294	$ 19,906
Accounts receivable	18,637	2,530	3,273
Inventories	13,253	16,441	28,068
Income taxes receivable	—	763	3,542
Deferred tax assets	978	1,989	252
Restricted cash	1,250	—	190
Prepaid expenses and other current assets	756	1,099	1,961
Total current assets	41,695	59,116	57,192
Property, plant and equipment, net	27,269	30,645	59,632
Deferred tax assets, net of current	24	9,981	10,785
Other assets	68	590	3,222
Total assets	$ 69,056	$ 100,332	$ 130,831
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable, related party	$ 15	$ 22	$ —
Accounts payable, operations	5,505	10,403	16,571
Accrued compensation	3,710	6,177	4,898
Indebtedness under lines of credit	—	—	2,168
Long-term indebtedness, current portion	572	902	1,687
Notes payable to employees, current portion	474	506	63
Income taxes payable	3,761	2,134	—
Deferred revenue, current portion	18,256	7,340	8,978
Other current liabilities	1,893	2,609	4,101
Total current liabilities	34,186	30,093	38,466
Long-term indebtedness, net of current portion	11,347	10,471	32,555
Notes payable to employees, net of current portion	474	31	—
Deferred revenue, net of current portion	—	—	3,001
Other liabilities	100	—	50
Total liabilities	46,107	40,595	74,072
Stockholders' equity:			
Preferred Stock, $0.001 par value; 3,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2004 and 2005 and September 30, 2006	—	—	—
Common Stock, Class A, $0.001 par value; 100,000,000 shares authorized, 18,666,479, 22,303,280 and 22,303,280 shares issued and outstanding at December 31, 2004 and 2005 and September 30, 2006, respectively	19	22	22
Common Stock, Class B, $0.01 par value; 2,000,000 shares authorized, 0, 21,283 and 86,340 shares issued and outstanding at December 31, 2004 and 2005 and September 30, 2006, respectively	—	—	1
Additional paid-in capital	7,610	34,595	35,079
Accumulated other comprehensive loss	—	(276)	(182)
Retained earnings	15,320	25,396	21,839
Total stockholders' equity	22,949	59,737	56,759
Total liabilities and stockholders' equity	$ 69,056	$ 100,332	$ 130,831

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)	Year ended December 31,			Nine months ended September 30, (unaudited)	
	2003	2004	2005	2005	2006
Revenues:					
Product sales	$ 55,536	$ 81,014	$ 127,271	$ 85,807	$ 61,263
Contracts and grants	233	2,480	3,417	1,093	4,580
Total revenues	55,769	83,494	130,688	86,900	65,843
Operating expense (income):					
Cost of product sales	22,342	30,102	31,603	23,147	11,645
Research and development	6,327	10,117	18,381	9,632	26,640
Selling, general and administrative	19,547	30,323	42,793	28,924	32,952
Purchased in-process research and development	1,824	—	26,575	26,575	477
Settlement of State of Michigan obligation	—	(3,819)	—	—	—
Litigation settlement	—	—	(10,000)	(10,000)	—
Income (loss) from operations	5,729	16,771	21,336	8,622	(5,871)
Other income (expense):					
Interest income	100	65	485	338	405
Interest expense	(293)	(241)	(767)	(575)	(778)
Other income (expense), net	168	6	55	(24)	291
Total other income (expense)	(25)	(170)	(227)	(261)	(82)
Income (loss) before provision for (benefit from) income taxes	5,704	16,601	21,109	8,361	(5,953)
Provision for (benefit from) income taxes	1,250	5,129	5,325	2,109	(2,617)
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Earnings (loss) per share — basic	$ 0.24	$ 0.61	$ 0.77	$ 0.31	$ (0.15)
Earnings (loss) per share — diluted	$ 0.22	$ 0.56	$ 0.69	$ 0.28	$ (0.15)
Weighted average number of shares — basic	18,904,992	18,919,850	20,533,471	19,930,498	22,370,191
Weighted average number of shares — diluted	20,316,752	20,439,252	22,751,733	22,048,412	22,370,191
Cash dividends per share — basic	$ —	$ —	$ 0.26	$ 0.27	$ —

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

Emergent BioSolutions Inc. and subsidiaries
Consolidated statements of changes in stockholders' equity

(in thousands, except share and per share data)	Class A no-par common stock		Class B no-par common stock		Class A $0.001 par value common stock		Class B $0.01 par value common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2002	18,017,994	$ 2,940	731,886	$ 69	—	$ —	—	$ —	$ —	$ —	$ 1,146	$ 4,155
Redemption of common stock	—	—	(71,927)	(7)	—	—	—	—	—	—	(193)	(200)
Issuance of common stock	—	—	439,264	39	—	—	—	—	—	—	—	39
Net income	—	—	—	—	—	—	—	—	—	—	4,454	4,454
Balance at December 31, 2003	18,017,994	2,940	1,099,223	101	—	—	—	—	—	—	5,407	8,448
Redemption of common stock	—	—	(573,322)	(53)	—	—	—	—	—	—	(1,559)	(1,612)
Issuance of common stock	—	—	122,584	12	—	—	—	—	—	—	—	12
Conversion of class A no-par common stock to class A $0.001 par value common stock	(18,017,994)	(2,940)	—	—	18,017,994	18	—	—	2,922	—	—	—
Conversion of class B no-par common stock to class A $0.01 par value common stock	—	—	(648,485)	(60)	648,485	1	—	—	59	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	4,310	—	—	4,310
Tax benefit related to the disqualifying disposition	—	—	—	—	—	—	—	—	319	—	—	319
Net income	—	—	—	—	—	—	—	—	—	—	11,472	11,472
Balance at December 31, 2004	—	—	—	—	18,666,479	19	—	—	7,610	—	15,320	22,949
Issuance of common stock to acquire Microscience Limited	—	—	—	—	3,636,801	3	—	—	26,998	—	—	27,001
Exercise of stock options	—	—	—	—	—	—	133,451	1	32	—	—	33
Redemption of common stock	—	—	—	—	—	—	(112,168)	(1)	(28)	—	(308)	(337)
Forfeiture of stock options	—	—	—	—	—	—	—	—	(17)	—	—	(17)
Payment of dividend	—	—	—	—	—	—	—	—	—	—	(5,400)	(5,400)
Net income	—	—	—	—	—	—	—	—	—	—	15,784	15,784
Foreign currency translation	—	—	—	—	—	—	—	—	—	(276)	—	(276)
Comprehensive income	—	—	—	—	—	—	—	—	—	—	—	15,508
Balance at December 31, 2005	—	—	—	—	22,303,280	22	21,283	—	34,595	(276)	25,396	59,737
Redemption of common stock	—	—	—	—	—	—	—	—	—	—	(221)	(221)
Issuance of common stock	—	—	—	—	—	—	65,057	1	42	—	—	43
Stock-based compensation expense	—	—	—	—	—	—	—	—	442	—	—	442
Net loss	—	—	—	—	—	—	—	—	—	—	(3,336)	(3,336)
Foreign currency translation	—	—	—	—	—	—	—	—	—	94	—	94
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(3,242)
Balance at September 30, 2006 (unaudited)	—	$ —	—	$ —	22,303,280	$ 22	86,340	$ 1	$ 35,079	$ (182)	$ 21,839	$ 56,759

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

Emergent BioSolutions Inc. and subsidiaries
Consolidated statements of cash flows

(in thousands)	Year ended December 31, 2003	2004	2005	Nine months ended September 30, (unaudited) 2005	2006
Cash flows from operating activities:					
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities (net of effects of acquisitions):					
Stock-based compensation expense (credit)	—	4,310	(17)	—	442
Non-cash gain on settlement	—	(3,819)	—	—	—
Depreciation and amortization	1,214	1,867	3,549	2,495	3,265
Deferred income taxes	(467)	(418)	(10,968)	(10,313)	933
Other obligations	—	200	—	—	—
Loss on disposal of property and equipment	13	43	32	31	82
Purchased in-process research and development	1,824	—	26,575	26,575	477
Cash payment on State of Michigan obligation	540	—	—	—	—
Changes in operating assets and liabilities:					
Accounts receivable	(528)	(15,664)	16,107	16,299	(744)
Inventories	(4,656)	(1,609)	(3,189)	(3,009)	(11,627)
Income taxes	(1,713)	5,794	(2,390)	(2,509)	(4,913)
Prepaid expenses and other assets	(244)	50	(865)	(939)	(3,653)
Accounts payable	983	2,472	5,463	(1,275)	6,146
Accrued compensation	(583)	585	2,466	(1,163)	(1,279)
Other current liabilities	(1,617)	44	619	103	1,442
Deferred revenue	11,852	3,869	(10,916)	(10,916)	4,639
Net cash provided by (used in) operating activities	11,072	9,196	42,250	21,631	(8,126)
Cash flows from investing activities:					
Purchases of property, plant and equipment	(4,123)	(17,072)	(6,532)	(2,300)	(32,333)
Acquisitions, net of cash received	(3,794)	—	(559)	—	(218)
Restricted cash deposits	—	(1,250)	1,250	(17)	(190)
Proceeds from investment maturities	—	147	—	—	—
Net cash used in investing activities	(7,917)	(18,175)	(5,841)	(2,317)	(32,741)
Cash flows from financing activities:					
Proceeds from long-term debt and lines of credit	172	10,992	31	—	35,853
Proceeds from notes payable to employees	—	947	123	123	—
Repayments on product supply and royalty obligations	(900)	(2,351)	—	—	—
Issuance of Class B common stock	39	12	33	—	43
Redemption of Class B common stock	(200)	(665)	(337)	(339)	(221)
Principal payments on long-term debt and lines of credit	(38)	(184)	(1,110)	(958)	(11,290)
Debt issuance costs	—	(70)	—	—	—
Payment of dividend	—	—	(5,400)	(5,400)	—
Net cash provided by (used in) financing activities	(927)	8,681	(6,660)	(6,574)	24,385
Effect of exchange rate changes on cash and cash equivalents	—	—	(276)	(50)	94
Net increase (decrease) in cash and cash equivalents	2,228	(298)	29,473	12,690	(16,388)
Cash and cash equivalents at beginning of period	4,891	7,119	6,821	6,821	36,294
Cash and cash equivalents at end of period	$ 7,119	$ 6,821	$ 36,294	$ 19,511	$ 19,906
Supplemental disclosure of cash flow information:					
Cash paid during the year for interest	$ 99	$ 170	$ 696	$ 501	$ 665
Cash paid during the year for income taxes	$ 4,280	$ —	$ 17,985	$ 3,835	$ 1,470
Supplemental information on non cash investing and financing activities:					
Issuance of common stock to acquire Microscience Limited	$ —	$ —	$ 27,001	$ 27,001	$ —

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

Emergent BioSolutions Inc. and subsidiaries
Notes to consolidated financial statements
(dollars in thousands, except per share data)

1. Nature of the business and organization

Emergent Biosolutions Inc. (the Company or Emergent) is a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. The Company operates in two business segments: biodefense and commercial. The Company commenced operations as BioPort Corporation (BioPort) in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to the marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. Following this acquisition, the Company completed renovations at the Lansing facilities that had been initiated by the State of Michigan. In December 2001, the U.S. Food and Drug Administration (FDA) approved a supplement to the Company's manufacturing facility license for the manufacture of BioThrax at the renovated facilities. In June 2004, the Company completed a corporate reorganization (Reorganization) in which:

- Emergent issued 18,666,479 shares of Class A Common Stock in exchange for 18,017,994 shares of BioPort class A common stock and 648,485 shares of BioPort class B common stock;
- all other issued and outstanding shares of BioPort class B common stock were repurchased and retired; and
- all outstanding stock options to purchase BioPort class B common stock were assumed by Emergent and option holders were granted replacement stock options to purchase an equal number of shares of Class B Common Stock of Emergent.

As a result of the Reorganization, BioPort became a wholly owned subsidiary of Emergent. The Company has renamed BioPort as Emergent BioDefense Operations Lansing Inc. (Emergent BioDefense Operations). The Company acquired its portfolio of commercial vaccine candidates through an acquisition of Microscience Limited (Microscience) in a share exchange in June 2005 and an acquisition of substantially all of the assets of Antex Biologics Inc. (Antex) for cash in May 2003. The Company has renamed Microscience as Emergent Product Development UK Limited.

2. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying consolidated financial statements include the accounts of Emergent and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Unaudited interim financial information

The accompanying interim consolidated balance sheet as of September 30, 2006, the statements of operations and cash flows for the nine months ended September 30, 2005 and 2006 and the consolidated statement of changes in stockholders' equity for the nine months ended September 30, 2006 are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. In the opinion of the Company's management, the unaudited interim consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments necessary for the fair presentation of the Company's statement of financial position, results of operations and its cash flows for the nine months ended September 30, 2005 and 2006. The results for the nine months ended September 30, 2006 are not necessarily indicative of the results to be expected for the year ending

December 31, 2006. All references to September 30, 2006 or to the nine months ended September 30, 2005 and 2006 in the notes to the consolidated financial statements are unaudited.

Use of estimates

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

Cash and cash equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions and high-quality corporate bonds. Also, the Company maintains cash balances with financial institutions in excess of insured limits. The Company does not anticipate any losses with such cash balances. At December 31, 2004 and 2005 and September 30, 2006, the Company maintained all of its cash and cash equivalents in three financial institutions.

Fair value of financial instruments

The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The carrying value and fair value of long-term indebtedness were $11,821 and $11,409, respectively, at December 31, 2004 and $10,502 and $10,089, respectively, at December 31, 2005. The carrying value and fair value of long-term indebtedness were $35,606 and $34,998, respectively, at September 30, 2006.

Restricted cash

Restricted cash at December 31, 2004 and September 30, 2006 consists, in each case, of a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. The certificate of deposit outstanding as of December 31, 2004 was redeemed by the Company in October 2005.

Significant customers and accounts receivable

The Company's primary customers are the U.S. Department of Defense (DoD) and U.S. Department of Health and Human Services (HHS). For the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and 2006, sales of BioThrax to the DoD and HHS comprised 100%, 99% and 96% and 96% and 92% of total revenues, respectively. As of December 31, 2004 and 2005 and September 30, 2006, the Company's receivable balances were comprised of 96% and 38% and 98%, respectively, from these customers. Unbilled accounts receivable, included in accounts receivable, totaling $3,772 and $1,418 and $107 as of December 31, 2004 and 2005 and September 30, 2006, respectively, relate to various service contracts for which product has been delivered or work has been performed, though invoicing has not yet occurred. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from the DoD and HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. If necessary, the Company records a provision for doubtful receivables to allow for any amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends. As of December 31, 2004 and 2005 and September 30, 2006, an allowance for doubtful accounts was not recorded, as the prior collection history from these customers indicates collection is likely.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company places its cash and cash equivalents with high quality financial institutions. Management believes that the financial risks associated with its cash and cash equivalents are minimal. Because accounts receivable consist of amounts due from the U.S. federal government for product sales and from government agencies under government grants, management deems there to be minimal credit risk.

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. The Company analyzes its inventory levels quarterly and writes 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. The Company also writes off in the applicable period the costs related to expired inventory.

Property, plant and equipment

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the following estimated useful lives:

Buildings	39 years
Furniture and equipment	3-7 years
Internal-use software	Lesser of 3 years or product life
Leasehold improvements	Lesser of the asset life or life of lease

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

The Company capitalizes costs associated with purchased software from the time the preliminary project stage is completed until the software is ready for use. Under the provisions of the Statement of Position No. 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*, the Company capitalizes costs associated with software developed or obtained for internal use when the preliminary project stage is completed. Capitalized costs include only: (1) external direct costs of materials and services consumed in developing or obtaining internal use software and (2) payroll and payroll-related costs for employees who are directly associated with and who devote time to the internal use software project during the development stage. Capitalization of such costs ceases before training and other post implementation software activities occur. Computer software maintenance costs related to software development are expensed as incurred.

Income taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

The Company records valuation allowances to reduce deferred tax assets to the amounts that it anticipates will be realized. The Company considers future taxable income and ongoing tax planning

strategies in assessing the need for valuation allowances. In general, if the Company determines that it is able to realize more than the recorded amounts of net deferred tax assets in the future, net income will increase in the period in which the determination is made. Likewise, if the Company determines that it is not able to realize all or part of the net deferred tax asset in the future, net income will decrease in the period in which the determination is made. The Company applies any reversals of valuation allowance related to an acquired deferred tax asset against other intangibles before impacting net income.

Under sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a “loss corporation”, as defined, there are annual limitations on the amount of net operating losses and deductions that are available. Due to the acquisition of Microscience in 2005, the Company believes the use of the operating losses will be significantly limited.

The Company’s ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed above. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized prior to expiration.

Revenue recognition

The Company recognizes revenues from product sales in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB No. 104). SAB No. 104 requires recognition of revenues from product sales that require no continuing performance by the Company if four basic criteria have been met:

- there is persuasive evidence of an arrangement;
- delivery has occurred and title has passed to the Company’s customer;
- the fee is fixed and determinable and no further obligation exists; and
- collectibility is reasonably assured.

All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, special promotional programs, and discounts. For arrangements where the risk of loss has not passed to the customer, the Company defers the recognition of revenue until such time that risk of loss has passed. Also, the cost of revenue associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

Under the Company’s contract with the DoD, title to the product passes to the DoD upon submission of the first invoice. The earnings process is complete upon FDA release of the product for sale and distribution. Following FDA release of the product, the product is segregated for later shipment, and all deferred revenue related to the released product is recognized in accordance with the “bill and hold” requirements under SAB 104.

In December 2005, the Securities and Exchange Commission released an interpretation with respect to the accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into the strategic national stockpile. This interpretation provides for revenue recognition for specifically identified products purchased for the strategic national stockpile in the event that all requirements for revenue recognition, as specified in Statement of Financial Accounting Concepts No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*, are not met. This interpretation is applicable to the Company’s contracts with HHS, but because the Company recognizes revenue upon delivery of product, the Company has not applied this guidance.

The Company recognizes revenue from upfront and milestone payments in accordance with Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF No. 00-21), which addresses whether, for revenue recognition purposes, there is one or several elements in an arrangement. The Company recognizes revenue from milestone payments upon

achievement of pre-defined scientific events that require substantive effort if achievement of the milestone was not readily assured at the inception of the agreement.

Payments received by the Company for the reimbursement of expenses for research and development activities are recorded in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent* (EITF No. 99-19). Pursuant to EITF No. 99-19, for transactions in which the Company acts as principal, with discretion to choose suppliers, bears credit risk and performs a substantive part of the services, revenue is recorded at the gross amount of the reimbursement. Costs associated with these reimbursements are reflected as a component of research and development expenses.

Impairment of long-lived assets

In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), the Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. The Company has recorded no impairment losses for the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2006.

Research and development

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries, materials and related expenses for personnel and facility expenses. Other research and development expenses include fees paid to consultants and outside service providers and the costs of materials used in clinical trials and research and development.

Purchased in-process research and development

The Company accounts for purchased in-process research and development in accordance with the Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development Costs* (SFAS No. 2) along with Financial Accounting Standards Board (FASB) Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method — an interpretation of FASB Statement No. 2* (FIN 4). Under these standards, the Company is required to determine whether the technology relating to a particular research and development project acquired through an acquisition has an alternative future use. If the determination is that the technology has no alternative future use, the acquisition amount not directly attributed to fixed assets is expensed. Otherwise, the Company capitalizes and amortizes the costs incurred over their estimated useful lives of the technology acquired.

Comprehensive income (loss)

Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income* (SFAS No. 130), requires the presentation of the comprehensive income (loss) and its components as part of the financial statements. Comprehensive income 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).

Foreign currencies

The local currency is the functional currency for the Company's foreign subsidiaries and, as such, assets and liabilities are translated into U.S. dollars at year-end exchange rates. Income and expense items are

translated at average exchange rates during the year. Translation adjustments resulting from this process are charged or credited to other comprehensive income (loss).

Certain risks and uncertainties

The Company has derived substantially all of its revenue from sales of BioThrax under contracts with the DoD and HHS. The Company's ongoing U.S. government contracts do not necessarily increase the likelihood that it will secure future comparable contracts with the U.S. government. The Company expects that a significant portion of the business that it will seek in the near future, in particular for BioThrax, will be under government contracts that present a number of risks that are not typically present in the commercial contracting process. U.S. government contracts for BioThrax require annual funding decisions by the government and are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, which would harm its growth opportunities. The Company may not be able to sustain or increase profitability. The Company is spending significant amounts for the expansion of its manufacturing facilities. The Company may not be able to manufacture BioThrax consistently in accordance with FDA specifications. Other than BioThrax, all of the Company's product candidates are undergoing clinical trials or are in early stages of development, and failure is common and can occur at any stage of development. None of the Company's product candidates other than BioThrax has received regulatory approval.

Earnings per share

Basic net income (loss) attributable to common stockholders per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of shares outstanding for the period. Diluted net income (loss) attributable to common stockholders 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.

The following table presents the calculation of basic and diluted net income per share:

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Numerator:					
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Denominator:					
Weighted-average number of shares — basic	18,904,992	18,919,850	20,533,471	19,930,498	22,370,191
Dilutive securities — stock options	1,411,761	1,519,402	2,218,262	2,117,914	—
Weighted-average number of shares — diluted	20,316,752	20,439,252	22,751,733	22,048,412	22,370,191
Earnings (loss) per share — basic	$ 0.24	$ 0.61	$ 0.77	$ 0.31	$ (0.15)
Earnings (loss) per share — diluted	$ 0.22	$ 0.56	$ 0.69	$ 0.28	$ (0.15)

The Company has taken into consideration the disclosure required by the Participating Securities and the Two-Class Method under FASB Statement No. 128 (EITF No. 03-6).

Accounting for stock-based compensation

As of September 30, 2006, the Company has one stock-based employee compensation plan, the Emergent BioSolutions Employee Stock Option Plan (the Emergent Plan), described more fully in Note 10 — Stockholders' Equity. Through December 31, 2005, the Company accounted for grants under the Emergent Plan using the intrinsic value method in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25) and has provided the pro forma disclosures of net income (loss) and net income (loss) per share in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123) using the fair value method. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company's stock and the exercise price of the option and is recognized ratably over the vesting period of the option. The Company accounted for equity instruments issued to non-employees in accordance with SFAS No. 123 and 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* (EITF No. 96-18).

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 the fair value recognition provisions of SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate.

Under the modified prospective method, compensation cost recognized in 2006 includes: (1) compensation cost for all share-based payments granted prior to but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and

(2) compensation cost for all share-based payments granted subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). As a result of adopting SFAS No. 123(R) on January 1, 2006, the Company's loss before income taxes and net loss for the nine months ended September 30, 2006 is approximately $442 higher than if it had continued to account for share-based compensation under APB No. 25. Both basic and diluted losses per share for the nine months ended September 30, 2006 are $0.01 lower than if the Company had continued to account for share-based compensation under APB No. 25. Results for prior periods have not been restated. Based on options granted to employees as of September 30, 2006, total compensation expense not yet recognized related to unvested options is approximately $970, after tax. The Company expects to recognize that expense over a weighted average period of 2.8 years.

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:

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Expected dividend yield	0%	0%	0%	0%	0%
Expected volatility	100%	52%	50%	50%	50%
Risk-free interest rate	3.15%	2.93%	3.68%	4.18%	4.69%
Expected average life of options (years)	2.7	2.5	2.9	2.7	2.9
Forfeiture rate	0%	0%	0%	0%	5%

- *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 uses the historical volatility of similar companies over the preceding three-year period to estimate expected volatility. Since 2003, the annual volatility of these similar companies has ranged from 18.4% to 29.4%, with an average of 23.4%.
- *Risk-free interest rate* — This is the average U.S. Treasury rate with a term that most closely resembles the expected life of the option for the quarter in 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 employee position profile of option holders and the trading lock out periods that result from the employees access to stock price sensitive information.
- *Forfeiture rate* — This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on past turnover data with further consideration given to the level of the employees to whom the options were granted.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the statement of cash flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits of deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. There were no excess tax benefits classified as a financing cash inflow in the period ended September 30, 2006.

The following table illustrates the effect on net income (loss) and net income (loss) per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the three years ended December 31, 2003, 2004 and 2005 and for the nine months ended September 30, 2005 and 2006. The reported and pro forma net income (loss) and net income (loss) per share for the nine month period ended September 30, 2006 are the same because stock-based compensation expense is recorded under the provisions of SFAS No. 123(R) for that period.

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Net income, as reported	$4,454	$11,472	$15,784	$6,252	$(3,336)
Add: Stock-based compensation in reported net income, net of taxes	—	2,801	—	—	248
Deduct: Total stock-based compensation expense determined under the fair value based method for all awards, net of taxes	(133)	(3,185)	(258)	(161)	(248)
Pro forma net income	$4,321	$11,088	$15,526	$6,091	$(3,336)
Net income (loss) attributable to common stockholders per common share — basic	$ 0.24	$ 0.61	$ 0.77	$ 0.31	$ (0.15)
Net income (loss) attributable to common stockholders per common share — diluted	$ 0.22	$ 0.56	$ 0.69	$ 0.28	$ (0.15)
Pro forma net income (loss) attributable to common stockholders per common share — basic	$ 0.23	$ 0.59	$ 0.76	$ 0.31	$ (0.15)
Pro forma net income (loss) attributable to common stockholders per common share — diluted	$ 0.21	$ 0.54	$ 0.68	$ 0.28	$ (0.15)

Recent accounting pronouncements

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Prior to adoption, the Company will evaluate the impact of adopting SFAS No. 157 on the financial statements.

In June 2006, the FASB issued FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109, Accounting for Income Taxes* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes. 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. FIN 48 requires that the Company recognize in its 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. The provisions of FIN 48 are effective for

fiscal years beginning after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on the financial statements.

In March 2006, the FASB issued Statement No. 156, *Accounting for Servicing of Financial Assets — an amendment of FASB Statement No. 140* (SFAS No. 156). SFAS No. 156 requires an entity to recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset by entering into a servicing contract based on certain conditions. The provisions of SFAS No. 156 are effective for fiscal years beginning after September 15, 2006. The adoption of SFAS No. 156 will not have a material impact on the Company's consolidated financial statements.

In February 2006, the FASB issued Statement No. 155, *Accounting for Certain Hybrid Financial Instruments — an amendment of FASB Statements No. 133 and 140* (SFAS No. 155). SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement No. 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives and amends Statement No. 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. The provisions of SFAS No. 155 are effective for fiscal years beginning after September 15, 2006. The adoption of SFAS No. 155 will not have a material impact on the Company's consolidated financial statements.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation.

3. Acquisitions

ViVacs GmbH

On July 14, 2006, Emergent International, Inc., a wholly owned subsidiary of the Company incorporated in Delaware (EII), completed the acquisition of ViVacs GmbH, a German limited liability company (ViVacs), pursuant to the terms and conditions of the Share Exchange Agreement dated July 14, 2006 by and between EII and ViVacs. EII paid $150 in cash on the closing date of the agreement and agreed to pay $50 on each of the first and second anniversaries of the closing date. The acquisition agreement also provides for a potential variable earn-out purchase price of up to $220, based on future payments from third party licensees of the technology. As of September 30, 2006, the Company has not received any such payments from third party licensees. Because ViVacs was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Total purchase consideration consisted of:

Cash (including the present value of future guaranteed cash payments of $100)	$250
Direct acquisition costs	180
Total purchase consideration	$430

The assets acquired were accounted for in accordance with the provisions of SFAS No. 141, *Business Combinations* (SFAS No. 141). All of the tangible and intangible assets acquired and liabilities assumed of ViVacs were recorded at their estimated fair market values on the acquisition date.

The purchase price was allocated as follows:

Current assets	$ 153
Property and equipment	97
Current liabilities	(297)
Net liabilities acquired	47
In-process research and development	477
Total purchase consideration	$ 430

In connection with the transaction, the Company recorded a charge of $477 for acquired research projects associated with product candidates in development for which, at the acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed.

Microscience Limited

On June 23, 2005, Emergent Europe, Inc., a wholly owned subsidiary of the Company incorporated in Delaware (EEI), completed the acquisition of Microscience pursuant to the terms and conditions of the Share Exchange Agreement dated June 23, 2005 by and between EEI and Microscience Holdings plc, a public limited liability company incorporated in England. At the closing date, the Company, through EEI, issued Microscience shareholders 3,636,801 shares of the Company's Class A Common Stock in exchange for all of the outstanding stock of Microscience. Shares of Class A Common Stock of the Company were valued for financial statement purposes at $7.42 per share based on a determination of the estimated fair value by the Company's board of directors. Because Microscience was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Total purchase consideration consisted of:

Fair value of common stock	$27,001
Direct acquisition costs	1,194
Total purchase consideration	$28,195

The assets acquired were accounted for in accordance with the provisions of SFAS No. 141. All of the tangible and intangible assets acquired and liabilities assumed of Microscience were recorded at their estimated fair market values on the acquisition date.

The purchase price was allocated as follows:

Current assets	$ 1,441
Property and equipment	863
Current liabilities	(684)
Net assets acquired	1,620
In-process research and development	26,575
Total purchase consideration	$28,195

In connection with the transaction, the Company recorded a charge of $26,575 for acquired research projects associated with products in development for which, at the acquisition date, technological feasibility had not been established and no alternative future use existed.

Antex Biologics Inc.

On May 31, 2003, BioPort completed the acquisition of assets from Antex, a subsidiary of Antex Pharma Inc. (Pharma and, together with Antex, Sellers), pursuant to the terms and conditions of the Asset Purchase Agreement dated April 10, 2003 (the Purchase Agreement) by and among BioPort and Sellers. Pursuant to the Purchase Agreement, BioPort acquired from Sellers all of the assets and assumed certain liabilities for cash of $3,400 and transaction costs of $394. The amount of consideration was determined on the basis of arm's length negotiations between BioPort and Sellers. Because Antex was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Total purchase consideration consisted of:

Purchase price	$ 3,400
Direct acquisition costs	394
Total purchase consideration	$ 3,794

The assets acquired were accounted for in accordance with the provisions of SFAS No. 141. All of the tangible and intangible assets acquired and liabilities assumed of Antex were recorded at their estimated fair market value on the acquisition date.

The purchase price was allocated as follows:

Current assets	$ 279
Property and equipment	1,691
In-process research and development consideration	1,824
Total purchase consideration	$ 3,794

In connection with the transaction, the Company recorded a charge of $1,824 for acquired research projects associated with products in development for which, at the acquisition date, technological feasibility had not been established and no alternative future use existed.

4. Accounts receivable

Accounts receivable consist of the following:

	December 31,		September 30,
	2004	2005	2006
Billed	$ 14,865	$ 1,112	$ 3,166
Unbilled	3,772	1,418	107
Total	$ 18,637	$ 2,530	$ 3,273

5. Inventories

Inventories consist of the following:

	December 31, 2004	December 31, 2005	September 30, 2006
Raw materials and supplies	$ 1,947	$ 2,229	$ 2,165
Work-in-process	6,674	9,547	24,195
Finished goods	4,632	4,665	1,708
Inventories	$ 13,253	$ 16,441	$ 28,068

6. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31, 2004	December 31, 2005	September 30, 2006
Land and improvements	$ 2,963	$ 2,995	$ 5,124
Buildings and leasehold improvements	13,496	14,143	22,569
Furniture and equipment	10,563	12,520	14,597
Internal-use software	3,818	3,937	3,937
Construction in-progress	2,086	6,197	25,506
	32,925	39,792	71,733
Less: Accumulated depreciation and amortization	(5,657)	(9,147)	(12,101)
Property, plant and equipment, net	$27,269	$30,645	$ 59,632

Depreciation and amortization expense was $1,214, $1,867 and $3,549 for the years ended December 31, 2003, 2004 and 2005, respectively, and $2,495 and $3,265 for the nine months ended September 30, 2005 and 2006, respectively. For the years ended December 31, 2003, 2004 and 2005, depreciation and amortization expense included approximately $0, $209 and $1,257, respectively, related to internally developed software. For the nine months ended September 30, 2005 and 2006, depreciation and amortization expense included approximately $943 and $943, respectively, related to internally developed software.

7. Other assets

In connection with the acquisition of Microscience in 2005 as further described in Note 3 — Acquisitions, the Company acquired a facility lease deposit totaling $468. The deposit remains in effect as of December 31, 2005 and September 30, 2006.

8. Other current liabilities

Other current liabilities consist of the following:

	December 31, 2004	December 31, 2005	September 30, 2006
Contract costs	$ 3	$ 445	$ 1,948
Professional fees	1,462	1,390	1,056
Interest payable	71	146	259
Property taxes and other	357	628	838
	$ 1,893	$ 2,609	$ 4,101

9. Long-term debt and related party notes payable

The components of long term-debt and related party notes payable are as follows:

	December 31, 2004	December 31, 2005	September 30, 2006
Term loan dated August 2006, 9.151%, due August 2011	$ —	$ —	$ 10,000
Convertible Line of Credit dated August 2006	—	—	5,000
Term Loan dated October 2004; 6.625%, due October 2011	7,000	7,000	7,000
Forgivable Loan dated October 2004; 3.0%, due March 2013	2,500	2,500	2,500
ERP Term Loan dated August 2004; prime less 0.375%, due September 2007	2,280	1,760	1,280
Term Loan dated April 2006; LIBOR plus 3%, due April 2011	—	—	8,428
Employee notes payable for stock redemption; 6%, due 2006	947	537	63
Other	140	113	34
Total notes payable	12,867	11,909	34,305
Less current portion of notes payable	(1,046)	(1,408)	(1,750)
Long-term portion of notes payable	$11,821	$10,502	$ 32,555

In August 2006, the Company entered into a term loan for $10,000 and a revolving credit loan for up to $5,000. Under the term loan, the Company is required to make monthly principal payments beginning in April 2007. A residual principal payment of approximately $4,000 is due upon maturity in August 2011. At the Company's request, the term loan is subject to an extension term in the sole discretion of the lender for five additional years until August 2016 for an extension fee of 1.00% of the principal balance of the loan. If the term of the loan were extended, the Company would be required to continue to make monthly principal payments through maturity in August 2016 in lieu of the residual principal payment otherwise due in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75% (9.48% as of September 30, 2006).

Under the revolving credit loan, the Company is not required to repay outstanding principal until October 2007. In October 2007, the outstanding principal under the revolving credit loan will convert to a term loan with required monthly principal payments through maturity in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75% (9.48% as of September 30, 2006).

The Company also is required to pay a fee on a quarterly basis equal to 0.50% of the average daily difference between $5,000 and the amount outstanding under the revolving credit loan.

The term loan and revolving credit loan are secured by substantially all of Emergent BioDefense Operations' assets, other than accounts receivable under BioThrax supply contracts with the DoD and HHS. The Company is required to maintain on an annual basis a minimum tangible net worth of not less than the sum of 85% of tangible net worth for the most recently completed fiscal year plus 25% of current net operating profit after taxes. In addition, the Company is required to maintain on a quarterly basis a ratio of earnings before interest, taxes, depreciation and amortization for the most recent four quarters to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters, of not less than 1.25 to 1.00.

In April 2006, the Company completed the acquisition of a 150,000 square foot facility in Frederick, Maryland for $9,750. This facility was previously under a lease which contained an option to purchase the facility. The Company paid $1,250 in cash and financed the remaining balance with a bank loan in the amount of $8,500. This loan requires monthly principal and interest payments from May 2006 through April 2011 of $72 with a balloon payment for the remaining unpaid principal and interest due in April 2011. The interest rate is a floating rate based on the three month LIBOR plus 3% (8.37% as of September 30, 2006). The loan is collateralized by the 150,000 square foot facility. The loan requires the Company to comply with certain non-financial covenants.

In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund for $2.5 million. The proceeds of the loan were used to reimburse the Company for eligible costs it incurred to purchase a building in Frederick, Maryland. The loan is secured by a $1,250 letter of credit and a security interest in the building. The Company is required to pay an annual fee of 1% to maintain the letter of credit. The borrowing bears interest at 3% per annum, and the term of the loan ends March 31, 2013. The principal and related accrued interest may be forgiven if specified employment levels are achieved and maintained through December 2012, at least $42,900 in project costs are expended prior to December 2009 and the Company occupies the building through December 2012. The loan requires the Company to employ at least 280 full-time employees at the Company's facilities in Frederick, Maryland as of December 31, 2009 and maintain at least 280 full-time employees through December 31, 2012. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 280 and more than 225 full-time employees at the Company's facilities in Frederick, Maryland, then the Company will be required to repay $9 of principal plus accrued interest for each position not filled below the target level of 280 employees. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 225 full-time employees at the Company's facilities in Frederick, Maryland, then the Company will be required to repay the entire outstanding principal amount of the loan plus accrued interest. This loan is guaranteed by all of the subsidiaries of the Company.

In connection with the purchase of the building in Frederick, Maryland discussed above, the Company entered into a loan agreement for $7,000 with a bank to finance the remaining portion of the purchase price. The borrowing accrues interest at 6.625% per annum through October 2006. The Company is required to make interest only payments through that date. Beginning in November 2006, the Company will begin to make monthly payments of $62, based upon a 15 year amortization schedule. In November 2009, the monthly payments will be adjusted based upon a 12 year amortization schedule. All unpaid principal and interest is due in full in October 2011. The Company is required to maintain certain financial and non-financial covenants' including a minimum tangible net worth of not less than $5,000 and a debt coverage ratio of not less than 1.1 to 1. This loan is guaranteed by all of the subsidiaries of the Company.

During 2004, the Company implemented an Enterprise Resource Planning (ERP) system. The Company financed $2,280 of the costs through the issuance of a term loan. The loan bears interest at prime less 0.375% (8.63% as of September 30, 2006) and is due in September 2007. Monthly payments escalate from $40 to $106 over the term. The ERP system provides security for the loan.

In 2004, the Company issued notes as consideration for the repurchase of outstanding class B common stock of BioPort. These notes were issued to various current and past employees who were issued equity as a result of earlier stock option exercises. Amounts are payable in annual installments, through 2006, and bear interest at 6%.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2005 are as follows:

2006	$	1,408
2007		1,302
2008		317
2009		2,838
2010 and thereafter		6,045
	$	11,910

Line of credit

On April 1, 2005, the Company, through Emergent BioDefense Operations, formerly BioPort, obtained a line of credit that provides for borrowings of up to $10,000. The line of credit is scheduled to expire on November 15, 2006. The line of credit is secured by accounts receivable under our DOD and HHS contracts and bears interest at the prime rate less 0.375% (8.63% as of September 30, 2006). Emergent BioDefense Operations is subjected to certain covenants, including maintenance of specified equity levels on a quarterly basis. Emergent BioDefense Operations is currently in compliance with those covenants. There was $2,168 outstanding under this line of credit as of September 30, 2006. No borrowings were outstanding under this line of credit as of December 31, 2005.

10. Stockholders' equity

Preferred stock

The Company is authorized to issue up to 3,000,000 shares of preferred stock, $0.001 par value per share (Preferred Stock). Any preferred stock issued may have dividend rates, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's board of directors. As of September 30, 2006, no preferred stock has been issued.

Common stock

The Company currently has two classes of common stock authorized and outstanding: class A common stock, $0.001 par value per share (Class A Common Stock), and class B common stock, $0.01 par value per share (Class B Common Stock). The Company is authorized to issue up to 100,000,000 shares of the Class A Common Stock and 2,000,000 shares of the Class B Common Stock. Holders of Class A Common Stock are entitled to one vote for each share of Class A Common Stock held on all matters as may be provided by law. Holders of Class B Common Stock are not entitled to vote the shares of Class B Common Stock, except as otherwise required by law.

Holders of Class A Common Stock and Class B Common Stock are entitled to receive ratably dividends payable as and when declared by the Company's board of directors. On June 15, 2005, the Company's

board of directors declared a special cash dividend to the holders of outstanding shares of Class A Common Stock and Class B Common Stock in an aggregate amount of $5,400. The Company's board of directors declared this special dividend in order to distribute the net proceeds of a payment received as a result of the settlement of litigation initiated in 2002 by the Company against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which the Company believed it was entitled under a series of agreements regarding the development of botulinum toxin products. The Company paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. No regular dividends have been declared or paid.

Each share of Class B Common Stock will automatically convert into one share of Class A Common Stock immediately prior to the closing of the first underwritten sale of the Company's securities pursuant to an effective registration statement under the Securities Act of 1933, as amended. Following conversion, the Class B Common Stock will be eliminated and no further shares may be issued.

Prior to the formation of the Company, BioPort issued class A no-par voting common stock (BioPort Class A Common Stock) and class B no-par non-voting common stock (BioPort Class B Common Stock) to fund operations. BioPort, at its sole discretion, elected to redeem 71,927 shares of BioPort Class B Common Stock for $200 during the year ended December 31, 2003.

In June 2004, in the Reorganization, the Company issued 18,666,479 shares of Class A Common Stock in exchange for 18,017,994 shares of BioPort Class A Common Stock and 648,485 shares of BioPort Class B Common Stock held by BioPharm, L.L.C. The Company repurchased and retired the remaining issued and outstanding shares of BioPort Class B Common Stock from former employees. Approximately 544,000 BioPort shares were repurchased at $2.74 per share and approximately 28,000 BioPort shares were repurchased at $4.12 per share. Shares were repurchased for $665 in cash and the issuance of $947 in notes payable. See Note 9 — Long-term debt and related party notes payable, for additional information related to the former employee notes payable.

During the year ended December 31, 2005, the Company repurchased 112,168 shares of Class B Common Stock with an original weighted average cost of $0.26 per share, for $337.

Stock options

As of September 30, 2006, the Company has one stock-based employee compensation plan, the Emergent Plan, under which the Company has granted options to purchase shares of Class B Common Stock.

Prior to the Reorganization, BioPort had a separate stock option plan (BioPort plan) under which options were granted to purchase BioPort Class B Common Stock. The exercise price and vesting schedule for options were determined by BioPort's board of directors, or a committee thereof, which was established to administer the BioPort plan options.

As of June 30, 2004, options to purchase 1,948,892 shares of BioPort Class B Common Stock were outstanding under the BioPort plan. Pursuant to the Reorganization, all outstanding BioPort plan options were assumed by Emergent and option holders were granted replacement stock options to purchase an equal number of shares of Class B Common Stock of Emergent. The exercise period for the replacement options was extended to June 30, 2007. The BioPort options were scheduled to expire on June 30, 2004.

In connection with the Reorganization, the Company recorded stock-based compensation expense as a result of the issuance of the stock options to purchase Class B Common Stock. Based upon the guidance in APB No. 25, because the stock options granted for Class B Common Stock provided for an extended term over that of the cancelled BioPort plan options, a new measurement date was created and the Company recorded as stock-based compensation expense the excess of the intrinsic value of the

modified options over the intrinsic value of the BioPort plan options when originally issued. This resulted in stock-based compensation expense of $2,801, net of taxes, for the year ended December 31, 2004.

Outside of the reorganization, options to purchase an additional 322,235 shares of Class B common stock of Emergent under the Emergent Plan were granted during the year ended December 31, 2004.

The terms and conditions of stock options (including price, vesting schedule, term and number of shares) under the Emergent Plan are determined by the Company's compensation committee, which administers the Emergent Plan.

Each option granted under the Emergent Plan becomes exercisable as specified in the relevant option agreement, and no option can be exercised after ten years from the date of grant.

The Emergent Plan has both incentive and non-qualified stock option features. Under the plan, the Company may grant options totaling up to 3,596,375 shares of Class B Common Stock. The exercise price of each incentive option must be not less than 100% of the fair market value of the shares on the date of grant, except in the case of the incentive stock options being granted to a 10% stockholder, in which case the exercise price must be not less than 110% of the fair market value of the shares on the date of grant.

The following is a summary of stock option plan activity:

	BioPort Plan		Emergent Plan		
	Number of shares	Weighted average exercise price	Number of shares	Weighted average exercise price	Aggregate intrinsic value
Outstanding at December 31, 2002	2,311,007	$ 0.09	—	$ —	—
Granted	297,779	4.54	—	—	—
Exercised	(439,264)	0.09	—	—	—
Forfeited	(222,212)	0.28	—	—	—
Outstanding at December 31, 2003	1,947,310	0.75	—	—	—
Exercisable at December 31, 2003	1,319,714	0.20	—	—	—
Granted	136,348	1.08	810,866	2.74	—
Exercised	(122,584)	0.09	—	—	—
Converted from BioPort to Emergent Plan	(1,948,892)	0.43	1,948,892	0.43	—
Forfeited	(12,182)	0.47	(166,250)	1.20	—
Outstanding at December 31, 2004	—	—	2,593,508	$ 1.14	—
Exercisable at December 31, 2004	—	—	2,475,108	1.03	—
Granted	—	—	805,579	3.83	—
Exercised	—	—	(133,451)	0.32	—
Forfeited	—	—	(123,807)	2.63	—
Outstanding at December 31, 2005	—	—	3,141,829	$ 1.78	—

	BioPort Plan		Emergent Plan		
	Number of shares	Weighted average exercise price	Number of shares	Weighted average exercise price	Aggregate intrinsic value
Exercisable at December 31, 2005	—	—	2,452,483	$ 1.22	—
Granted (unaudited)	—	—	258,933	11.36	—
Exercised (unaudited)	—	—	(65,057)	0.65	—
Forfeited (unaudited)	—	—	(194,702)	2.62	—
Outstanding at September 30, 2006 (unaudited)	—	—	3,141,003	$ 2.54	$ 33,682,677
Exercisable at September 30, 2006 (unaudited)	—	—	2,334,176	$ 1.33	$ 27,854,588

The weighted average remaining contractual term of options outstanding and exercisable as of December 31, 2005 and September 30, 2006 was 2.46 years and 1.82 years, and 2.12 years and 1.26 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2003, 2004 and 2005 was $0.68, $0.95 and $1.37, respectively, and $4.28 for the nine months ended September 30, 2006. The total intrinsic value of options exercised during the years ended December 31, 2003, 2004 and 2005 and during the nine months ended September 30, 2006 was $1,165, $325 and $563 and $518, respectively.

At December 31, 2005, stock options outstanding and vested by exercise price were as follows:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted average remaining contractual life (years)	Weighted average exercise price	Number exercisable	Weighted average exercise price
$0.09	986,413	1.50	$ 0.09	986,413	$ 0.09
0.10	467,528	1.50	0.10	467,528	0.10
1.54	46,298	1.50	1.54	46,298	1.54
2.74	1,152,489	2.69	2.74	802,637	2.74
3.50	388,406	4.96	3.50	138,099	3.50
8.52	100,695	4.65	8.52	11,508	8.52
	3,141,829	2.46	$ 1.78	2,452,483	$ 1.22

Options granted from October 1, 2005 through September 30, 2006 are as follows:

Month of grant	Number of options granted	Weighted average exercise price	Weighted average fair value of common stock	Weighted average intrinsic value(1)
November 2005	28,770	8.52	8.52	—
June 2006	165,430	10.28	10.28	—
September 2006	93,503	13.26	13.26	—

(1) Intrinsic value reflects the amount by which the value of the shares as of the grant date exceeds the exercise price of the options.

11. Income taxes

Significant components of the provision for income taxes attributable to operations consist of the following:

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Current					
Federal	$1,717	$5,547	$ 16,093	$ 12,222	$(3,650)
State	—	—	200	200	100
Total current	1,717	5,547	16,293	12,422	(3,550)
Deferred					
Federal	(416)	(372)	(9,769)	(9,177)	833
State	(51)	(46)	(1,199)	(1,136)	100
Total deferred	(467)	(418)	(10,968)	(10,313)	933
Total provision (benefit) for income taxes	$1,250	$5,129	$ 5,325	$ 2,109	$(2,617)

The Company's net deferred tax asset consists of the following:

	December 31,		September 30,
	2004	2005	2006
Net operating loss carryforward	$ 666	$ 2,242	$ 4,180
Purchased in-process research and development	645	721	703
Stock compensation	1,457	1,696	1,393
Foreign deferrals	—	27,797	30,343
Other	883	1,219	1,245
Deferred tax asset	3,651	33,675	37,864
Fixed assets	(1,859)	(1,387)	(941)
Other	(124)	(393)	(673)
Deferred tax liability	(1,983)	(1,780)	(1,614)
Valuation allowance	(666)	(19,925)	(25,213)
Net deferred tax asset	$ 1,002	$ 11,970	$ 11,037

Net operating loss carryforwards consist of $92 million for state jurisdictions and $70 million for foreign jurisdictions. The state net operating loss carryforwards will begin to expire in 2018. The foreign net operating loss carryforwards will have an indefinite life unless the foreign entities have a change in the nature or conduct of the business in the three years following a change in ownership. The use of the Company's net operating loss carryforwards may be restricted due to changes in Company ownership. The Company paid $4,280, $0, and $17,985 in income taxes in 2003, 2004, and 2005, respectively. For the nine months ended September 30, 2005 and 2006, the Company paid $3,335 and $1,470 in income taxes, respectively.

The provision for income taxes differs from the amount of taxes determined by applying the U.S. federal statutory rate to loss before provision for income taxes as a result of the following:

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Federal tax at statutory rates	$1,996	$5,863	$ 7,388	$ 2,926	(1,794)
State taxes, net of federal benefit	(230)	(714)	(2,329)	(1,864)	(962)
Impact of foreign operations	—	—	(17,982)	(17,368)	(3,599)
Change in valuation allowance	187	479	19,259	17,712	5,288
Tax credits	(441)	(492)	(474)	(474)	—
Other differences	(255)	11	(211)	1,198	(1,840)
Permanent differences	(7)	(18)	(326)	(21)	290
Federal tax at statutory rates	$1,250	$5,129	$ 5,325	$ 2,109	$(2,617)

The estimated effective annual tax rate for the nine months ended September 30, 2005 and 2006 was 25% and 44%, respectively. The increase in the estimated rate is due primarily to an increase in the valuation allowance related to estimated foreign and state net operating losses.

The Company is the subject of an ongoing federal income tax audit for the tax year ended December 31, 2004. The financial statement impact of the audit has been estimated at approximately $500. This amount has been accrued as of September 30, 2006.

12. 401(k) savings plan

During 1999, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all employees. Under the 401(k) Plan, employees may make elective salary deferrals. The Company provides for matching of qualified deferrals up to 50% of the first 6% of the employee's salary. During the years ended December 31, 2003, 2004 and 2005, the Company made matching contributions of approximately $182, $452 and $520, respectively. During the nine months ended September 30, 2005 and 2006, the Company made matching contributions of approximately $384 and $431, respectively.

13. Commitments and settlement gains

Leases

The Company leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases office and laboratory space in Gaithersburg, Maryland under a noncancelable operating lease that contains a 3% annual escalation and expires on November 30, 2008. For the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and 2006, total rent expense was $890, $1,334 and $2,526 and $1,834 and $1,428, respectively.

Future minimum payments under operating lease obligations as of December 31, 2005 are as follows:

2006	$ 1,689
2007	1,249
2008	1,188
2009	56
Total minimum lease payments	$ 4,182

In July 2006, the Company entered into a lease agreement for approximately 23,000 square feet of office space in Rockville, Maryland. Annual rent begins at $600 per year and escalates at approximately

3% per year over the ten year term of the lease. The Company has a five year renewal option at the end of the initial term.

Vendor contracts

In accordance with a recently signed research contract, the Company is committed to spending a minimum of $200 in research and development activities by September 2007. To date, the Company has incurred minimal expenditures under this contract.

Litigation

In June 2002, the Company initiated a lawsuit against Élan Pharmaceuticals and related entities in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which the Company believed it was entitled under a set of 1991 agreements and to clarify intellectual property rights associated with those agreements. The Company sought damages, injunctive relief and declaratory relief. On June 27, 2005, the Company obtained a settlement pursuant to which Élan and related entities agreed to pay the Company $10,000. Payment of such settlement was received by the Company in July 2005. The agreement also clarified the parties' intellectual property rights. Upon receipt of the settlement from Élan Pharmaceuticals and related entities, the Company distributed a net settlement amount (total proceeds from the settlement less reserves for applicable federal and state income taxes, legal expenses related to the suit and other miscellaneous expenses) of $5,400 to all Company stockholders of record as of June 15, 2005.

In 1998, the Company recorded obligations related to the initial purchase agreement of Michigan Biologic Products Institute of $10,119. During 2004, the Company settled its entire remaining purchase obligations to the State of Michigan for $6,300, resulting in a gain of $3,819, which is reflected as a component of operations on the accompanying statement of operations.

From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material, adverse effect on the results of its operations.

14. Related party transactions

Simba LLC, a Maryland based limited liability company 100% owned by the Company's Chief Executive Officer and his wife, provides chartered air transportation. Simba offers its services to the Company on a discount from Simba's normal commercial rate. For the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and 2006, the Company paid approximately $0, $32 and $34 and $34 and $13, respectively, for transportation on an as needed basis for business purposes. As of May 2006, this arrangement has been terminated.

The Company has entered into marketing and sales contracts with family members of the Chief Executive Officer to market and sell BioThrax in certain international territories if certain conditions are met. A consulting arrangement with the Chief Executive Officer's sister requires a payment of 4% of net sales, not to exceed $2.00 per dose, under the agreement. A marketing arrangement with an entity affiliated with the Chief Executive Officer and his family requires a payment of 40% of gross sales in countries in the Middle East and North Africa, except Israel. No royalty payments under these agreements have been triggered for the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and 2006. The arrangement with the Chief Executive Officer's sister has been terminated.

For the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and 2006, the Company paid approximately $116, $494 and $794, and $630 and $370, respectively, in consulting and lease and transportation arrangements with various persons or entities affiliated with the Chief Executive Officer or two members of the board of directors. There was no

accounts payable balance for these services at September 30, 2006. The Company currently has an agreement with a director to perform corporate strategic issues consultation and directed project support to the marketing and communications group and an agreement with East West Resources Corporation, a company owned by the Chief Executive Officer, to provide transportation and logistical support.

15. Segment information

The Company operates in two business segments: biodefense and commercial. In the biodefense business, the Company develops and commercializes products for use against biological agents that are potential weapons of bioterrorism. Revenues in this segment relate to the Company's FDA approved product, BioThrax. In the commercial business, the Company develops products for use against infectious diseases with significant unmet or underserved medical needs. Revenues in this segment consist primarily of development and grant revenues received under collaboration and grant arrangements. The all other segment relates to the general operating costs of the business and includes costs of the centralized services departments, which are not allocated to the other segments. The assets in this segment consist of cash and fixed assets.

	Reportable segments			
	Biodefense	**Commercial**	**All other**	**Total**
Year Ended December 31, 2005				
External revenue	$ 128,219	$ 2,469	$ —	$ 130,688
Research and development	10,327	6,962	1,092	18,381
Interest revenue	—	—	485	485
Interest expense	—	—	(767)	(767)
Depreciation and amortization	2,911	411	226	3,548
Net income (loss)	58,632	(40,325)	(2,523)	15,784
Assets	40,502	5,489	54,341	100,332
Expenditures for long-lived assets	$ 3,286	$ 3,052	$ 194	$ 6,532
Year Ended December 31, 2004				
External revenue	$ 82,585	$ 909	$ —	$ 83,494
Research and development	6,279	1,136	2,702	10,117
Interest revenue	—	—	65	65
Interest expense	—	—	(241)	(241)
Depreciation and amortization	1,685	169	10	1,867
Net income (loss)	21,776	(5,428)	(4,876)	11,472
Assets	51,626	3,491	13,939	69,056
Expenditures for long-lived assets	$ 8,320	$ 668	$ 8,084	$ 17,072

	Reportable segments			
	Biodefense	Commercial	All other	Total
Year Ended December 31, 2003				
External revenue	$ 55,536	$ 233	$ —	$ 55,769
Research and development	4,352	477	1,498	6,327
Interest revenue	—	—	100	100
Interest expense	—	—	(293)	(293)
Depreciation and amortization	1,153	61	—	1,214
Net income (loss)	6,106	(1,459)	(193)	(4,454)
Asset	28,266	2,462	7,119	37,847
Expenditures for long-lived assets	$ 4,020	$ 103	$ —	$ 4,123

The accounting policies of the segments are the same as those described in the summary of significant accounting policies in Note 2 — Summary of significant accounting policies. There are no inter-segment transactions.

16. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2005 and 2004 is presented in the following tables:

	Three months ended			
	March 31	June 30	September 30	December 31
Fiscal year 2005				
Revenues	$15,261	$44,058	$27,581	$43,788
Income (loss) from operations	425	3,699	4,498	12,714
Net income (loss)	225	2,616	3,410	9,533
Net income (loss) per share, basic	0.01	0.14	0.15	0.43
Net income (loss) per share, diluted	0.01	0.12	0.13	0.38
Fiscal year 2004				
Revenues	$20,360	$13,044	$22,241	$27,848
Income (loss) from operations	3,758	(7,632)	8,063	12,582
Net income (loss)	2,582	(5,271)	5,580	8,560
Net income (loss) per share, basic	0.14	(0.27)	0.30	0.46
Net income (loss) per share, diluted	0.13	(0.27)	0.27	0.41

17. Subsequent events

On September 20, 2006, the Company's board of directors recommended to the stockholders of the Company an amendment of the Company's amended and restated certificate of incorporation, which the stockholders approved on October 27, 2006, that, among other things, reclassifies the Class A Common Stock as common stock, $0.001 par value per share (Common Stock), increases the number of authorized shares of Common Stock to 100,000,000 shares and adjusts the par value of the Preferred Stock from $0.01 par value per share to $0.001 par value per share. The amendment became effective on October 27, 2006. On September 20, 2006, the Company's board of directors also authorized the pricing committee of the board of directors to effect a stock split of both the Common Stock, in the form of a dividend of shares of Common Stock, and the Class B Common Stock, in the form of a

dividend of shares of Class B Common Stock. The pricing committee subsequently declared a 2.8771-for-one stock split of the Common Stock and the Class B Common Stock effective as of October 27, 2006. The par values, the number of authorized shares and all share and per share amounts in the consolidated financial statements have been retroactively adjusted to give effect to the filing of the certificate of amendment of the Company's amended and restated certificate of incorporation and the stock split. The consolidated financial statements do not reflect the reclassification of the Class A Common Stock as Common Stock, other than the related adjustment to par value and the increase in the number of authorized shares.

Emergent Product Development UK Limited
Report of Independent Auditors

The Board of Directors and Stockholders
Emergent Product Development UK Limited

We have audited the accompanying profit and loss account and statement of cash flows of Emergent Product Development UK Limited for each of the two years in the period ended December 31, 2004. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of the operations and the cash flows of Emergent Product Development UK Limited for each of the two years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United Kingdom which differ in certain respects from those generally accepted in the United States (see Note 17 of Notes to the financial statements).

/s/ Ernst & Young LLP

London, England
October 24, 2006

Emergent Product Development UK Limited

Profit and loss account

	Notes	For the year ended December 31, 2003 £'000	2004 £'000
Turnover and gross profit	3	93	42
Research and development costs		10,337	9,601
Other costs		800	948
Total administrative expenses		11,137	10,549
Operating loss		(11,044)	(10,507)
Interest receivable	5	144	131
Loss on ordinary activities before taxation	3	(10,900)	(10,376)
Taxation on loss on ordinary activities	7	1,173	1,256
Loss for the financial year	9	(9,727)	(9,120)

All results are in respect of continuing operations. There were no recognised gains and losses other than for the loss for the year of £9,120,000 (2003: £9,727,000).

A summary of the significant adjustments to loss for the financial year that would be required had United States generally accepted accounting principles been applied instead of those generally accepted in the United Kingdom, is set out in Note 17 of Notes to the Financial Statements.

The accompanying notes are an integral part of this profit and loss account.

Emergent Product Development UK Limited

Statement of cash flows

	Notes	For the year ended December 31, 2003 £'000	2004 £'000
Net cash outflow from operating activities	10	(11,111)	(8,329)
Returns on investments and servicing of finance	11	144	131
Taxation	11	949	1,124
Capital expenditure and financial investment	11	(244)	(160)
Net cash outflow before management of liquid resources and financing		(10,262)	(7,234)
Management of liquid resources	11	(3,200)	1,700
Financing	11	6,000	5,500
Decrease in cash	12	(7,462)	(34)

The significant differences between the statement of cash flows presented above and that required under United States generally accepted accounting principles are described in Note 17 of Notes to the Financial Statements.

The accompanying notes are an integral part of this statement of cash flows.

Emergent Product Development UK Limited
Notes to the financial statements

1. Accounting policies

The company's principal activity is the research and development of novel vaccines to combat infectious diseases. The company's scientific platforms offer the potential both to identify genes implicated in causing infectious diseases and to target and develop novel vaccines and anti-microbial compounds for those diseases.

Accounting convention

The financial statements are prepared under the historical cost convention and in accordance with United Kingdom accounting standards.

Group reorganisation

On June 4, 2004, Microscience Investments Limited (formerly Microscience Holdings plc) acquired 100% of the entire share capital (and all of the voting rights) of Emergent Product Development UK Limited (formerly Microscience Limited) in an exchange of shares, which resulted in the former shareholders of Emergent Product Development UK Limited holding the same proportion of the issued share capital of Microscience Investments Limited as they had held in Emergent Product Development UK Limited.

Basis of preparing the financial statements — going concern

The financial statements have been prepared on a going concern basis, which assumes that the company will continue in operational existence for the foreseeable future. During the year ended December 31, 2004, the company incurred a loss of £9,120,000 (2003: loss £9,727,000).

The validity of the going concern assumption depends on continued financial support from the ultimate parent company, Microscience Investments Limited, up to June 23, 2005, and from Emergent BioSolutions Inc. from June 24, 2005.

To fund its continued trading since December 31, 2004, the company obtained working capital funding from Microscience Investments Limited until June 23, 2005. On June 24, 2005, the entire working capital funding balance of £3,281,000 with Microscience Investments Limited was repaid via the issue of 5,553,603 ordinary shares of 5p each. On the same date, the entire share capital of the company was acquired by Emergent Europe Inc., a wholly owned subsidiary of Emergent BioSolutions Inc. Since that date, the company has obtained working capital funding from Emergent BioSolutions Inc., together with confirmation that adequate funding will be made available to enable the company to discharge its liabilities as they fall due. With this support in place, the directors believe that it is appropriate for the financial statements to be prepared on a going concern basis.

Related parties transactions

The company was a wholly owned subsidiary of Microscience Investments Limited until June 23, 2005, the consolidated financial statements of which are publicly available for the two years ended December 31, 2004. Accordingly, the company has taken advantage of the exemption in FRS 8 from disclosing transactions with members or investees of the Microscience group.

Revenue recognition

Revenues are earned from collaborative research agreements and licence fee agreements. Licence fees are recognised up-front where the fee is non-refundable and there are no ongoing obligations. Milestone payments under collaborative research agreements are recognised as revenue when earned, as evidenced by achievement of the specified milestones and the absence of ongoing performance obligations. Any

amounts received in advance of performance are recorded as deferred revenue. None of the revenues recognised to date are refundable if the relevant research effort is not successful.

Tangible fixed assets

All fixed assets are initially recorded at cost.

Depreciation

Depreciation is provided on all tangible fixed assets, at rates calculated to write off the cost or valuation, less estimated residual value based on prices prevailing at the date of acquisition or revaluation, of each asset evenly over its expected useful life, as follows:

Computers and office fixtures and fittings	Over 3-5 years
Research and development fixtures and fittings	Over 5 years
Leasehold improvements	Over the remaining term of the lease or the useful economic life, whichever is the shorter

The carrying values of tangible fixed assets are reviewed for impairment in periods if events or changes in circumstances indicate the carrying value may not be recoverable.

Research and development

Research and development expenditure is charged to the profit and loss account as incurred.

Leases

Assets held under finance leases, which are leases where substantially all the risks and rewards of ownership of the asset have passed to the company, and hire purchase contracts are capitalised in the balance sheet and are depreciated over their useful lives. The capital elements of future obligations under the leases and hire purchase contracts are included as liabilities in the balance sheet.

The interest elements of the rental obligations are charged in the profit and loss account over the periods of the contracts and represent a constant proportion of the balance of capital repayments outstanding.

Rentals payable under operating leases are charged in the profit and loss account on a straight-line basis over the lease term.

Pensions

The company makes contributions to personal pension plans for its employees. The contributions are charged to the profit and loss account as they become payable.

Deferred taxation

Deferred tax is recognised in respect of all timing differences that have originated but not reversed at the balance sheet date where transactions or events have occurred at that date that will result in an obligation to pay more, or a right to pay less or to receive more, tax, with the following exception:

- deferred tax assets are recognised only to the extent that the directors consider that it is more likely than not that there will be suitable taxable profits from which the future reversal of the underlying timing differences can be deducted.

Deferred tax is measured on an undiscounted basis at the tax rates that are expected to apply in the periods in which timing differences reverse, based on tax rates and laws enacted or substantively enacted at the balance sheet date.

Full provision for deferred tax is made in accordance with FRS 19.

Research and development tax credits

The Finance Act 2000 allows research companies of a certain size to claim a tax credit for qualifying research expenditures. The company has claimed these credits. The relevant tax credit for the year is shown in the profit and loss account as a reduction of any taxation due.

Employee share options

The company has granted share options to employees and, in accordance with Urgent Issues Task Force Abstract Number 17 (UITF17), records a non-cash charge to the profit and loss account for the difference between the exercise price of the option and the fair value of the underlying shares on the date of grant. The profit and loss charge is recognised over the period during which the incentive benefits of the option relate. During 2004, the company was acquired by Microscience Investments Limited and options previously granted to employees were rolled over into equivalent options over shares in the holding company. The effect of this reorganisation on options granted by the company is shown in Note 8.

Foreign currency

Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the balance sheet date. All differences are taken to the profit and loss account.

Collaboration arrangements

The company has entered into certain collaboration arrangements whereby the parties agree to work jointly on research and development of potential therapeutic products. Under such arrangements, the parties agree which element of research and development each will perform. These arrangements do not include the creation of any separate entity to conduct the activities nor any separate and distinct assets or liabilities. The parties agree that the combined cost of all relevant activities will be borne by the parties in a particular proportion and that net revenues derived from sales of any resulting product will be shared similarly. The sharing of costs will result in balancing payments between the parties and such payments receivable will be respectively added to or deducted from research and development costs in the profit and loss account. Any amounts receivable or payable at a period end are included in the balance sheet under debtors or creditors.

2. Turnover

Turnover, which is stated net of value added tax, represents revenues recognised from collaborative research agreements, and is generated wholly in Europe. Turnover is attributable to one business segment.

3. Loss on ordinary activities before taxation

The loss on ordinary activities before taxation is stated after charging:

	2003 £'000	2004 £'000
Auditors' remuneration — audit services	8	11
— non-audit services	5	111
Depreciation of owned fixed assets	323	333
Depreciation of assets held under finance leases	7	—
Loss on disposal of fixed assets	3	—
Operating lease rentals — land and buildings	256	250
— plant and machinery	7	7

For the year ended December 31, 2004, fees paid to the auditors, Ernst & Young LLP, include fees for work as reporting accountants in connection with an aborted UK initial public offering.

4. Exceptional items

	2003 £'000	2004 £'000
Recognised in arriving at operating loss:		
Costs associated with aborted initial public offering	—	494

5. Interest receivable

	2003 £'000	2004 £'000
Bank interest receivable	144	131

6. Staff costs

The average monthly number of employees (including executive directors) employed by the company during the year was:

	2003 No.	2004 No.
Research and development	65	64
Management and administration	7	6
	72	70

Staff costs, including executive directors, were:

	2003 £'000	2004 £'000
Wages and salaries	2,741	3,203
Social security costs	300	359
Pension costs	192	212
	3,233	3,774

Directors' emoluments were:

	2003 £'000	2004 £'000
Wages, salaries and other benefits	633	786
Pension costs	39	53
Compensation for loss of office	—	114
	672	953

The emoluments of the highest paid director were:

	2003 £'000	2004 £'000
Wages, salaries and other benefits	176	191
Pension costs	14	15
	190	206

7. Taxation

(a) Tax on loss on ordinary activities

The tax credit represents:

	2003 £'000	2004 £'000
Research and development tax credit	1,124	1,303
Adjustments in respect of previous periods	49	(47)
Total current tax (note 7(b))	1,173	1,256

(b) Factors affecting the tax charge

The tax assessed on the loss on ordinary activities for the year is lower than the standard rate of corporation tax in the United Kingdom of 30% (2003: 30%). The differences are reconciled below:

	2003 £'000	2004 £'000
Loss on ordinary activities before tax	(10,900)	(10,376)
Loss on ordinary activities multiplied by the standard rate of tax	(3,270)	(3,113)
Effect of:		
Disallowed expenses and non-taxable income	1,333	1,785
Capital allowances in arrears of depreciation	48	48
Tax losses	1,850	1,310
Research and development tax credit	(1,124)	(1,303)
Adjustments in respect of previous periods	(49)	47
Other timing differences	39	(30)
Total current tax (note 7(a))	(1,173)	(1,256)

(c) Factors that may affect future tax charges

There are tax losses of approximately £27,200,000 (2003**:** £22,400,000) available to carry forward against future trading profits, subject to the agreement of the Inland Revenue. No deferred tax assets have been recognised in respect of these amounts since the company does not anticipate generating taxable profits in the immediate future. The company claimed research and development tax credits for the year ended December 31, 2004 of £1,303,000 (year ended December 31, 2003: £1,124,000).

8. Share capital

As at January 1, 2003, and December 31, 2003 and 2004, the authorised and issued share capital of the company was as follows:

Authorised

	January 1, 2003, and December 31, 2003 No.	January 1, 2003 and December 31, 2003 £
'A' Ordinary shares of 0.001p each	16,670,000	167
'B' Ordinary shares of 0.001p each	48,123,900	481
'A' Preferred Ordinary shares of 0.001p each	29,640,573	296
'B' Preferred Ordinary shares of 0.001p each	86,148,649	861
Deferred shares of 99.998p each	11,434,241	11,434,012
	192,017,363	11,435,817

	December 31, 2004 No.	December 31, 2004 £
'A' Ordinary shares of 5p each	8,640,000	432,000
'B' Ordinary shares of 5p each	27,034,698	1,351,735
'A' Preferred Ordinary shares of 5p each	14,820,287	741,014
'B' Preferred Ordinary shares of 5p each	43,074,325	2,153,716
	93,569,310	4,678,465

Allotted, called up and fully paid

	January 1, 2003 No.	January 1, 2003 £
'A' Ordinary shares of 0.001p each	4,188,400	42
'B' Ordinary shares of 0.001p each	47,013,800	470
'A' Preferred Ordinary shares of 0.001p each	23,376,320	234
'B' Preferred Ordinary shares of 0.001p each	46,469,673	465
Deferred shares of 99.998p each	11,434,241	11,434,012
	132,482,434	11,435,223

	December 31, 2003 No.	December 31, 2003 £
'A' Ordinary shares of 0.001p each	4,188,400	42
'B' Ordinary shares of 0.001p each	47,013,800	470
'A' Preferred Ordinary shares of 0.001p each	23,396,392	234
'B' Preferred Ordinary shares of 0.001p each	65,039,776	650
Deferred shares of 99.998p each	11,434,241	11,434,012
	151,072,609	11,435,408

	December 31, 2004 No.	December 31, 2004 £
'A' Ordinary shares of 5p each	2,260,900	113,045
'B' Ordinary shares of 5p each	25,756,900	1,287,845
'A' Preferred Ordinary shares of 5p each	11,698,197	584,910
'B' Preferred Ordinary shares of 5p each	40,798,037	2,039,902
	80,514,034	4,025,702

Movements in share capital

On September 30, 2003, pursuant to a Subscription and Shareholders' Agreement dated February 18, 2002, the third tranche of 18,570,103 'B' Preferred Ordinary shares with an aggregate nominal value of

£185 were allotted to investors for gross proceeds of £6,000,000. During the year ended December 31, 2003, 20,072 'A' Preferred Ordinary shares were issued in relation to the exercise of share options at par.

On March 11, 2004, the company issued 16,556,290 'B' Preferred Ordinary shares of 0.001p each for aggregate cash consideration of £5.5 million.

On May 13, 2004, the company agreed to a reorganisation of its share capital prior to its acquisition by Microscience Investments Limited by way of a share for share exchange. The principal features of the reorganisation were:

(a) The issue of shares in the following amounts:

	2004 No.	2004 Gross proceeds £
'A' Preferred Ordinary shares of 0.001p each	2	1
'B' Preferred Ordinary shares of 0.001p each	8	2
	10	3

(b) The exercise of options held by certain shareholders over shares in the company as follows:

	2004 No.	2004 Gross proceeds £
'A' Ordinary shares of 0.001p each	333,400	3
'B' Ordinary shares of 0.001p each	4,500,000	45
	4,833,400	48

(c) The redemption of all of the deferred shares in issue for £1 out of the proceeds of the share issue noted above.

(d) A bonus issue of 2,499 shares of the same class for every share then owned by the holders of each of the 'A' Ordinary, 'A' Preferred Ordinary, 'B' Ordinary and 'B' Preferred Ordinary shares.

(e) The consolidation of every 5,000 shares of each class subject to the bonus issue in (d) above into one new share of each respective class with a nominal value of 5p.

Rights of the shares

Ordinary and Preferred Ordinary shares

The 'A' and 'B' Ordinary and the 'A' and 'B' Preferred Ordinary shares rank *pari passu* as regards both dividends and voting rights but constitute separate classes of equity shares. In a sale or liquidation the 'B' Preferred Ordinary shareholders take precedence over the 'A' Preferred Ordinary shareholders, who in turn take precedence over the 'A' and 'B' Ordinary shareholders.

Deferred shares

The rights of the deferred shares are as follows:

Priority on a winding up

On a return of assets on a liquidation or otherwise, the deferred shareholders are entitled to receive payment of the subscription price paid for the shares after the holders of the 'A' and 'B' Preferred

Ordinary and ‘A’ and ‘B’ Ordinary shares have received £1,000,000 in respect of each such Preferred Ordinary share and Ordinary share.

Voting rights

Deferred shareholders have no voting rights.

Redemption

The company may redeem the deferred shares for an aggregate price of £1 at any time.

Dividends

The deferred shareholders have no dividend rights.

Classification

The deferred shares are classed as non-equity.

Share options

Options over ‘A’ Ordinary shares have been granted to directors, employees and consultants under unapproved and approved share option schemes. Details of movements in share options for the two years ended December 31, 2003 and 2004 are as follows:

	‘A’ Ordinary shares No.	**‘A’ Preferred Ordinary shares No.**
At January 1, 2003 (over shares of 0.001p each)	9,611,476	—
Granted	2,300,000	—
Exercised	(20,072)	—
Lapsed	(216,300)	—
At December 31, 2003 (over shares of 0.001p each)	11,675,104	—
Granted	1,000,000	—
Reclassified	(377,504)	377,504
Exercised	(333,400)	—
Lapsed	(1,403,600)	—
Terms varied as a result of capital reorganisation	(50,000)	(188,752)
Options cancelled in exchange for options in Microscience Investments Limited	(10,460,600)	—
At December 31, 2004 (over shares of 5p each)	50,000	188,752

To the extent not previously exercised the options outstanding at December 31, 2004 expired on May 31, 2005.

As part of the capital reorganisation undertaken by the group, certain options in issue at the date of reorganisation were rolled over into options on exactly equivalent terms over the equivalent class of share in the company’s holding company, Microscience Investments Limited.

Where options were retained in Emergent Product Development UK Limited, the terms of the options were varied to provide an equivalent interest and economic benefit in the shares of the company under

the new capital structure. On exercise of these options provision has been made for the resulting issued shares to be exchanged for equivalent shares in Microscience Investments Limited.

Shareholders' share options

At January 1, 2003 and 2004, the Merlin Fund held 3,000,000 options over 'B' Ordinary shares exercisable at par and Apax Funds Nominees Limited held a further 1,500,000 options over 'B' Ordinary shares exercisable at par. These options were exercised immediately prior to the capital reorganisation on May 7, 2004.

In addition to the above, at January 1, 2003 and 2004, Imperial College held options over 500,000 'B' Ordinary shares at an exercise price of 30p per share and Apax Funds Nominees Limited held options over 2,055,596 'B' Ordinary shares at an exercise price of 50p per share.

Under the terms of the capital reorganisation on May 13, 2004, the terms of the options were varied to provide an equivalent interest and economic benefit in the shares of the company under the new capital structure. On exercise of these options, provision was made for the resulting issued shares to be exchanged for equivalent shares in Microscience Investments Limited. As a result of the above, at December 31, 2004 Imperial College retained an option over 250,000 5p 'B' Ordinary shares with an exercise price of 60p per share and Apax Funds Nominees Limited retained an option over 1,027,798 5p 'B' Ordinary shares with an exercise price of £1 per share.

9. Reconciliation of movements on reserves and shareholders' funds

	Called up share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Profit and loss account £'000	Total share-holders' funds £'000
At January 1, 2003	11,435	17,055	—	(20,611)	7,879
Issue of share capital	—	6,000	—	—	6,000
Loss for the year	—	—	—	(9,727)	(9,727)
At December 31, 2003	11,435	23,055	—	(30,338)	4,152
Issue of share capital	—	5,500	—	—	5,500
Loss for the year	—	—	—	(9,120)	(9,120)
Deferred shares redeemed out of proceeds of fresh issue	(11,434)	—	11,434	—	—
Effect of capital reorganisation	4,025	(4,025)	—	—	—
At December 31, 2004	4,026	24,530	11,434	(39,458)	532

10. Reconciliation of operating loss to operating cash flows

	2003 £'000	2004 £'000
Operating loss	(11,044)	(10,507)
Depreciation	330	333
Loss on disposal of tangible fixed assets	3	—
Write-off of investment and loan to joint venture	65	—
(Increase)/decrease in debtors	(114)	183
(Decrease)/increase in creditors	(351)	1,742
Decrease in provisions	—	(80)
Net cash outflow from operating activities	(11,111)	(8,329)

11. Analysis of cash flows

	2003 £'000	2004 £'000
Returns on investments and servicing of finance:		
Interest received	144	131
Taxation:		
Research and development tax credit received	949	1,124
Capital expenditure and financial investment:		
Purchase of tangible fixed assets	(184)	(160)
Proceeds from the sale of tangible fixed assets	5	—
Investment and loan to joint venture	(65)	—
Net cash outflow	(244)	(160)
Management of liquid resources:		
(Increase)/decrease in short-term deposits	(3,200)	1,700
Net cash (outflow)/inflow	(3,200)	1,700
Financing:		
Issue of Preferred ordinary share capital	6,000	5,500
Net cash inflow	6,000	5,500

Liquid resources comprise short-term cash deposits.

12. Analysis and reconciliation of net funds

	At January 1, 2003 £'000	Cash flow £'000	At December 31, 2003 £'000
Bank current account	7,878	(7,462)	416
Short-term deposits*	—	3,200	3,200
Cash at bank and in hand/net funds	7,878	(4,262)	3,616

* Short-term deposits are included within cash at bank and in hand in the balance sheet.

	At January 1, 2004 £'000	Cash flow £'000	At December 31, 2004 £'000
Bank current account	416	(34)	382
Short-term deposits*	3,200	(1,700)	1,500
Cash at bank and in hand/net funds	3,616	(1,734)	1,882

	2003 £'000	2004 £'000
Decrease in cash in the year	(7,462)	(34)
Increase/(decrease) in liquid resources	3,200	(1,700)
Change in net funds resulting from cash flows	(4,262)	(1,734)
Movement in net funds in year	(4,262)	(1,734)
Net funds at January 1,	7,878	3,616
Net funds at December 31,	3,616	1,882

13. Operating leases

At December 31, 2004 the company had annual commitments under operating leases expiring as set out below:

	Land and buildings		Other	
	2003 £'000	2004 £'000	2003 £'000	2004 £'000
Between two and five years	256	250	7	3

14. Pension costs

The company makes contributions to personal pension plans for its employees. During the year, contributions payable amounted to £212,000 (2003: £192,000).

15. Related party transactions

Imperial College of Science, Technology and Medicine, a shareholder, recharged expenses of £253,000 (2003: £206,000) incurred on behalf of the company, principally related to research and development costs.

The following fees were paid to major shareholders during the year for the provision of directors' services:

	Paid during year	
	2003 £'000	2004 £'000
Merlin Biosciences Limited	16	16
Apax Europe IV GP Co Limited	15	16
Advent Venture Partners	15	20
JP Morgan Partners	15	16
	61	68

The following shareholders charged expenses for their services as directors and for consultancy work as follows:

	Paid during year	
	2003 £'000	2004 £'000
M. Redmond	22	23
S. Harris	16	10
A. Lindberg	15	51
	53	84

16. Post balance sheet events

On June 24, 2005, the company was acquired by Emergent Europe Inc., a wholly owned subsidiary of Emergent BioSolutions Inc.

On July 22, 2005, the company changed its name from Microscience Limited to Emergent Europe Limited.

On November 11, 2005, the company changed its accounting reference date from December 31 to June 23, in order to prepare financial statements for the period up to acquisition by Emergent Europe Inc.

On May 4, 2006, the company entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialisation of the company's meningitis B vaccine candidate and received a €3 million upfront licence fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialisation objectives, payments for development work under the collaboration and royalties on net sales of this product.

On May 25, 2006, the company changed its name from Emergent Europe Limited to Emergent Product Development UK Limited.

On September 26, 2006 the company changed its accounting reference date from June 23 to December 31 in order to align its statutory financial statements period to that of its ultimate parent company, Emergent BioSolutions Inc.

17. Reconciliation to US GAAP

Summary of significant differences between UK GAAP followed by the company and US GAAP

The company's financial statements have been prepared in accordance with accounting principles generally accepted in the United Kingdom (UK GAAP), which differ in certain significant respects from accounting principles generally accepted in the United States (US GAAP). The following is a summary of adjustments to net loss and cash flows required when reconciling such amounts recorded in the financial statements to the corresponding amounts in accordance with US GAAP.

(a) Employee share options modification

The company modified certain options over 'A' Ordinary shares to employees during the year ended December 31, 2004, such that the awards now pertain to 'A' Preferred Ordinary shares.

Under UK GAAP, there is no accounting for the cost of these grants after the initial grant date.

Under US GAAP, Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, as interpreted by Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, the modification is treated as a cancellation of the original award with replacement by a new award over 'A' Preferred Ordinary shares. The intrinsic value of the replacement awards on the date of grant has been recorded as compensation expense for the year ended December 31, 2004.

(b) Accounting for national insurance on share options

Under UK GAAP, the company has accounted for a potential liability to employee's National Insurance on certain employee share options. The provision has been made systematically by reference to the market value of shares at the balance sheet dates over the period from the date of grant to the end of the relevant vesting period and from that date to the date of actual exercise the provision is being adjusted by reference to changes in market value. The provisions as at December 31, 2003 and 2004 were £80,000 and nil, respectively. The net credits to the profit and loss account for the years ended December 31, 2003 and 2004 amounted to £nil and £80,000, respectively.

Under US GAAP, Emerging Issues Task Force Issue No. 00-16, *Recognition and Measurement of Employer Payroll Taxes on Employer Stock Based Compensation*, no liability to national insurance is recognised until such time as the share option is exercised since this is when the liability crystallises. This adjustment removes the timing difference relating to the expense in the income statement.

(c) Vacation pay

Under UK GAAP, the company does not record accruals at the balance sheet date for employees' vacation earned but not taken. Under US GAAP, such accruals are required.

The charge/(credit) for the years ended December 31, 2004 and 2003 would be £1,000 and £(1,000), respectively.

(d) Taxation

Under UK GAAP, deferred tax is provided in full on timing differences which results in an obligation at the balance sheet date to pay more tax, or a right to pay less tax, at a future date, at rates expected to apply when they crystallise based on current tax rates and law. Net deferred tax assets are recognised to the extent that it is regarded as more likely than not that they will be recovered.

Under US GAAP, deferred tax is recognised in full in respect of temporary differences between the reported carrying amount of an asset or liability and its corresponding tax basis. Deferred tax assets are also recognised in full subject to a valuation allowance to reduce the amount of such assets to that which is more likely than not to be realised.

As at December 31, 2004 and 2003, the company had approximately £27,200,000 and £22,400,000 of cumulative tax losses respectively. These losses represent a deferred tax asset for accounting purposes. In accordance with both UK GAAP and US GAAP, no asset has been recognised in respect of these tax losses due to the uncertainty as to whether these losses can be offset against future profits.

Reconciliation of net loss from UK GAAP to US GAAP

	Notes	2003 £'000	2004 £'000
Net loss as reported under UK GAAP		(9,727)	(9,120)
Adjustments for: *			
Employee share options modifications	(a)	—	(5)
Accounting for National Insurance on share options	(b)	—	(80)
Vacation pay	(c)	(1)	1
Net loss as reported under US GAAP		(9,728)	(9,204)

* The deferred tax effect of reconciling items has not been reflected as, where a deferred tax asset arises, a valuation allowance would be recognised against that asset, and where a deferred tax liability arises, the valuation allowance would be reduced accordingly.

Statement of cash flows

The statement of cash flows prepared under UK GAAP presents substantially the same information as that required under US GAAP by Statement of Financial Accounting Standards No. 95, *Statement of Cash Flows*. These standards differ however with regard to classification of items within the statement and the definition of cash and cash equivalents.

Under UK GAAP, cash comprises cash in hand, deposits repayable on demand and bank overdrafts. Deposits are repayable on demand if they can be withdrawn at any time without notice and without penalty or if a maturity or period of notice of not more than 24 hours or one working day has been agreed. Under US GAAP, cash equivalents are short-term highly liquid investments, generally with original maturities of three months or less, that are readily convertible to known amounts of cash and present insignificant risk of changes in value because of changes in interest rates.

Under UK GAAP, cash flows are presented separately for operating activities, returns on investments and servicing of finance, taxation, capital expenditure and financial investment, management of liquid resources and financing activities. US GAAP requires only three categories of cash flow activity to be reported: operating, investing and financing. Cash flows from taxation and returns on investments and servicing of finance under UK GAAP would, with the exception of dividends paid, be shown under operating activities under US GAAP. The payment of dividends and the payment to acquire own shares (treasury stock) would be included as a financing activity under US GAAP. Management of liquid resources under UK GAAP would be included as cash and cash equivalents. Under US GAAP management of liquid resources would be included as an investing activity to the extent that such amounts have an original maturity of more than three months and are convertible into known amounts of cash.

Summary statements of cash flows presented under US GAAP using UK GAAP measurement principles are given below:

	2003 £'000	2004 £'000
Net cash used in operating activities	(10,018)	(7,074)
Net cash used in investing activities	(244)	(160)
Net cash provided by financing activities	6,000	5,500
Decrease in cash and cash equivalents	(4,262)	(1,734)
Beginning cash and cash equivalents	7,878	3,616
Ending cash and cash equivalents	3,616	1,882

Emergent BioSolutions Inc. and subsidiaries
Unaudited pro forma condensed combined statement of operations
For the year ended December 31, 2005

The unaudited pro forma condensed combined financial information is presented to give effect to the acquisition of Microscience by Emergent and represents the combined company's unaudited pro forma statements of operations for the year ended December 31, 2005. The statement of operations for the year ended December 31, 2005 was derived by combining the results for the year ended December 31, 2005 of Emergent with the results of Microscience as if the acquisition had occurred on January 1, 2005.

	Emergent	Microscience	Pro forma adjustments	Pro forma combined
Revenues:				
Product sales	$ 127,271	$ —	$ —	$ 127,271
Contracts and grants	3,417	—	—	3,417
	130,688	—	—	130,688
Operating expense (income):				
Cost of product sales	31,603	—	—	31,603
Research and development	18,381	5,963	—	24,344
Selling, general and administrative	42,793	557	—	43,350
Purchased in-process research and development	26,575	—	—	26,575
Litigation settlement	(10,000)	—	—	(10,000)
Income (loss) from operations:	21,336	(6,520)	—	14,816
Other income (expense)	(227)	22	—	(205)
Income (loss) before provision for (benefit from) income taxes	21,109	(6,498)	—	14,611
Provision for (benefit from) income taxes	5,325	(781)	—	4,544
Net income (loss)	$ 15,784	$ (5,717)	$ —	$ 10,067
Earnings (loss) per share — basic	$ 0.77			$ 0.45
Earnings (loss) per share — diluted	$ 0.69			$ 0.41
Weighted-average number of shares — basic	20,533,471		1,769,809	22,303,280
Weighted-average number of shares — diluted	22,751,733		1,769,809	24,521,542

The accompanying note is an integral part of this pro forma condensed combined statement of operations.

Emergent BioSolutions Inc. and subsidiaries
Note to unaudited pro forma condensed combined statement of operations
For the year ended December 31, 2005

On June 23, 2005, Emergent Europe, Inc., a wholly owned subsidiary of Emergent incorporated in Delaware (EEI), completed the acquisition of Microscience pursuant to the terms and conditions of the Share Exchange Agreement dated June 23, 2005 by and among EEI and Microscience Holdings plc, a public limited liability company incorporated in England. At the closing date, Emergent, through EEI, issued Microscience shareholders 3,636,801 shares of Emergent's Class A Common Stock in exchange for all of the outstanding stock of Microscience.

The pro forma condensed combined statement of operations has been prepared by management of Emergent without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. However, management believes that the disclosures are adequate to make the information not misleading.

The unaudited pro forma condensed combined financial statements do not reflect one-off items directly attributable to the acquisition, such as the write-off of purchased in-process research and development. The unaudited pro forma condensed combined financial statements should be read in conjunction with the historical consolidated financial statements and related notes and other financial information pertaining to Emergent and Microscience, including "Management's discussion and analysis of financial condition and results of operations" and "Risk factors," which appear elsewhere in this prospectus.

5,000,000 shares

Common stock

Prospectus

JPMorgan
Cowen and Company
HSBC

November 14, 2006

Until December 9, 2006 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.