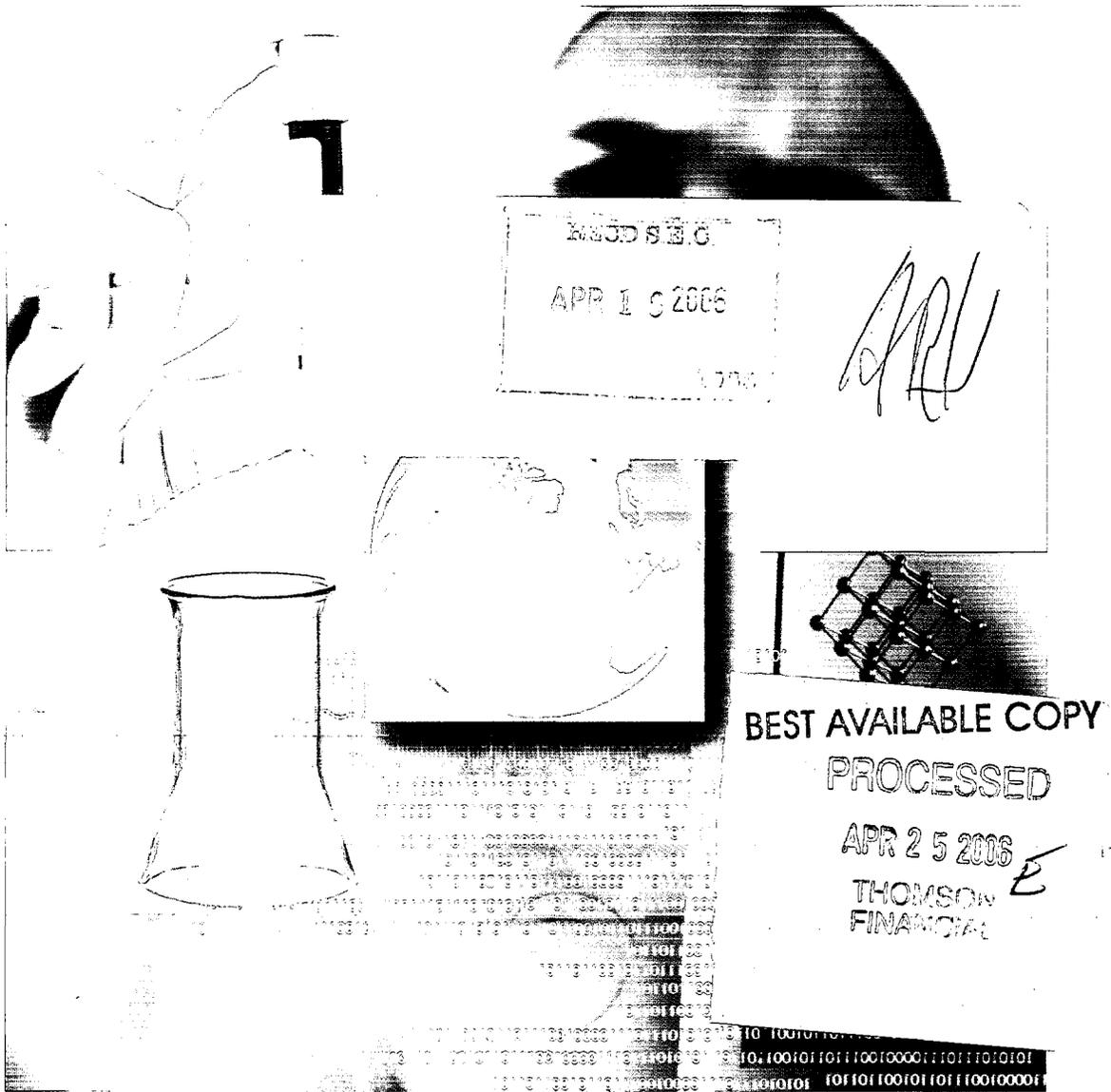


Inhibitex, Inc.

2005 Annual Report



06032993



Revolutionary Thinking. Evolutionary Medicine.

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

**Form 10-K**

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

For the fiscal year ended December 31, 2005

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-50772

**Inhibitex, Inc.**

*(Exact name of Registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**9005 Westside Parkway  
Alpharetta, GA**

*(Address of Principal Executive Offices)*

**74-2708737**

*(I.R.S. Employer  
Identification Number)*

**30004**

*(Zip Code)*

**(678) 746-1100**

*(Registrant's telephone number, including area code)*

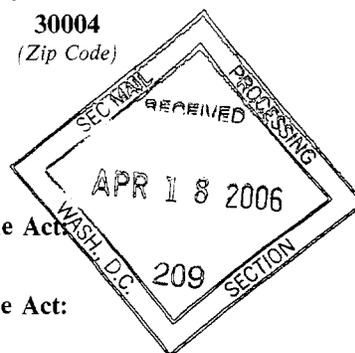
**Securities registered pursuant to Section 12(b) of the Act:**

**None**

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

**Common Stock, par value \$0.001 per share**

*(Title of Class)*



Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  
Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

The approximate aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price on June 30, 2005 was \$190,539,087

Number of shares of Common Stock outstanding as of March 1, 2006: 30,243,649

**Documents incorporated by reference:**

Portions of the definitive Proxy Statement with respect to the 2006 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (Part III).

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*Inhibitex®*, *MSCRAMM®*, *Veronate®* and *Aurexis®* are registered trademarks of *Inhibitex, Inc.*  
*MSCRAMM* is an acronym for *Microbial Surface Components Recognizing Adhesive Matrix Molecules.*

## PART I

### ITEM 1. BUSINESS

#### SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. These forward-looking statements are principally contained in the sections entitled “Item 1-Business”, “Item 2-Properties” and “Item 7-Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “project,” “predict,” “forecast,” “potential,” “likely” or “possible”, as well as the negative of such expressions, and similar expressions intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements relating to:

- our ability to discover and develop novel therapies to prevent or treat serious, life threatening infections based on our expertise in MSCRAMM proteins;
- the potential advantages of using antibody-based products over existing therapies;
- the ability of antibodies that target MSCRAMM proteins to reduce the incidence and severity of bacterial and fungal infections;
- the ability of Veronate to reduce the number of hospital-associated infections caused by *Staphylococcus aureus*, *coagulase negative staphylococci*, and *Candida* and reduce overall mortality in very low birth weight, or VLBW infants;
- potential future revenue from collaborative research agreements, partnerships, or materials transfer agreements;
- our ability to successfully commercialize our products and generate product-related revenue in the future;
- the potential volatility of our quarterly and annual operating results;
- the potential to discover, develop or commercialize any product candidates resulting from existing or future collaborations, including those with Dyax and Wyeth;
- the anticipated length of time to generate data from our Phase III Veronate trial;
- results of the Phase III trial for Veronate being sufficient to complete a rolling Biological License Application (“BLA”) submission for Veronate and the timing of completing such a submission;
- the availability of suitable sources of plasma for the manufacture of Veronate;
- the ability to successfully manufacture Veronate;
- our intention and timing to proceed to a clinical trial to assess the safety and efficacy of two doses of Aurexis;
- our intention to proceed to a larger, well-powered clinical trial of Aurexis in patients with *S. aureus* bloodstream infections, the timing, design and size of such clinical trial and the concurrence by the U.S. Food and Drug Administration, or FDA therewith;
- the initiation of additional clinical trials for Aurexis in other indications;
- our intention to apply for Fast Track and Orphan Drug status for our other product candidates;

- our plans to establish a specialized hospital-based sales force and commercialize our product candidates, particularly Veronate, in the United States;
- the potential market opportunity for our product candidates, particularly Veronate;
- our plan to establish partnerships or collaborations with other entities to develop and commercialize our product candidates in other countries outside of the United States;
- the potential benefits related to Fast Track, Orphan Drug and Orphan Medicinal Product status;
- increases in our research and development expenses, general and administrative expenses and operating losses in the future;
- the planned adoption of Statement of Financial Accounting Standard No. 123 (Revised 2004), *Share-Based Payments* (“SFAS No. 123(R)”) and the expected future amortization of stock compensation;
- our future financing requirements and how we expect to fund them;
- the number of months that our current cash, cash equivalents, short-term investments, and our borrowing capacity under existing arrangements will allow us to operate.

These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties including, without limitation: that the preceding preclinical and clinical results related to our antibody-based products, including Veronate and Aurexis, are not reflective of future results; Wyeth terminating our license and collaborative research agreement; our ability to contract with a sufficient number of clinical trial sites to perform our clinical trials; the cost and rate at which investigators at such sites can recruit patients into our clinical trials; our ongoing or future clinical trials not demonstrating the appropriate safety and efficacy of our product candidates; our ability to successfully develop current and future product candidates either independently or in collaboration with business partners; our ability to secure and our use of third-party contract clinical research and data management organizations, raw material suppliers and manufacturers, who may not fulfill their contractual obligations or otherwise perform satisfactorily in the future; manufacturing and maintaining sufficient quantities of clinical trial material on hand to complete our clinical trials on a timely basis; our failure to obtain Data Safety Monitoring Board, or DSMB, or regulatory approval to commence or continue our clinical trials or to market our product candidates; our ability to protect and maintain our proprietary intellectual property rights from unauthorized use by others; our collaborators do not fulfill their obligations under our agreements with them in the future; our successful development of a marketing, sales and corporate infrastructure capable of supporting the commercialization of Veronate; our ability to attract suitable organizations to collaborate on the development and commercialization of our product candidates, particularly outside of the United States; that no viable product candidates result from the collaborations with Wyeth or Dyax or that product candidates from these collaborations do not demonstrate any therapeutic benefit or an acceptable safety profile in clinical trials; our collaborators do not fulfill their obligations under the our agreements with them in the future; the condition of the financial equity and debt markets and our ability to raise sufficient funding in such markets; our ability to manage our current cash reserves as planned; changes in related governmental laws and regulations; changes in general economic business or competitive conditions; and other statements contained elsewhere in this Form 10-K and risk factors described in or referred to in greater detail in the “Risk Factors” section of this Form 10-K. There may be events in the future that we are unable to predict accurately, or over which we have no control. You should read this Form 10-K and the documents that we reference herein and have been filed or incorporated by reference as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. Our business, financial condition, results of operations, and prospects may change. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information. We qualify all of the information presented in this Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

Inhibitex®, MSCRAMM®, Veronate®, and Aurexis® are registered trademarks of Inhibitex, Inc. MSCRAMM is an acronym for Microbial Surface Components Recognizing Adhesive Matrix Molecules.

## Overview

We are a biopharmaceutical company committed to the discovery, development and commercialization of novel antibody-based products for the prevention and treatment of serious bacterial and fungal infections. We currently have two product candidates in clinical development and four product candidates in preclinical development. In November 2005, we completed enrollment in a 2,018 patient Phase III clinical trial for our lead product candidate, Veronate, which we are developing for the prevention of certain hospital-associated infections in premature, very low birth weight, or VLBW, infants. We anticipate top-line data from this trial to be available in April 2006. Veronate has been granted Fast Track and Orphan Drug status by the FDA, and in December 2005 was designated as an Orphan Medicinal Product, or OMP, by the European Medicines Agency, or EMEA.

Our second product candidate is Aurexis, for which we completed a 60 patient Phase II clinical trial in May 2005 evaluating it as a first-line therapy, in combination with antibiotics, to treat serious, life-threatening *Staphylococcus aureus*, or *S. aureus* bloodstream infections in hospitalized patients. The Phase II trial was designed to evaluate the safety, pharmacokinetics and biological activity of a single administration of Aurexis in patients with a confirmed *S. aureus* bloodstream infection. Based on these results, and pending the outcome of ongoing discussions with the FDA, we plan to initiate a clinical trial to evaluate two administrations of Aurexis in this same indication later this year. We have also initiated a Phase II clinical trial to evaluate Aurexis in patients with cystic fibrosis. We may also initiate future clinical trials for Aurexis for other indications. Aurexis has also been granted Fast Track status by the FDA.

Our product candidates have all been developed based on our expertise in MSCRAMM proteins, for which we own or have licensed numerous patents and patent applications. MSCRAMM proteins are located on the surface of pathogenic organisms, such as bacteria and fungi, and play a prominent role in the process of infection. These proteins enable such organisms to initiate and maintain an infection by adhering to specific sites on human tissue or implanted medical devices. Our antibody-based product candidates are designed to bind to specific MSCRAMM proteins, thereby preventing or reducing the severity of infections. We believe that antibody-based product candidates that utilize MSCRAMM proteins may provide a number of advantages over existing anti-infective therapies, including: the ability to be used prophylactically in patients for whom the preventive use of antibiotics is not appropriate or recommended; improving patient outcomes by reducing the incidence of secondary site infections, relapse rates, mortality and length of stay in the intensive care unit or hospital; a lower likelihood of inducing patterns of drug resistance due to their mechanisms of action; and fewer side effects.

We have retained all worldwide rights to both Veronate and Aurexis and intend to commercialize Veronate, and potentially Aurexis, in the United States by establishing a specialized, hospital-based sales force. We currently have limited commercialization capabilities, and it is possible that we may never be able to successfully commercialize or sell any of our product candidates. Further, we have neither received regulatory approval for, nor derived any commercial revenues from, either of these product candidates or any other product candidate.

We currently have four other product candidates in preclinical development, all of which are based on the use of MSCRAMM proteins. One of these candidates targets hospital-associated enterococcal infections and is the subject of a joint development agreement with Dyax Corp., and another is a human staphylococcal vaccine being developed by Wyeth that is the subject of a worldwide license and collaboration agreement.

## Hospital-Associated Infections

Hospital-associated infections generally refer to infections that patients acquire while being treated or cared for in a hospital or out-patient setting and include, among others, pneumonia, endocarditis and bloodstream infections, or bacteremia. These infections are for the most part caused by bacterial or fungal organisms that are present in the hospital. Most healthy individuals generally are not susceptible to these organisms, but immunocompromised persons, such as VLBW infants and the elderly, or persons who have had

surgical procedures or have in-dwelling catheters or medical devices, are particularly vulnerable. According to the Centers for Disease Control, or CDC, the most prevalent organisms causing hospital-associated infections in the United States are bacterial organisms such as *S. aureus*, *Staphylococcus epidermidis*, or *S. epidermidis*, enterococcal species and fungal organisms such as *Candida* species.

Based on data from the CDC there were an estimated four million infection associated hospital discharges in the U.S. in 2003. Hospital-associated infections are implicated in approximately 90,000 deaths per annum and result in an estimated \$5.0 billion in healthcare costs annually in the United States.

Antibiotics are the predominant anti-microbial agents used to treat hospital-associated infections. Antibiotics are small molecule compounds whose primary mechanism of action is killing or inhibiting the growth of bacteria. Antibiotics commonly used to treat hospital-associated infections include methicillin and vancomycin. Many bacteria have become increasingly resistant, or unresponsive, to antibiotics, leading to an increase in the incidence of antibiotic-resistant infections. Drug resistance is the result of bacteria undergoing a biochemical mutation that circumvents the mechanisms of action that generally allow antibiotics to work. Some of the most virulent organisms that demonstrate significant patterns of antibiotic resistance include methicillin-resistant *S. aureus*, or MRSA, and vancomycin-resistant enterococci, or VRE. In light of increasing antibiotic resistance, we believe there is a significant unmet medical need for novel anti-infective therapies that can prevent or treat these serious, life-threatening infections.

### **Our Solution**

We believe there is a substantial opportunity to utilize our expertise in MSCRAMM proteins to discover, develop and commercialize novel antibody-based products that address the increasing prevalence of life-threatening hospital-associated infections and the lack of effective therapies currently available to treat these infections. The human immune system normally protects the body against a variety of infections and other illnesses by recognizing, neutralizing and eliminating pathogens and malignant cells from the body. One of the primary functions of the immune system is the production of antibodies. Antibodies are soluble proteins found in the plasma portion of whole blood capable of recognizing and binding to pathogens that are potentially harmful to the human body. Antibodies recognize and attach themselves, or bind to antigens, examples of which include MSCRAMM proteins present on the surface of bacteria and fungi. In order for an effective immune response to occur without harming normal cells, the immune system generates antibodies that recognize and bind tightly to one specific antigen. Once an antibody binds to its targeted antigen, it triggers the cellular components of the immune system to clear the pathogen from the body.

We have identified antibodies that specifically bind to a number of different MSCRAMM proteins located on the surface of certain pathogenic organisms. MSCRAMM proteins enable organisms to initiate and maintain an infection by adhering to specific binding sites within human tissue or to implanted or in-dwelling materials, such as orthopedic implants, catheters and vascular grafts. We believe that antibodies that target MSCRAMM proteins can reduce the incidence and severity of bacterial and fungal infections through two important biological mechanisms of action. First, by binding to the MSCRAMM proteins, these antibodies inhibit or block the invading organism from attaching to tissue, or implanted or in-dwelling medical devices. Second, these antibodies can cover or coat the invading organism, identifying it for clearance by other cellular components of the immune system through a process commonly referred to as opsonization.

We believe that antibody-based products developed utilizing our expertise in MSCRAMM proteins may provide the following advantages over existing anti-infective therapies:

- the ability to be used prophylactically in patient in whom the preventive use of antibiotics is not appropriate or recommended;
- improve patient outcomes by reducing the incidence of secondary site infections, relapse rates, mortality and length of hospital stay;

- a lower likelihood of inducing patterns of drug resistance due to their novel mechanisms of action; and
- fewer side effects.

### Our Product Candidates

Our antibody-based product candidates are summarized below:

<u>Product Candidate</u>	<u>Intended Use</u>	<u>Stage of Development</u>	<u>Worldwide Commercial Rights</u>
Veronate .....	Prevention of hospital-associated infections in VLBW infants	Phase III	Inhibitex
Aurexis.....	First-line therapy for serious <i>S. aureus</i> infections in combination with standard of care antibiotics	Phase II	Inhibitex
<i>Staphylococcus epidermidis</i> monoclonal antibodies.....	Prevention of <i>coagulase negative staphylococci</i> (CoNS)	Preclinical	Inhibitex
Enterococcal monoclonal antibodies.....	Hospital-associated enterococcal infections	Preclinical	Inhibitex/Dyax Corp.
<i>Candida</i> monoclonal antibodies .....	Hospital-associated <i>Candida</i> infections	Preclinical	Inhibitex
Staphylococcal vaccine.....	Prevention of staphylococcal infections	Preclinical	Wyeth

### Veronate

Veronate is an immune globulin product candidate that contains concentrated amounts of human antibodies that target specific MSCRAMM proteins found on the surface of staphylococci. We are developing Veronate for the prevention of hospital-associated infections in VLBW infants weighing 500 to 1250 grams whose infections occur after the second day of life. Infections that occur after the second day of life are generally referred to by neonatologists as late-onset sepsis. In November 2005, we completed enrollment in a 2,018 patient Phase III clinical trial of Veronate. We anticipate top-line data from this trial will be available in April 2006. Based on our Phase II clinical trial results, we believe that Veronate can reduce the number of hospital-associated infections caused by *S. aureus* and *Candida* organisms in VLBW infants. Further, we believe the prophylactic use of Veronate may also reduce the overall mortality rate in VLBW infants in part, because infections caused by *S. aureus* and *Candida* organisms are associated with an increased risk of death among these infants. Veronate has been granted Fast Track status by the FDA. Fast Track status allows for submission of a “rolling” BLA and may allow for a priority review by the FDA and is afforded to those proposed products that the FDA believes address life-threatening and unmet medical needs. A BLA is the application that must be submitted to, accepted and approved by the FDA before a biologic product can be marketed or sold in the United States. A “rolling” submission allows for a BLA to be filed in separate, completed sections over a period of time during the drug’s clinical development period. In February 2006, we initiated a rolling BLA submission for Veronate by filing the chemistry, manufacturing and controls, or CMC, section of the BLA. We also intend to file the Pre-clinical sections of this BLA in April 2006 and pending data from the pivotal Phase III trial,

complete the rolling submission with the filing of the Clinical section in the Fall of 2006. In addition, we filed a request with the FDA for a priority review for the Veronate BLA. If the FDA accepts our request for a priority review, the length of time it takes for Veronate to proceed through the FDA approval process may be shortened. We cannot assure you that the FDA will accept our rolling BLA submission, in whole or in part, or whether we will be granted a priority review or whether the duration of the approval process for Veronate will be reduced, or whether Veronate will be approved by the FDA.

Veronate has also been granted Orphan Drug status for the reduction of nosocomial bacteremia caused by staphylococci in VLBW infants, which may provide for market exclusivity for seven years from the date of FDA approval in certain circumstances. Further, in December 2005, the EMEA formally designated Veronate as an Orphan Medicinal Product, or OMP, in Europe.

#### *Market Opportunity for the Prevention of Hospital-Associated Infections in VLBW Infants*

According to the National Center for Health Statistics, a division of the CDC, there were 60,500 VLBW infants born in the United States in 2003, or about 1.45% of all live births. The term VLBW infants refers to those infants that weigh less than 1,500 grams at birth or that are generally less than 32 weeks gestational age. Approximately 42,500, or 70%, of these VLBW infants weighed 1,250 grams or less at birth. Given the rate of mortality generally associated with these smaller infants, we believe that approximately 35,000 to 38,000 of these infants could potentially receive Veronate.

The vast majority of VLBW infants are cared for in neonatal intensive care units, or NICUs. The average length of stay in the NICU for VLBW infants is approximately two months.

VLBW infants are highly susceptible to infection while in the NICU, given the intensity of the medical care they receive, the duration of their hospitalization, compromised immune system, and the use of intravenous catheters to deliver nutritional fluids and medication. Various studies, including our 512 patient Phase II trial of Veronate indicate that 30-50% of VLBW infants weighing 1,250 grams or less at birth will develop at least one hospital-associated infection. There is an inverse relationship between a VLBW infant's birth weight and the risk of acquiring a hospital-associated infection. According to a retrospective study conducted by the Neonatal Institute of Child Health and Human Development, or NICHD, covering the calendar years 2000-2002 the mortality rate among VLBW infants who acquire a hospital-associated infection caused by *S. aureus* or *Candida* is approximately 17% and 34%, respectively, as compared to 7% for those VLBW infants who do not develop a hospital-associated infection. In addition to associated mortality, several studies indicate that VLBW infants that develop a hospital-associated infection stay, on average, 19 additional days in the NICU when compared to those that do not acquire an infection. For those VLBW infants that weigh less than 1,250 grams at birth and develop a hospital-associated infection, data indicates that their average incremental stay in the NICU is an additional 26 days. A study published by the NICHD further indicated that those VLBW infants that acquire an infection during their stay in the NICU may also experience significant impairment in their neurological development, including cerebral palsy and mental development, as compared to those that did not acquire an infection.

Based upon the morbidity, mortality, incremental length of stay in the NICU and potential long-term neurological impairment associated with these hospital-associated infections, we believe the medical benefits that Veronate may provide VLBW infants compare favorably to certain other critical-care drugs utilized in high-risk neonatal and pediatric patients, such as Synagis® for the prevention of respiratory syncytial virus, or RSV, and INOmax® for the treatment of respiratory failure due to pulmonary hypertension, which can cost from \$5,000 to \$12,000 per course of treatment. We cannot assure you that any medical benefits that Veronate may provide, or be perceived to provide, will compare favorably, if at all, with these other critical-care drugs utilized in high-risk neonatal and pediatric patients, or how the selling price of Veronate, if approved, will compare to these drugs.

## *Veronate Clinical Trials*

*Phase III.* In November 2005, we completed enrollment in a pivotal Phase III trial of Veronate in VLBW infants weighing between 500 and 1,250 grams at birth. We anticipate that top-line data from this trial will be available in April 2006. This trial, in which we enrolled 2,018 patients, is a multi-center, placebo controlled, double-blind study and is substantially the same in design as the Phase II trial we completed for Veronate in 2004. The trial was conducted at over 90 NICUs across the United States and Canada, and no single site accounted for more than 4.5% of the patients enrolled. Patients were randomized equally into one of two arms: Veronate at a dose of 750 mg/kg or placebo, both administered intravenously. The primary endpoint of this trial is the reduction in the frequency of *S. aureus* infections in VLBW infants weighing 500-1,250 grams at birth, the same patient population evaluated in our Phase II clinical trial. The design of the trial provides a 90% power to detect a 50% reduction in the frequency of *S. aureus* infections among infants randomized to receive Veronate compared to those that receive placebo based on an assumed 6% infection rate in the placebo group. Secondary endpoints of this Phase III trial include the reduction in the frequency of candidemia, coagulase-negative staphylococcal, or CoNS, infections, all staphylococcal infections and all-cause mortality. If the primary endpoint is achieved, we believe this trial will be sufficient for the submission of a complete BLA for Veronate.

*Phase II.* In February 2004, we completed a 512 patient, multi-center, randomized, double-blind, placebo-controlled Phase II clinical trial of Veronate for the prevention of hospital-associated infections in VLBW infants weighing 500 to 1,250 grams at birth. This trial was designed to evaluate the safety, dosing and preliminary efficacy of Veronate in this patient population. Infants in this trial were initially randomized by birth weight to receive one of four intravenous treatments: placebo or Veronate at a dose of 250mg/kg, 500mg/kg or 750mg/kg. This trial was conducted at 53 different NICUs across the United States, and no single site accounted for more than 7% of the patients enrolled.

The most common adverse events in this trial, which occurred with similar frequency among those infants who received placebo and those who were administered Veronate, included low serum sodium, metabolic acidosis, food intolerance, high blood glucose, low blood platelets and low blood pressure. There were no dose related trends observed for adverse events, severe adverse events or morbidities associated with prematurity. Nine infants experienced 14 adverse events possibly related to Veronate, including low heart rate, apnea, fast heart rate, diaper rash, jaundice, low blood glucose, high blood glucose, high blood pressure and abdominal distention. Only four of 1,280 infusions were discontinued or interrupted due to adverse events possibly related to Veronate.

The preliminary findings from this trial comparing Veronate at a dose of 750 mg/kg to placebo were:

- A 63% reduction in the frequency of infection due to *S. aureus*;
- A 67% reduction in the frequency of infection due to *Candida*; and
- A 36% reduction in mortality.

These preliminary findings were not statistically significant. The Phase II trial was not powered or designed to demonstrate statistically significant differences among the treatment arms in measures of efficacy. We cannot guarantee that the results of the Phase III trial will be similar to the findings of the Phase II trial.

*Phase I.* In 2002, we conducted a Phase I dose-escalating clinical trial of Veronate in 36 VLBW infants weighing 500 to 1,250 grams at birth. Two cohorts of 18 infants each were studied. One cohort received 500mg/kg of Veronate and the second cohort received 750mg/kg, both intravenously. The infants were monitored for a period of 70 days subsequent to their first infusion.

## *Aurexis*

Aurexis is a humanized monoclonal antibody currently in development as a first-line therapy, in combination with antibiotics, for the treatment of serious, life-threatening *S. aureus* bloodstream infections in hospitalized patients. Aurexis and Veronate both target the same MSCRAMM protein on *S. aureus*.

In May 2005 we completed a 60 patient Phase II trial of Aurexis in patients with confirmed *S. aureus* bloodstream infections. We have also completed enrollment in a Phase I trial of Aurexis in patients with end stage renal disease, and in the second quarter of 2005, initiated a Phase II clinical trial of Aurexis in patients with cystic fibrosis. We are considering additional clinical trials of Aurexis in other patient populations in the future. Aurexis has been granted Fast Track designation by the FDA for the adjunctive treatment of *S. aureus* bloodstream infections.

#### *Market Opportunity for the Treatment of S. aureus Infections*

*S. aureus* is one of the leading causes of hospital-associated infections. Based on data compiled by the CDC, an estimated 300,000 *S. aureus* infections occur in the United States annually. We estimate, based on compiled data, that approximately 60,000 to 90,000 of these *S. aureus* infections are bloodstream infections. According to the CDC and other sources, the percentage of hospital-associated *S. aureus* infections in intensive care units in the United States caused by methicillin-resistant *S. aureus*, or MRSA, doubled between 1994 and 2002, increasing from 30% to nearly 60%. MRSA refer to organisms that are resistant to a class of antibiotics regarded as the first-line treatment for staphylococcal infections. The mortality rate for bloodstream infections associated with MRSA infections is approximately 25-35%, as compared to a 15% mortality rate associated with methicillin-susceptible *S. aureus* bloodstream infections. Studies further indicate that patients who acquire a MRSA bloodstream infection, as compared to those that do not, require, on average, an additional 12 days in an intensive care unit, at an average cost of more than \$27,000. We are developing Aurexis to be used adjunctively as a first-line therapy to treat *S. aureus* bloodstream infections, independent of which antibiotic is prescribed for treatment. We also believe that the degree to which the medical community will adopt the use of Aurexis will be based on its ability to reduce the incidence of infection-associated mortality, the relapse rate associated with these infections, the frequency of related secondary site infections, and the number of days that patients with such infections stay in the intensive care unit or hospital.

#### *Aurexis Clinical Trials*

*Phase II.* In May 2005, we reported results from a 60 patient Phase II trial of Aurexis, in combination with antibiotics, for the treatment of documented *S. aureus* bloodstream infections in hospitalized patients. Patients were randomized to receive antibiotic therapy in combination with either Aurexis, at 20 mg/kg, or placebo. Both Aurexis and the placebo were administered intravenously as a single dose. In this trial, standard of care antibiotic therapy was selected by the individual investigators. Subjects were followed for 57 days, or until early termination from the trial.

The primary objectives of the Phase II trial were to evaluate:

- the safety of a single administration of Aurexis;
- the pharmacokinetics of a single dose of Aurexis; and
- the biological activity of a single dose of Aurexis.

Favorable trends were observed in the composite primary endpoint of mortality, relapse rate and infection-related complications, and a number of secondary endpoints and ad-hoc analyses, including the progression in the severity of sepsis, the number of days in the intensive care unit, and the resolution of complications due to *S. aureus* bacteremia. However, the difference in pharmacokinetics observed in patients that received Aurexis in this trial, as compared to the healthy volunteers that received Aurexis in a Phase I trial, resulted in our decision to evaluate utilizing a two dose strategy for this indication, rather than a single administration. Based on these results, and pending the outcome of ongoing discussions with the FDA, we plan to initiate a clinical trial to evaluate two administrations of Aurexis in this same patient population later this year.

These preliminary findings were not statistically significant. The Phase II trial was not powered or designed to demonstrate statistically significant differences among the treatment arms in measures of

efficacy. We cannot guarantee that the results of subsequent trials will be similar to the findings of the Phase II trial.

*Phase I.* In May 2005, we reported the completion of an eight-patient Phase I clinical trial of Aurexis to evaluate its safety and pharmacokinetics in patients with end-stage renal disease (ESRD). Based on the pharmacokinetic data from this trial, we intend to include patients with ESRD in any follow-on trials of Aurexis for the treatment of documented *S. aureus* bloodstream infections in hospitalized patients.

In 2003, we completed an open-label, randomized, dose-escalating Phase I clinical trial in 19 healthy volunteers to assess the safety of Aurexis and determine dose-related pharmacokinetics. Patients were intravenously administered four dose levels of Aurexis at 2, 5, 10, or 20 mg/kg. The volunteers were monitored for a period of 56 days subsequent to the administration of the drug. Safety was monitored by physical examinations, clinical and laboratory tests, and adverse experience assessments. The following adverse events were noted among participants: headache, low white blood cell count, gastro esophageal reflux and red rash. None of these adverse events was severe or believed to be definitely related to Aurexis. No other safety issues were identified and no dose reached the protocol-specified definition of maximum tolerated dose. Pharmacokinetic analysis demonstrated that doses of 10mg/kg or greater achieved plasma levels of Aurexis associated with therapeutic efficacy in preclinical animal models. The half life of Aurexis was determined to be approximately 21 days. We selected the 20mg/kg dose for our Phase II trial of Aurexis.

*Preclinical Results.* We have conducted a number of preclinical studies in animals to assess both the safety and potential efficacy of Aurexis. These studies include using Aurexis both prophylactically as a monotherapy to prevent and in combination with vancomycin to treat, MRSA infections. In these studies, no safety or toxicity issues were observed. These studies demonstrated that when used prophylactically, a single dose of Aurexis administered intravenously provided statistically significant levels of protection against MRSA infections as compared to the control. The therapeutic administration of Aurexis intravenously, in combination with vancomycin, significantly enhanced the clearance of MRSA from the animals' critical organs as compared to vancomycin alone. We believe that the preclinical models that yielded these results are generally viewed by the scientific community as supportive and appropriate for assessing the biological activity of anti-infective product candidates in humans.

#### ***Other Product Candidates***

In addition to Veronate and Aurexis, we currently have four product candidates in preclinical development, all of which are based on the use of MSCRAMM proteins.

#### ***Staphylococcus Epidermidis Monoclonal Antibodies***

*Staphylococcus epidermidis* (*S. epidermidis*) is often reported as the most frequent isolate among *coagulase negative staphylococci* or (CoNS), which are a major constituent of the normal flora on human skin. Although often considered a contaminant of blood cultures, *S. epidermidis* is now recognized as an opportunistic pathogen and is one of the leading causes of bacteremia. We have identified a panel of MSCRAMM proteins expressed by *S. epidermidis*. Humanized monoclonal antibodies that specifically recognize these MSCRAMM proteins have been produced and are being evaluated in a series of *in vitro* preclinical studies.

#### ***Enterococcal Monoclonal Antibodies***

Enterococci account for approximately 8% of all hospital-associated infections and have been reported as the second most common cause of nosocomial endocarditis in the United States. Further, greater than 24% of confirmed enterococcal infections reported in the June 2000 report of U.S. hospitals included in the National Nosocomial Infectious Surveillance System were caused by vancomycin-resistant enterococci, or VRE. In these same hospitals, the reported incidence of VRE strains increased by 40% from 1994 to 1998. We have identified and characterized MSCRAMM protein targets expressed by enterococci and we have generated monoclonal antibodies that recognize these targets. In October 2004, we entered into an

agreement with Dyax Corp. to collaborate on the discovery, development, and commercialization of fully human monoclonal antibodies against MSCRAMM proteins on enterococci. Under the terms of the agreement, we and Dyax will jointly develop product candidates that may be identified during the collaboration and will share in the costs to develop any resulting product candidates and the commercialization rights and profits from any marketed products.

#### *Candida Monoclonal Antibodies*

*Candida albicans*, or *C. albicans*, is the causative organism of the majority of invasive fungal infections in an expanding population of immunosuppressed or immunocompromised patients such as those undergoing chemotherapy, with organ transplants or with AIDS. We have identified and characterized MSCRAMM proteins on the surface of *C. albicans* and we have generated monoclonal antibodies that target these proteins.

#### *Staphylococcal Vaccine*

There are a number of patient groups, including approximately 300,000 end stage renal disease patients in the United States, patients receiving chronic long-term care, and patients undergoing certain elective surgeries, who are at risk of acquiring a staphylococcal infection. For these high-risk groups, we believe an active vaccine that can enhance immunity against staphylococcal organisms may be a less costly and preferred mode of therapy. We have entered into a license and collaboration agreement with Wyeth to develop human vaccines against staphylococcal organisms.

#### **Our Strategy**

Our goal is to become a leading biopharmaceutical company that discovers, develops and commercializes novel, antibody-based products to prevent and treat serious bacterial and fungal infections in the hospital setting. In order to achieve this goal, we are focused on the following key strategies:

*Obtain Regulatory Approval for Veronate.* We are focused on completing the clinical and regulatory development of Veronate. Pending satisfactory data from the pivotal Phase III trial for Veronate, we intend to complete the rolling BLA submission for Veronate for the prevention of hospital-associated infections in VLBW infants to obtain approval to market Veronate in the United States.

*Advance the Development of Aurexis.* We are developing Aurexis as a first-line therapy for the treatment of serious *S. aureus* infections in combination with antibiotics. We have evaluated Aurexis in a Phase II clinical trial in patients with *S. aureus* bloodstream infections and a Phase I trial in patients with end stage renal disease. Based upon the results of these trials, we intend to further evaluate Aurexis in future clinical trials for the treatment of serious *S. aureus* bloodstream infections in combination with antibiotics. We may also evaluate Aurexis in other indications in the future.

*Establish a Specialized, Hospital-Based Sales Force in the United States.* We have retained all worldwide rights to Veronate and Aurexis. We intend to establish a specialized hospital-based sales force of approximately 40-50 field representatives to promote Veronate, and potentially Aurexis, in the United States. We believe that the vast majority of the potential demand for Veronate in the United States exists in approximately 1,000 hospitals that operate NICUs. As a result, we believe a relatively small sales force can effectively address this market. While we intend to enter into a worldwide collaboration to further develop and commercialize Aurexis, we plan to leverage our domestic hospital-based sales force by retaining certain co-promotion rights to Aurexis in the United States. In markets outside of the United States, we currently plan to establish partnerships with other companies to commercialize any products we may successfully develop.

*Utilize Our Expertise in MSCRAMM Proteins to Discover and Develop Additional First-in-Class Products.* Our goal is to be the first to market antibody-based products to prevent and treat specific bacterial and fungal infections. We have used our expertise in MSCRAMM proteins to discover and develop Veronate, Aurexis and certain preclinical candidates that may represent first-in-class products. We plan to advance a

number of our preclinical product candidates that are focused on monoclonal antibodies directed towards MSCRAMM proteins on staphylococcus epidermidis, enterococcal and *Candida* organisms. We believe that first-in-class drugs may capture superior market share and have competitive advantages over drugs subsequently introduced. We plan to continue to devote resources to the discovery and development of product candidates that originate from our expertise in MSCRAMM proteins.

*Expand Our Product Portfolio through In-Licensing and Acquisitions.* Further in the future, we intend to capitalize upon our expertise in MSCRAMM proteins, antibody development, commercialization and infectious diseases to in-license or acquire selected product candidates in various stages of development. We will also evaluate opportunities to leverage our sales force by in-licensing or acquiring and promoting additional therapeutics which target the hospital-based market.

## **Sales and Marketing**

According to data compiled by the American Hospital Association, there are approximately 5,000 hospitals in the United States; however, we believe that the vast majority of the demand for Veronate will occur in approximately 1,000 hospitals where there are NICUs equipped to handle the special needs of VLBW infants. Furthermore, approximately 80% of the NICU beds in the United States are concentrated in approximately 500 of these hospitals. We believe that a specialized, hospital-based field sales force of approximately 40-50 qualified individuals can effectively promote and sell Veronate in this market. We have retained all worldwide rights to Veronate and intend to establish such a sales force and create a commercial infrastructure capable of supporting the independent commercialization of Veronate in the United States.

We have also retained worldwide rights to Aurexis and several of our product candidates in preclinical development. While we plan to establish a worldwide collaboration to develop and commercialize Aurexis, we intend to retain certain co-promotion rights to Aurexis in the United States. Assuming Veronate is approved for sale by the FDA and we successfully develop a hospital-based sales force, we may promote or co-promote our other product candidates, if approved for sale, in the United States through this sales force. There are approximately 1,000 hospitals that contain NICUs and also account for 45% of all hospital beds in the United States. We believe the sales force we intend to build will be able to effectively market Aurexis and our other product candidates in these hospitals if and when they are approved for sale. We currently have limited commercialization capabilities, and it is possible that we may never be able to successfully commercialize or sell any of our product candidates. We anticipate partnering or collaborating with other companies to develop and commercialize our product candidates in countries and regions outside of the United States.

## **Raw Materials and Manufacturing**

*Raw Materials.* Veronate is an immune globulin product candidate derived from human plasma. Accordingly, the critical raw material used in the manufacture of Veronate is plasma that contains a sufficient concentration of naturally occurring human antibodies that specifically target certain MSCRAMM proteins found on the surfaces of *S. aureus* and *S. epidermidis*. The plasma that we use to manufacture Veronate is collected only at FDA-approved donor centers in the United States. The qualification of donors, the collection process, and the general operation of donor centers are highly regulated by the FDA and other domestic and foreign regulatory bodies. Further, this plasma is required to be tested for certain viral markers prior to being allowed to be shipped from the donor center and into production. We currently do not, nor do we intend to, own or operate any such donor centers or viral market testing facilities. We outsource, and intend to continue to outsource, the collection and testing of this critical raw material to qualified, FDA-approved third-party vendors who own and operate these donor centers and testing facilities.

In 2002, we entered into a ten-year supply agreement with DCI Management Group, LLC, or DCI. Pursuant to this supply agreement, no later than 90 days prior to each calendar-year end, we and DCI must agree on the quantity of plasma that we intend to purchase, and they will provide, for the next

calendar year. Once this quantity is established, we are generally obligated to purchase at least 90% of this predetermined quantity during the subsequent year. We may terminate this agreement upon mutual agreement of the parties, a material breach by DCI or upon 30 days notice if the clinical development of Veronate is halted or terminated by the FDA or us for any reason.

In January 2005, we entered into a second supply agreement with another supplier of plasma. This agreement has a ten-year term; however we may terminate the agreement upon mutual agreement of the parties, a material breach by the supplier, or upon 30 days notice that the clinical development of Veronate is terminated by the FDA or us for any reason. In September 2005, we entered into a third plasma supply agreement with another supplier of plasma for a defined volume of plasma. This agreement has a three-year term; however we may terminate the agreement upon mutual consent of the parties, a material breach by the supplier, or upon 30 days notice that the clinical development of Veronate is halted or terminated by the FDA or us for any reason. In addition to DCI and these new suppliers, we believe there are additional sources of plasma for Veronate, and we anticipate either entering into supply agreements with other suppliers or expanding existing agreements in the future, as necessary.

The number of potential donors whose plasma contains a sufficient concentration of naturally occurring human antibodies to manufacture Veronate is limited. Therefore, we cannot assure you that our current or future third-party suppliers will be able to provide us with an adequate quantity of plasma to manufacture a sufficient amount of Veronate for future clinical trials or for commercial purposes.

*Manufacturing.* We do not own or operate any manufacturing facilities. We currently outsource the manufacture of our product candidates to qualified contract manufacturers. We anticipate we will continue to rely on these or other qualified contract manufacturers for the foreseeable future. Since the manufacturing processes used to manufacture Veronate and Aurexis are vastly different, we use different manufacturers for each of these product candidates.

The manufacturing process for Veronate is referred to as fractionation and purification. The fractionation process involves separating plasma into various components or fractions. Fractions are then purified from the appropriate fraction. This process has been used for over thirty years by major pharmaceutical companies to manufacture antibody-based products such as immune globulins. In December 2001, we entered into a ten-year contract manufacturing agreement with Nabi Biopharmaceuticals, Inc., or Nabi, to manufacture Veronate on our behalf. Nabi operates a FDA-approved facility in the Boca Raton, Florida, and is approved to manufacture its proprietary, as well as third-party, immune globulin products. Pursuant to our contract with Nabi, we must provide three-year forecasts as to how much Veronate we want it to manufacture on our behalf. As of December 31, 2005, our maximum purchase commitments under this agreement through December 31, 2008, were approximately \$6.7 million. However, if we cancel or postpone the production of one or more batches of Veronate in accordance with the terms of this agreement, financial penalties would instead apply, which could be substantially less, and in no case more, than the minimum purchase commitments, depending on the length of the notice provided by us to Nabi. The amount of the cancellation penalty payable ranges from \$25,000 per batch if we provide notice of cancellation more than twelve months in advance, to \$425,000 per batch if we provide notice of cancellation less than 90 days in advance of the scheduled production date of the related batch. We believe Nabi is qualified and has the available capacity to manufacture Phase III clinical trial material and commercial quantities of Veronate. Nabi has manufactured five lots of Veronate to date. During the term of this agreement, we may not grant any rights allowing any other party to manufacture Veronate, and therefore we may not engage an alternative manufacturer until the agreement is terminated. We may terminate the agreement with Nabi if Nabi materially breaches the agreement, subject to a 20-day cure period, or if the clinical development of Veronate is halted or terminated. We do not have alternative manufacturing plans for Veronate at this time. If our agreement with Nabi were terminated for any reason, it may be difficult or impossible for us to find alternative manufacturers on commercially acceptable terms, if at all. Even in the event we find such an alternative manufacturer, in accordance with FDA-mandated current good manufacturing practices, or cGMPs, changing manufacturers generally requires re-validation of the manufacturing processes and procedures and may require further clinical trials, which may be costly

and require several years to complete. Because Nabi is developing antibody-based products to prevent or treat *S. aureus* infections or *S. epidermidis* infections, we consider Nabi to be a potential competitor.

We have used a contract manufacturer, Avid Bioservices, Inc., or Avid, to produce clinical trial material for Aurexis for use in our Phase I and II clinical trials. As of December 31, 2005, we have no long-term obligations under any of our prior agreements with Avid, although we anticipate utilizing its services in 2006 to manufacture additional clinical trial material for our Aurexis program. In November 2004, we entered into an agreement with Lonza Biologics PLC for the manufacture of a second clone of Aurexis. Under the terms of the agreement, Lonza agreed to perform numerous process development related services and manufacture a cGMP lot of Aurexis for potential use in future clinical trials, which they have completed. As of December 31, 2005, our maximum purchase commitments under this agreement through June 30, 2008, were approximately \$0.2 million.

## Competition

Our industry is highly competitive and characterized by rapid technological change. Significant competitive factors in our industry include, among others, product efficacy and safety; the timing and scope of regulatory approvals; the government reimbursement rates for and the average selling price of products; the availability of raw materials and qualified manufacturing capacity; manufacturing costs; intellectual property and patent rights and their protection; and sales and marketing capabilities. Any product candidates that we successfully develop and are approved for sale by the FDA or similar regulatory authorities in other countries may compete with existing products and products that may become available in the future. Many organizations, including large pharmaceutical and biopharmaceutical companies, such as Cubist Pharmaceuticals, Inc., Merck & Co., Inc., Pfizer, Inc., and MedImmune, Inc. as well as academic and research organizations and government agencies, continue to pursue the research and development of novel anti-infective therapies that target staphylococcal as well as other bacterial and fungal organisms. Many of these organizations have more substantial capital resources than we have, and greater capabilities and experience than we do in basic research, conducting preclinical studies and clinical trials, regulatory affairs, manufacturing, marketing and sales. As a result, we may face competitive disadvantages relative to these organizations should they develop or commercialize a competitive product. Therefore, we cannot assure you that any of our product candidates, if approved for sale, will compete successfully and that another organization will not succeed in developing and commercializing products that render our technology or product candidates non-competitive or obsolete.

Currently, we are not aware of any antibody-based products approved by the FDA specifically for the prevention or treatment of *S. aureus*, CoNS, *Candida* or enterococcal infections in any patient population. However, we are aware of several biopharmaceutical companies developing antibody-based therapies directed towards the prevention or treatment of bacterial and fungal, and particularly staphylococcal, infections.

Nabi Biopharmaceuticals, Inc. is a publicly-held biopharmaceutical company that discovers, develops, manufactures and markets antibody-based therapies. Nabi has antibody-based product candidates and vaccines currently in various stages of development that are directed towards preventing or treating staphylococcal infections. One of these product candidates has received Orphan Drug status from the FDA. Nabi is our contract manufacturer for Veronate.

In 2005, Medimmune, Inc. in-licensed intellectual property from Biosynexus, Inc., a privately-held biotechnology company that is developing a portfolio of protein-based products including monoclonal antibodies, enzymes and peptides, for the prevention and treatment of staphylococcal infections. Medimmune, Inc. has indicated it expects to continue the development of monoclonal antibodies against staphylococcal organisms in the future.

NeuTec, PLC is a publicly-held biopharmaceutical company that is developing a portfolio of antibody-based therapeutic products designed to treat life-threatening infections, particularly hospital-acquired infections such as MRSA and *Candida*.

## Intellectual Property Rights and Patents

We own or are licensed under numerous issued United States patents and pending patent applications, as well as corresponding international filings in the field of MSCRAMMs and surface adhesins. The issued United States patents expire between 2009 and 2021. In addition to our patents and patent applications, we have registered trademarks for Inhibitex, MSCRAMM, Aurexis and Veronate.

Of the patents and applications in our portfolio, the following pertain directly to Veronate and Aurexis:

- Our United States patent describing Veronate is directed to purified human immune globulin antibodies to certain MSCRAMM proteins found on *S. aureus* and *S. epidermidis*. This patent will expire in 2018 if not extended. Our pending United States Veronate patent application includes claims directed to methods used in preparing Veronate. Corresponding international applications are pending.
- Our United States SdrG patent is directed to the nucleic acid sequence, or DNA, encoding the SdrG protein of *S. epidermidis*. The SdrG MSCRAMM protein is used in identifying donors for the preparation of Veronate. This patent will expire in 2018 if not extended. Our pending United States SdrG patent applications are directed to the SdrG protein and related methods. Corresponding international applications are pending.
- Our two United States ClfA patents relate to both Veronate and Aurexis and are directed to the DNA encoding ClfA and the ClfA MSCRAMM protein on *S. aureus*. These patents will expire in 2016 and 2014, respectively, if not extended. The ClfA protein is used in the identification of donors for the preparation of Veronate and is also the protein recognized by the Aurexis monoclonal antibody. There are no corresponding foreign rights available for the ClfA protein and nucleic acid sequences. Our pending United States ClfA patent application claims antibodies to the ClfA protein. Our United States ClfA monoclonal antibody patent relates to Aurexis and contains claims to monoclonal antibodies recognizing the ClfA protein. This patent will expire in 2021 if not extended. Corresponding international applications are pending.

Patent rights and other proprietary rights are important in our business and for the development of our product candidates. We have sought, and intend to continue to seek patent protection for our inventions and rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain a competitive advantage. In order to protect these rights, know-how and trade secrets, we typically require employees, consultants, collaborators and advisors to enter into confidentiality agreements with us, generally stating that they will not disclose any confidential information about us to third parties for a certain period of time, and will otherwise not use confidential information for anyone's benefit but ours.

The patent positions of companies like ours involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with any certainty. Our issued patents, those licensed to us, and those that may issue to us in the future may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. Expiration of patents we own or license could adversely affect our ability to protect future product development and, consequently, our operating results and financial position.

We have filed two opposition proceedings with the European Patent Office, or EPO, to revoke or substantially narrow two patents issued to the Henry M. Jackson Foundation for the Advancement of Military Medicine relating to staphylococcal surface proteins. These patents have been licensed to Biosynexus. In the first opposition, on November 5, 2003 an oral proceeding took place in which the EPO concluded that the patent was limited to a single claim having no relevance to our products. The patentee has appealed the decision and a ruling is not expected to occur until late 2006. No preliminary

recommendation has been issued in the second opposition proceeding, which we anticipate will occur in 2006. We believe that we do not infringe the corresponding United States patents, which have narrower claims than those issued in Europe.

### **Licensing and Collaborative Agreements**

To date, we have entered into a number of license and collaborative agreements with various institutions to obtain intellectual property rights and patents relating to MSCRAMM proteins and our product candidates. We have also entered into an exclusive worldwide license and collaboration agreement with Wyeth with respect to their use of our MSCRAMM protein intellectual property to develop human staphylococcal vaccines and a joint development agreement with Dyax Corp. for the discovery, development, and commercialization of therapeutic products for the treatment of infections caused by enterococci. Our strategy includes possible future in-licensing of intellectual property or product candidates, as well as collaborations with companies that may utilize our intellectual property in their products, or develop, co-develop, market and sell our product candidates in markets outside of the United States.

#### ***Texas A&M University Health Science Center***

We have an exclusive royalty-bearing license from the Texas A&M University System, or Texas A&M, for an issued United States patent with claims directed toward the SdrG nucleic acid sequence and related pending United States divisional applications directed toward the SdrG protein and antibodies to it, as well as corresponding foreign applications. SdrG is the MSCRAMM protein that we target on *S. epidermidis* and is used in the manufacture of Veronate. We also have an exclusive royalty-bearing license to Texas A&M's rights in an allowed United States patent application and foreign counterparts directed to the methods we use for screening and selecting donor plasma using MSCRAMMs for both SdrG and ClfA in the manufacture of Veronate. BioResearch Ireland/Trinity College Dublin is a co-owner of these patents and applications. All of these licenses are subject to certain research rights retained by Texas A&M. Texas A&M may terminate the license if we fail to use commercially reasonable efforts to bring our products candidates to market. *We may terminate the license without cause upon 60 days written notice. Otherwise,* this agreement will terminate upon the expiration of all of the licensed patents. Currently, the latest to expire of the issued patents under the license agreement expires in 2019. We have agreed to pay Texas A&M a royalty based on net sales for any product sold utilizing these licenses.

In connection with these license agreements, in 1995 we entered into the first of several cooperative research agreements with Texas A&M. Pursuant to these agreements, we have the exclusive worldwide right to any discoveries resulting from this collaboration, subject to research rights retained by Texas A&M and certain rights of the United States government. We also have a right of first refusal to acquire the rights to and file patents on discoveries made by Texas A&M in the field of MSCRAMM proteins that are made outside of the scope of the collaboration. Texas A&M is entitled to a royalty on revenues that we receive for products that incorporate technology developed through this collaboration. We may terminate this collaboration upon 90 days written notice if the work is not performed satisfactorily.

Pursuant to these agreements, we have paid Texas A&M approximately \$1.7 million through December 31, 2005. We have no future minimum royalty or milestone obligations pursuant to these agreements, but we currently pay Texas A&M approximately \$382,000 in annual sponsored research payments. Our obligation to pay sponsored research payments ends in November 2006. If we do not continue to pay sponsored research payments beyond that time, we will be obligated to pay a minimum royalty of \$25,000 annually.

#### ***BioResearch Ireland/Trinity College Dublin***

In 1996 we obtained an exclusive royalty-bearing license from BioResearch Ireland, or (BRI), for an issued United States patent with claims directed toward the SdrG nucleic acid sequence and related pending United States divisional applications directed toward the SdrG protein and antibodies to it, as well

as corresponding foreign applications. SdrG is the MSCRAMM protein that we target on *S. epidermidis* and is used in the manufacture of Veronate. We also have an exclusive royalty-bearing license to BRI's rights in an allowed United States patent application and foreign counterparts directed to the methods we use for screening and selecting donor plasma using MSCRAMMs for both SdrG and ClfA in the manufacture of Veronate. We also have an exclusive royalty-bearing license from BRI under two issued United States patents and a pending United States patent application directed to the ClfA nucleic acid and protein. The license also covers pending international applications relating to antibodies to ClfA. BRI may terminate the license if we fail to use commercially reasonable efforts to bring one or more products that use the licensed technology to market. Otherwise, this license will terminate upon the expiration of the licensed patents. We may terminate the license agreement as to any patent or patent application upon 90 days notice. Currently, the latest to expire of the issued patents under the license agreement expires in 2019.

Since 1996, we have entered into several cooperative research agreements with BRI and Trinity College Dublin, or TCD, for technologies relating to staphylococcal surface proteins. We have exclusive worldwide rights to, and are entitled to file patents on, any discoveries resulting from this collaboration. All licenses from BRI and TCD are subject to research rights retained by BRI or TCD. BRI or TCD is entitled to a royalty on any revenues that we receive from the sale of products that incorporate technology developed through the collaborative arrangement. We may terminate the collaboration agreement on two months written notice. BRI may terminate in the event of an uncured material breach by us.

Pursuant to these agreements, we have paid BRI approximately \$256,000 and TCD approximately \$105,000 through December 31, 2005. We have no future minimum royalty or milestone obligations pursuant to these agreements, but we currently pay TCD approximately \$35,000 in annual sponsored research payments.

#### *Other Licensing Agreements*

##### *Wyeth*

In August 2001, we entered into a license and development collaboration agreement with Wyeth for the development of human staphylococcal vaccines. Under the terms of this agreement, we granted Wyeth an exclusive worldwide license to our MSCRAMM protein intellectual property with respect to human vaccines against staphylococcal organisms. The development, manufacture and sale of any products resulting from the collaboration will be the responsibility of Wyeth. We may terminate this agreement if Wyeth fails to use reasonable commercial efforts to bring related products to market. Wyeth may terminate the agreement without cause on six months notice. Otherwise, this agreement will terminate upon the expiration of all of the licensed patents. Currently, the latest to expire of the issued patents under the license agreement expires in 2019.

Pursuant to this agreement, we have received \$4.3 million in an upfront license fee and annual research support payments from Wyeth as of December 31, 2005. We are entitled to receive minimum research support payments of \$500,000 per year until the first commercial sale of any product developed under this agreement. The minimum annual research payment we receive from Wyeth increases to \$1.0 million if Wyeth does not initiate a Phase I trial by July 31, 2007. We are also entitled to receive milestone payments upon the filing of an Investigational New Drug application, or IND, the commencement of both Phase II and Phase III clinical trials, the filing of a BLA, and FDA approval of a licensed product. If all such milestones are achieved relative to one or more licensed products, we would be entitled to receive a minimum of \$10.0 million in milestone payments from Wyeth. The maximum milestone payments we could receive with respect to all licensed products are \$15.5 million. Finally, we are also entitled to royalties on net sales of licensed products manufactured, sold or distributed by Wyeth.

##### *Dyax*

In October 2004, we entered into a collaboration agreement with Dyax. to co-develop monoclonal antibodies to prevent or treat serious infections caused by enterococci. Under the terms of the agreement,

we and Dyax have agreed to collaborate and share in the costs to perform preclinical research and development activities intended to identify and select a fully human monoclonal antibody, or antibodies, against MSCRAMM proteins located on the surface of enterococci, that we could jointly advance into clinical development. During this preclinical phase, we and Dyax are responsible only for our respective internal development costs. Accordingly, neither party is responsible to make any upfront payments to the other party, nor is either party obligated to make future milestone or royalty payments to the other party at this time. Our internal development costs are expected to consist largely of salaries and other personnel-related costs associated with existing employees, certain supplies and other costs, such as travel and entertainment, associated with supporting existing employees. If at the end of the collaborative preclinical development activities, we mutually agree to advance one or more human monoclonal antibodies into clinical trials, we expect to continue to share in the clinical development costs of any such product candidates. The agreement also contemplates that we would share in the commercialization rights and profits from any approved and marketed products resulting from the collaboration. In the event that the parties mutually agree that the collaboration has been unable to identify a suitable monoclonal antibody to advance into clinical development, the collaboration agreement will immediately and automatically terminate without any further obligations to either party. Otherwise, this agreement can only be terminated during the initial preclinical development phase upon the mutual consent of both parties, or by one party in the event that the other party has committed a material breach, or filed for insolvency or bankruptcy.

#### *Aurexis Manufacturing Licenses*

The following four agreements relate to intellectual property associated with the production of monoclonal antibodies that we have in-licensed.

In November 2001, we entered into a research evaluation and worldwide non-exclusive license agreement with Lonza Biologics for intellectual property and materials relating to the expression of recombinant monoclonal antibodies to bacterial surface proteins for use in the manufacture of Aurexis. Under the terms of the agreement, we agreed to pay an annual fee of up to 100,000 pounds sterling and a royalty on the net selling price of any products that we market that utilize the underlying technology. In the event we do not use Lonza to manufacture Aurexis, if and when it is approved by the FDA for sale, the annual payment would increase to 300,000 pounds sterling per year. We may terminate the agreement upon 60 days notice. The agreement terminates upon the expiration of the last valid patent or 15 years, whichever is longer. Currently, the latest to expire of the issued patents under the license agreement expires in 2016. Pursuant to this agreement, we have paid Lonza \$761,000 as of December 31, 2005.

In June 2003, we obtained a non-exclusive, worldwide royalty-bearing license from Genentech for a patent, commonly known as the Cabilly patent, relating to the production of monoclonal antibodies for use in the manufacture of Aurexis. Under the agreement, we agreed to pay Genentech an up-front license fee and we are further obligated to pay a milestone payment due upon the approval of Aurexis and a royalty on the sale of any of our products that utilize the underlying technology. We may terminate this agreement without cause upon 90 days notice. Otherwise, this license will terminate upon the expiration of the patent, which will occur in 2018 if not extended. Pursuant to this agreement, we have paid \$500,000 to Genentech as of December 31, 2005. Our aggregate future payments under this agreement are \$5.0 million, which is payable if Aurexis is approved for sale by the FDA.

In July 2003, we obtained a non-exclusive, worldwide royalty-bearing license from the University of Iowa for patents, commonly known as the CMV promoter or Stinski patents, relating to the expression of recombinant proteins used in the manufacture of Aurexis. Under this agreement, we paid the University of Iowa an up-front license fee of \$35,000 and are obligated to make annual payments of \$35,000 per year. We also agreed to pay a royalty on the sale of any of our products that utilize the underlying technology and milestone payments of \$40,000 for each of the first four licensed products to receive FDA approval. We may terminate this agreement at any time. Otherwise, this license will terminate upon the expiration of the two licensed patents, which will be 2009 and 2012, respectively.

In March 2004, we obtained a non-exclusive, worldwide royalty-bearing license from the National Institutes of Health, or NIH, for patent applications relating to technology used in the humanization of monoclonal antibodies. Under this agreement we agreed to pay an up-front license fee, a minimum annual royalty of \$25,000 per year, a royalty on the sale of any of our products that would otherwise infringe any patent that may issue from the pending applications, and milestone payments. For any product covered by this license, the milestone payments are based upon the filing of an IND, the first subject enrolled in a Phase II and Phase III trial, the filing of a BLA, and upon the approval of a BLA by the FDA. We may terminate this agreement upon 60 days notice. This agreement terminates upon the expiration of the patent, which will occur in 2011 if not extended. Pursuant to this agreement, we have paid \$259,000 to the NIH as of December 31, 2005. If Aurexis is approved for sale by the FDA, our total future payments to the NIH under this agreement related to milestones would be approximately \$900,000 in the aggregate.

### **Pharmaceutical Pricing and Reimbursement**

In both the United States and foreign markets, any revenue associated with our products will depend largely upon the availability of reimbursement from third-party payers. Third-party payers include various government health authorities such as The Centers for Medicare and Medicaid Services, or CMS, which administers Medicare and Medicaid in the United States, managed-care providers, private health insurers and other organizations. Third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including pharmaceuticals. In addition, significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products. Our products may ultimately not be considered cost-effective, and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to support a profitable operation or generate an appropriate return on our investment in product development.

The United States and foreign governments periodically propose and pass legislation designed to reduce the cost of healthcare. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals may change before any of our product candidates are ever approved for marketing. Adoption of new legislation could further limit reimbursement for pharmaceuticals. In addition, an increasing emphasis on managed care in the United States has and will continue to increase the pressure on pharmaceutical pricing. The marketability of our products may suffer if the government and other third-party payers fail to provide adequate coverage and reimbursement rates for our product candidates.

We intend to obtain coverage and reimbursement for our products from these third-party payers; however we cannot assure you that we will be successful in obtaining adequate coverage, reimbursement, or pricing, if any.

### **Regulatory Matters**

#### *Overview*

The preclinical and clinical testing, manufacture, labeling, storage, distribution, promotion, sale and export, reporting and record-keeping of our product candidates are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA and corresponding state agencies, and regulatory agencies in foreign countries.

Non-compliance with applicable regulatory requirements can result in, among other things, fines, injunctions, seizure of products, total or partial suspension of product manufacturing and marketing, failure of the government to grant approval, withdrawal of marketing approvals and criminal prosecution.

### *United States Regulatory Approval*

Pursuant to FDA regulations, we are required to undertake a long and rigorous process before any of our product candidates may be marketed or sold in the United States. This regulatory process typically includes the following general steps:

- the performance of satisfactory preclinical laboratory and animal studies under the FDA's Good Laboratory Practices regulation;
- the development and demonstration of manufacturing processes which conform to FDA-mandated current Good Manufacturing Practices, or cGMPs;
- the submission and acceptance of an IND which must become effective before human clinical trials may begin in the United States;
- obtaining the approval of Institutional Review Boards, or IRBs, at each site where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials;
- the successful completion of a series of adequate and well-controlled human clinical trials to establish the safety, purity, potency and efficacy of any product candidate for its intended use, which conform to the FDA's good clinical practice regulations; and
- the submission to, and review and approval by the FDA of a Biologics License Application, or BLA, or for non-biologic pharmaceutical products, a New Drug Application, or NDA, prior to any commercial sale or shipment of a product.

This process requires a substantial amount of time and financial resources. We cannot assure you or be certain that this process will result in the granting of an approval for any of our product candidates on a timely basis, if at all. In 2002, the FDA announced a reorganization that has resulted in the shift of the oversight and approval process for certain therapeutic biologic drugs and the related staff from the Center for Biologics Evaluation and Research, or CBER, to the Center for Drug Evaluation and Research, or CDER. Our lead product candidate, Veronate, is being regulated through CBER, while Aurexis, which was originally regulated through CBER, and any other monoclonal product candidates that we may develop in the future, are now being regulated through CDER. This transition was not intended to result in any delays in the FDA's review of biopharmaceuticals, but there can be no assurance that there will not be any such delay.

### *Preclinical Testing*

Preclinical tests generally include laboratory evaluation of a product candidate, its chemistry, formulation, stability and toxicity, as well as certain animal studies to assess its potential safety and efficacy. We must submit the results of these preclinical tests, together with manufacturing information, analytical data and the clinical trial protocol, to the FDA as part of an IND, which must become effective before we may begin any human clinical trials. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within this 30-day time period, raises concerns or questions about the intended conduct of the trials and imposes what is referred to as a clinical hold. If one or more of our products is placed on clinical hold, we would be required to resolve any outstanding issues to the satisfaction of the FDA before we could begin, or continue clinical trials. Preclinical studies generally take several years to complete, and there is no guarantee that an IND based on those studies will become effective, allowing clinical testing to begin.

In addition to FDA review of an IND, each medical site that desires to participate in a proposed clinical trial must have the clinical protocol reviewed and approved by an independent IRB. The IRB considers, among other things, ethical factors, and the selection and safety of human subjects. Clinical trials must be conducted in accordance with the FDA's Good Clinical Practices requirements.

### *Clinical Trials*

Human clinical trials are typically conducted in three sequential phases:

*Phase I.* In Phase I clinical trials, a product candidate is typically introduced either into healthy human subjects or patients with the medical condition for which the new drug is intended to be used. Generally the main purpose of a Phase I trial is to assess a product candidate's safety and the ability of the human body to tolerate the product candidate. Absorption, metabolism, distribution and pharmacokinetic trials are also generally performed at this stage.

*Phase II.* During this phase, a product candidate is generally studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy or biologic activity of the product candidate for specific targeted diseases or medical conditions, and (iii) assess dosage tolerance and determine the optimal dose for a subsequent Phase II or Phase III trial. Phase II trials generally involve patients who are divided into one or more groups that will get one of several dose levels of the product candidate, and a control group that will not be treated with the product candidate and may receive a placebo.

*Phase III.* If and when one or more Phase II trials demonstrate that a specific dose or range of doses of a product candidate is potentially effective and has an acceptable safety profile, one or more Phase III trials are generally undertaken to further demonstrate or confirm clinical efficacy and to further test for safety in an expanded patient population with the goal of evaluating the overall risk-benefit relationship of the product candidate. Phase III trials will generally be designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the product candidate's potential clinical efficacy. The successful demonstration of clinical efficacy and safety in one or more Phase III trials is typically a prerequisite to the filing of a BLA or a NDA for a product candidate.

We cannot be certain that we will successfully complete any Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, we, the FDA, an IRB, or a Data Safety Monitoring Board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health or safety risk.

### *Biologics License Applications*

If and when our clinical trials have been completed with satisfactory clinical data we must submit a BLA to the FDA in order to obtain approval for the marketing and sale of a product candidate. Among many other items, a BLA typically includes a description of the manufacturing process and quality control methods, as well as the results of preclinical and toxicology studies and clinical trials. The FDA must approve the BLA prior to the marketing and sale of the related product. The FDA may deny a BLA if all applicable regulatory criteria are not satisfied or may require additional data, including clinical, toxicology, safety or manufacturing data. It can take several years for the FDA to approve a BLA once it is submitted, and the actual time required for any product candidate may vary substantially, depending upon the nature, complexity and novelty of the product candidate. We cannot be certain that the FDA, or any other similar regulatory agency in other countries, will grant approval for any of our product candidates on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if such regulatory approval is granted, additional post-marketing, or Phase IV clinical trials, may be required that would add additional product development costs beyond those incurred through Phase III testing. The FDA generally requires products with Fast Track status, such as Veronate and Aurexis, to be further evaluated for safety in Phase IV clinical trials.

### *Post-Approval Regulations*

If and when a product candidate receives regulatory approval, the approval is typically limited to specific clinical indications. Further, even after regulatory approval is obtained, subsequent discovery of previously unknown safety problems with a product may result in restrictions on its use or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Further, drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with cGMP, which impose rigorous procedural and documentation requirements upon us and our contract manufacturers. Manufacturers of biologics must also comply with the FDA's general biological standards. We cannot be certain that we, or our present or future contract manufacturers or suppliers, will be able to comply with cGMP regulations and other FDA regulatory requirements. Failure to comply with these requirements may result in, among other things, total or partial suspension of production activities, failure of the FDA to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

If the FDA approves one or more of our product candidates, we and our contract manufacturers must provide the FDA with certain updated safety, efficacy, and manufacturing information. Product changes, as well as certain changes in the manufacturing process or facilities where the manufacturing occurs or other post-approval changes may necessitate additional FDA review and approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also comply with FDA and Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the company to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

The FDA's policies may change in the future 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 that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad, or the impact such changes could have on our business.

### *Fast Track and Orphan Drug Status*

Both Veronate and Aurexis have received Fast Track status as provided for under various FDA regulations. Veronate has also been designated as an Orphan Drug by the FDA for the reduction of nosocomial bacteremia caused by staphylococci in VLBW infants. If our other product candidates meet the criteria, we may also apply for Orphan Drug and Fast Track status for such product candidates.

The FDA has developed "Fast Track" policies, which provide for the potential for expedited review of a BLA. However, there is no assurance that the FDA will, in fact, accelerate the review process for a Fast Track product candidate. Fast Track status is provided only for those new and novel therapies that are intended to treat persons with life-threatening and severely debilitating diseases where there is a defined unmet medical need, especially where no satisfactory alternative therapy exists or the new therapy is significantly superior to alternative therapies. During the development of product candidates that qualify for this status, the FDA may expedite consultations and reviews of these experimental therapies. Fast Track status also provides for the potential for a "priority review", whereby the FDA agrees to reduce the time it takes to review a BLA or NDA. The FDA can base approval of a marketing application for a Fast Track product on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA generally requires as a condition of the approval of an application for certain Fast Track

products, additional post-approval studies or Phase IV clinical studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Further, Fast Track status allows for a rolling BLA or NDA submission, whereby portions of the application can be submitted to the FDA for review prior to the completion of the entire application. A rolling submission could result in a reduction in the length of time it would otherwise take the FDA to complete its review of the application. Fast Track status may be revoked by the FDA at any time if the clinical results of a trial fail to continue to support the assertion that the respective product candidate has the potential to address an unmet medical need. In addition Fast Track status may be granted for a specific application of a drug candidate.

The FDA may grant Orphan Drug status to drugs intended to treat a “rare disease or condition,” which, in the United States, is generally a disease or condition that affects fewer than 200,000 individuals. If and when the FDA grants Orphan Drug status, the generic name and trade name of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Aside from guidance concerning the non-clinical laboratory studies and clinical investigations necessary for approval of the BLA, Orphan Drug status does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The FDA may grant Orphan Drug status to multiple competing product candidates targeting the same indications. A product that has been designated as an Orphan Drug that subsequently receives the first FDA approval for the indication for which it has received such designation is entitled to Orphan Drug exclusivity, which means the FDA may not approve any other applications to market the same type of drug for the same indication, except in very limited circumstances, for seven years from the date of FDA approval. Drugs demonstrating superiority to a previously approved Orphan Drug may be approved within the seven year window. Orphan Drug status may also provide certain tax benefits.

#### *Foreign Regulatory Approval*

Outside of the United States, our ability to market our product candidates will also be contingent upon receiving marketing authorizations from the appropriate foreign regulatory authorities whether or not FDA approval has been obtained. The foreign regulatory approval process in most industrialized countries generally includes risks that are similar with the FDA approval process we have described herein. The requirements governing conduct of clinical trials and marketing authorizations, and the time required to obtain requisite approvals may vary widely from country to country and differ from that required for FDA approval.

In Europe, Orphan Medicinal Product, or OMP, designation is granted to drugs that are being developed to prevent or treat life-threatening or very serious conditions that impact not more than five out of 10,000 individuals in the European Union. OMP designation provides for 10 years of market exclusivity versus similar drugs for the same indication. Other benefits include a reduction in fees associated with marketing applications and access to scientific advice from the EMEA at no cost. In December 2005, Veronate was granted OMP designation.

## **Employees**

As of December 31, 2005, we had 80 full-time employees, 63 of whom were engaged in research and development, clinical, regulatory, and quality assurance and control, and 17 of whom were engaged in administration, sales and marketing, finance, and business development. All of our employees have entered into non-disclosure agreements with us regarding our intellectual property, trade secrets and other confidential information. None of our employees is represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe that we maintain satisfactory relations with our employees.

## **Available Information**

We file reports with the Securities and Exchange Commission ("SEC"), including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and other reports from time to time. The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We are an electronic filer and the SEC maintains an Internet site at [www.sec.gov](http://www.sec.gov) that contains the reports, proxy and information statements, and other information filed electronically. Our website address is [www.inhibitex.com](http://www.inhibitex.com). Please note that these website addresses are provided as inactive textual references only. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information provided on our website is not part of this report, and is therefore not incorporated by reference unless such information is otherwise specifically referenced elsewhere in this report.

## ITEM 1A. RISK FACTORS

*You should carefully consider the following discussion of risks, together with the other information contained in this Form 10-K. The occurrence of any of the following risks could materially harm our business, our financial condition, and our ability to raise additional capital in the future or ever become profitable. In that event, the market price of our common stock could decline and you could lose part or all of your investment.*

### Risks Relating to Our Business

*We depend heavily on the success of our lead product candidate, Veronate, which is in clinical development. If we are unable to successfully develop or commercialize Veronate, or experience significant delays in doing so, our business could be materially harmed.*

Since our inception, we have invested a significant portion of our time and financial resources on the development of Veronate. We anticipate that in the near-term, our potential to generate significant product revenues will depend heavily on the successful development and commercialization of Veronate in the United States. We believe we will need to raise additional funds before we can fully commercialize Veronate.

We expect top-line data from our pivotal Phase III trial of Veronate to be available in April 2006. If the data from this Phase III clinical trial for Veronate are not satisfactory:

- we may delay or terminate any further development of Veronate;
- we may not be able to complete the filing of a BLA for Veronate;
- we may be forced to narrow the indication for which we seek marketing approval; or
- we may be required to perform additional Phase III trials.

If we believe the results from our Phase III trial are satisfactory and we proceed to complete the filing of a BLA for Veronate, the FDA may not accept our filing, or may request additional information, require us to perform additional clinical trials, limit its approval to a subset of patients, or ultimately not grant marketing approval for Veronate at all.

Veronate has been granted Fast Track status by the FDA. Fast Track status may qualify Veronate for a priority review by the FDA, but does not assure it. Fast Track status may be withdrawn by the FDA at any time if it believes that such status is no longer supported by data from our clinical development program. If we are not successful in commercializing Veronate, or are significantly delayed in doing so, our business will be materially harmed and we may need to curtail or cease operations.

*No antibody-based products that target MSCRAMM proteins have been developed or approved.*

All of our product candidates, including Veronate and Aurexis, target various MSCRAMM proteins. The use of MSCRAMM proteins to develop antibody-based products is an untested approach. These proteins have yet to be used by us or others to successfully develop any approved drugs. MSCRAMM proteins may ultimately prove to be a non-viable target for developing anti-infective or other drug candidates. If Phase III clinical trial results for Veronate are unsatisfactory, this may cast doubt on the viability of our MSCRAMM protein approach, our entire portfolio of product candidates, and we may need to curtail or cease operations.

*If the clinical trials for our product candidates are unsuccessful or delayed, we could be delayed or precluded from further developing or ultimately selling our product candidates.*

You must evaluate us in light of the uncertainties, complexities and risks present in a development stage biopharmaceutical company. In order to receive regulatory approval to sell our product candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or other regulatory authorities. Clinical testing is expensive, takes many years to complete, and its

outcome is highly uncertain. Delays, or clinical setbacks or failures may occur at any time, or in any phase of the clinical development process for a number of reasons, including safety concerns, a lack of demonstrated efficacy, poor trial design, and manufacturing-related issues related to the material used to conduct the clinical trials. Further, many later-stage trials, such as our Phase III trial of Veronate, are “blinded”, meaning the status and outcome of the trial are unknown to all of the participants in the trial, including the company or organization sponsoring the trial, until the top-line data is compiled, finalized or locked, and made available. If the enrollment of patients into our clinical trials is delayed or proceeds at a slower pace than expected, our clinical trials will take longer, and cost more, to complete. The results of preclinical studies and prior clinical trials of our product candidates may not predict the results of later-stage clinical trials. Product candidates in later stages of clinical development may fail to show desired safety and efficacy traits despite having successfully demonstrated so in earlier clinical testing. Even if the data collected from clinical trials involving our product candidates are satisfactory and demonstrate safety and efficacy, such results may not be sufficient to support the submission of a BLA or to obtain regulatory approval from the FDA in the United States, or elsewhere. We have completed enrollment in a 2,018 patient Phase III trial for which we are awaiting top-line data, and completed a 512 patient Phase II trial for Veronate and a 60 patient Phase II trial for Aurexis. The results of the Phase II trials were not statistically significant. There can be no assurance that the results of these trials are predictive of the outcome of later-stage trials for Veronate and Aurexis. Even if our products are granted regulatory approval, post-approval or Phase IV clinical trials may demonstrate safety concerns that require removing the product from the marketplace.

***We must comply with extensive government regulations in order to obtain and maintain marketing approval for our products in the United States and abroad.***

Our product candidates are subject to extensive and rigorous domestic and foreign government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. Our product candidates are also subject to similar extensive regulation by foreign governments to the extent we seek to develop and commercialize them in those countries. We must provide the FDA and foreign regulatory authorities, if applicable, with clinical data that appropriately demonstrate our product candidates’ safety and efficacy in humans before they can be approved for the targeted indications. None of our product candidates has been approved for sale in the United States or any foreign market, and we cannot predict whether regulatory approval will be obtained for any product candidate we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and need for the product, requires the expenditure of substantial resources, involves post-marketing surveillance and vigilance, and generally involves ongoing requirements for post-marketing studies or Phase IV clinical trials. In addition, we may encounter delays in or fail to gain regulatory approval for our product candidates based upon additional governmental regulation resulting from future legislative or administrative action or changes in FDA policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approvals may:

- adversely affect our ability to further develop or commercialize any product candidates;
- diminish any competitive advantages that we may have or attain; and
- adversely affect revenues or the receipt of royalties from the sale of our products.

Furthermore, any regulatory approvals, if granted, may later be withdrawn. If we fail to comply with applicable regulatory requirements at any time, or if post-approval safety concerns arise, we may be subject to restrictions or a number of actions, including:

- delays in clinical trials or the commercialization of our products;
- refusal by the FDA to review pending applications or supplements to approved applications;
- product recalls or seizures;

- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

Additionally, we may voluntarily withdraw any approved product from the market if we believe that the product may pose a safety risk to patients, or if the approved product no longer meets our business objectives.

The ability to market a pharmaceutical product outside of the United States is contingent upon receiving marketing authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes typically include many, if not all, of the risks associated with the FDA as described above and may include additional risks.

***We may be forced to delay, curtail, or terminate the development or commercialization of our product candidates or significantly alter or abandon our business strategy if we are unable to obtain additional funding.***

We expect that we will need additional capital in the future, and the extent of this need will depend on many factors, some of which are beyond our control, including:

- the successful and continued development of our product candidates in preclinical and clinical testing;
- the establishment of marketing and sales capabilities and the costs to develop a corporate infrastructure to support the commercialization of our product candidates;
- the time it takes to receive regulatory approvals needed to market our product candidates;
- the level of market acceptance of our products;
- future payments, if any, received or made under existing or possible future collaborative arrangements;
- the costs associated with protecting and expanding our patent and other intellectual property rights; and
- the need to acquire licenses to new products or compounds.

We anticipate that our existing cash and cash equivalents, short-term investments, and available credit facilities will enable us to operate for a period of at least 12 months from the date of this filing. We have no other committed sources of additional capital at this time. We cannot assure you that funds will be available to us in the future on acceptable terms, if at all. If adequate funds are not available to us on terms that we find acceptable, or at all, we may be required to delay, reduce the scope of, or eliminate research and development efforts or clinical trials on any or all of our product candidates. We may also be forced to curtail or restructure our operations, obtain funds by entering into arrangements with collaborators or partners on unattractive terms, sell or relinquish rights to certain technologies, product candidates or our intellectual property that we would not otherwise sell or relinquish in order to continue our operations.

***If third-party vendors upon whom we rely to conduct our clinical trials do not perform or fail to comply with strict regulations, the clinical trials for our product candidates may be terminated, delayed, or unsuccessful.***

We have limited experience in conducting and managing large clinical trials. We rely on third parties, including clinical research organizations, consultants and principal investigators to assist us in managing, monitoring and conducting our clinical trials. We rely on these vendors and individuals to assist in the recruitment of sites and patients for participation in our clinical trials, to maintain positive relations with the clinical sites and to ensure that these sites are conducting our trials in compliance with the protocol, our instructions and applicable regulations. If these third parties fail to perform satisfactorily or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the

clinical trials for our product candidates may be delayed or unsuccessful. Further, the FDA may inspect some of the clinical sites participating in our clinical trials, or our third-party vendors' sites, to determine if our clinical trials are being conducted according to current good clinical practices. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to delay, repeat or terminate such clinical trials. Any delay, repetition or termination of our clinical trials could be very costly and materially harm our business.

***If third-party suppliers upon whom we rely or may rely to provide us with the critical raw material for Veronate do not perform or fail to comply with strict regulations, our clinical trials for, and the commercialization of, Veronate could be terminated, delayed, or adversely affected.***

We purchase the vast majority of the plasma we use to manufacture Veronate from DCI Management Group, LLC, or DCI, under a long-term supply contract. While we have also recently entered into long-term supply arrangements with two other suppliers to provide us with plasma for our planned commercialization of Veronate, we expect in the near-term to depend primarily on DCI for the majority of this critical raw material. Although our agreements with these other suppliers are intended to reduce our reliance on one supplier, in the event that DCI is not able to supply us pursuant to our contract with them, particularly in the near term, it may be difficult for us to find a sufficient supply of plasma from other vendors on commercially acceptable terms without undue delays, which could adversely impact our costs, as well as our ability to manufacture sufficient quantities of Veronate in the future to meet commercial demands.

The number of potential donors whose plasma contains a sufficient concentration of naturally occurring human antibodies to manufacture Veronate is limited. Therefore, we cannot assure you that our current or future third-party suppliers will be able to provide us with an adequate quantity of plasma to manufacture a sufficient amount of Veronate for future clinical trials or for commercial purposes.

The collection, shipment, storage and testing of plasma, including screening procedures for plasma donors, are subject to extensive and strict regulation by the FDA and other foreign regulatory authorities. In the event that DCI, or any other existing or future supplier, fails to comply with these stringent regulations, it could be precluded from shipping us an adequate supply of plasma, which could adversely impact our ability to manufacture Veronate on a timely basis, if at all.

***If third-party contract manufacturers, upon whom we rely to manufacture our product candidates do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our clinical trials and the commercialization of our products could be terminated, delayed, or adversely affected.***

We do not own or operate any manufacturing facilities. We have contracted with third-party manufacturers to make clinical trial materials for our product candidates in development. We also intend to rely on third-party contract manufacturers, at least for the foreseeable future, to manufacture our products if and when they are approved for sale. Our reliance on third-party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our clinical trials, the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- The number of potential contract manufacturers that are able to produce our product candidates is limited.
- Our third-party contract manufacturers may place a priority on the manufacture of their, or other customers' products.
- Our contract manufacturers may fail to perform as agreed or may not remain in the contract manufacturing business.
- The manufacture of biologic products requires compliance with numerous and strict safety, quality and regulatory standards. Our contract manufacturers may not produce our product candidates according to

their own standards, our specifications, cGMP requirements, or may otherwise manufacture material that we or the FDA may deem to be unusable in our clinical trials or commercially.

- Our manufacturers' plants may be closed as a result of regulatory sanctions or a natural disaster.
- To date, our product candidates have been manufactured by our contract manufacturers in small quantities for preclinical studies and clinical trials. If our contract manufacturers are unable to increase the manufacturing scale of, or increase the capacity for, our product candidates, we may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the profitability of our products. Further, regulatory approval or the commercialization of our products may be delayed. We cannot assure you that our current contract manufactures will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us who can do so.
- Notwithstanding our contract manufacturers' compliance with all specifications and cGMP requirements, antibody-based products are known to be susceptible to the aggregation or clumping of their protein content from time to time. In the event that an unacceptable level of protein aggregation occurs in any manufactured lot of our clinical trial materials or commercial products, that respective lot may not be usable, which could delay our clinical trials or result in the revocation of FDA approval, if obtained, or otherwise force us to suspend or cease marketing of such products .

Drug manufacturers are subject to ongoing periodic inspections by the FDA, the United States Drug Enforcement Administration, or DEA, and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third-party manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party product. These sanctions include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

***In the event that we need to change our third-party contract manufacturers, our clinical trials and the commercialization of our products could be delayed, adversely affected or terminated, result in higher costs, or deprive us of potential product revenues.***

Due to regulatory restrictions inherent in a BLA, the manufacture of many biologic-based products, including our product candidates, is generally sole-sourced. In accordance with FDA-mandated current good manufacturing practices, or cGMPs, changing manufacturers for these products generally requires re-validation of the manufacturing processes and procedures and may require further clinical trials. Changing our current or future contract manufacturers may be difficult for us and could be costly and take several years to complete, which could result in our inability to manufacture our products or product candidates for an extended period of time. Further, we do not have any alternate manufacturing plans for our product candidates at this time. It may be difficult or impossible for us to find alternative manufacturers on commercially acceptable terms, if at all.

***Our third-party contract manufacturer for Veronate is a potential competitor. If we fail to maintain or renew our manufacturing agreement with this manufacturer, the development and commercialization of Veronate could be delayed or adversely affected.***

In December 2001, we entered into a ten-year contract manufacturing agreement with Nabi Biopharmaceuticals, Inc., or Nabi, to be our contract manufacturer for Veronate. Nabi is a publicly-held company that discovers, develops, manufactures and markets antibody-based products. Nabi is developing antibody-based products to prevent or treat *S. aureus* and *S. epidermidis* infections, therefore we consider Nabi to be a potential competitor. Under our contract manufacturing agreement with Nabi, we may not be able to engage any other third party to manufacture Veronate until our agreement with Nabi is terminated.

If we fail to maintain or renew our manufacturing agreement with Nabi, the development and commercialization of Veronate could be delayed or adversely affected.

***If we fail to establish marketing and sales capabilities or fail to enter into effective sales, marketing and distribution arrangements with third parties, we may not be able to successfully commercialize our products.***

If approved by the FDA, we intend to sell Veronate, and possibly Aurexis, through our own hospital-based sales force in the United States and establish relationships with other companies to commercialize them in other countries around the world. Although we have a Vice President of Sales and Marketing, we currently have no infrastructure to support such activities, and have only limited experience in the commercialization of hospital-based pharmaceutical products. Therefore, our future profitability will depend in part on our ability to develop a capable hospital-based sales force and suitable marketing capabilities in a timely manner. The development of our own hospital-based sales force and marketing capabilities will result in us incurring significant costs before the time that we may generate significant revenues. We may not be able to attract and retain qualified marketing or sales personnel, or be able to establish an effective hospital-based sales force. To the extent that we enter into marketing and sales arrangements with other companies to sell, promote or market our products in the United States or abroad, our product revenues, which may be in the form of direct revenue, a royalty, or a split of profits, will depend on their efforts, which may not be successful.

Hospital-based products are typically distributed through third-party distributors rather than directly through the organization conducting the sale and marketing of the product. Our ability to accurately forecast the sales of our products will be directly linked to the quality and timeliness of inventory information provided by these third-party distributors.

***If government and third-party payers fail to provide adequate reimbursement or coverage for our products, our revenues and potential for profitability will be harmed.***

In the United States and most foreign markets, our product revenues will depend principally upon the reimbursement rates established by third-party payers for our products. Such third-party payers include government health administration authorities, managed-care providers, private health insurers and other organizations. These third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved drugs or pharmaceutical products. We may need to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial and other resources. We cannot assure you that our products will be reimbursed in part or at all by any third-party payers.

Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare, including pharmaceutical drugs. In some foreign markets, governments control prescription drugs' pricing and profitability. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put downward pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we receive for any of our products in the future, which would limit our revenues and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidates are approved for sale, which could further limit or eliminate reimbursement rates for our products.

Biologic-based products, such as Veronate and Aurexis, tend to be relatively expensive as compared to other pharmaceutical products. As such, these products may be more susceptible to the pressures associated with pricing challenges from and reimbursement status with third-party payers.

***Veronate is a blood product derived from human plasma. The administration of blood products could result in the transmission of infectious diseases or impurities that could prevent us from selling Veronate or expose us to liability.***

Veronate, our lead product candidate, is an immune globulin. Immune globulins contain antibodies derived from human plasma, which is a component of blood. Certain pathogenic organisms and impurities may be found in blood. While the collection, testing, processing, manufacture, and storage of immune globulins like Veronate are designed to eliminate harmful pathogens or other impurities, we cannot assure you that this will prevent the transmission of either known or unknown pathogens or impurities to patients that are treated with Veronate. If Veronate were suspected or known to have transmitted any harmful pathogens or impurities, approval of Veronate may be delayed, suspended or withdrawn, we could be forced to recall Veronate or certain lots of it, and we may be subject to product liability claims. Further, if public concern arises that any blood product other than Veronate or blood products in general may transmit a disease or unknown pathogens or impurities, approval for Veronate may be delayed or withdrawn, or the use of Veronate may be reduced or limited due to these concerns.

***If our products are approved, yet do not gain meaningful acceptance in their intended markets, we are not likely to generate significant revenues or become profitable.***

Even if we successfully develop our product candidates and obtain the requisite regulatory approvals to sell them in the future, they may not gain market acceptance or utilization among physicians and patients, or reimbursement or coverage from third-party payers. The degree of market acceptance for any product that we commercialize will depend on a number of factors, including:

- the therapeutic efficacy or perceived benefit of the product;
- the level of reimbursement available to cover the cost of the product;
- the cost of the product to the user or payer;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the effectiveness of our sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA.

There can be no assurance that hospitals or physicians will choose to administer our products to the intended patient population. If our products do not achieve meaningful market acceptance, or if the market for our products proves to be smaller than anticipated, we may not generate significant revenues or ever become profitable.

***If we are unable to adequately protect our intellectual property, our business prospects could be harmed.***

Our success depends in part on our ability to:

- obtain and maintain patents or rights to patents and maintain their validity;
- protect our trade secrets;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights or patents.

We will be able to protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or proprietary rights. Any patents that we own or licenses we have rights to may be challenged, invalidated or circumvented, and may not provide us with the protection

against competitors that we anticipate. Accordingly, we may be forced to engage in costly and time consuming litigation in order to protect our intellectual property rights. Our pending patent applications, or those we may file or license from third parties in the future, may not result in patents being issued. Until a patent is issued, the claims covered by the patent may be narrowed or removed entirely and therefore we may not obtain adequate patent protection. As a result, we may face unanticipated competition, or conclude that without patent rights the risk of bringing product candidates to the market is too great, thus adversely affecting our operating results. Because of the extensive time required for the development, testing and regulatory review of a product candidate, it is possible that before any of our product candidates can be approved for sale and commercialized, our relevant patent rights may expire or remain in force for only a short period following commercialization. Patent expiration could adversely affect our ability to protect future product development and, consequently, our operating results and financial position. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition to patents, we rely on trade secrets and proprietary know-how. We seek to protect these, in part, through confidentiality and non-disclosure agreements. These agreements may not provide meaningful protection for our technology or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information. Failure to protect our trade secrets and proprietary know-how could seriously impair our competitive position and harm our business. We may become involved in costly litigation in order to enforce patent rights or protect trade secrets or know-how that we own or license.

***If a third party claims we are infringing on its intellectual property rights, we could incur significant litigation or licensing expenses, or be prevented from further developing or commercializing our products.***

Our commercial success depends in part on our ability to operate without infringing the patents and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, United States Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming and their outcome is uncertain. We may become involved in litigation in order to determine the enforceability, scope and validity of the proprietary rights of others.

Scientific research relating to surface proteins located on pathogenic organisms has been conducted for many years in the areas in which we have focused our research and development efforts, which has resulted in third parties having a number of issued patents and still-pending patent applications. Patent applications in the United States are, in most cases, maintained in secrecy until the patent is issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to products similar to our product candidates may have already been filed by others without our knowledge. In the event an infringement claim is brought against us, we may be required to pay substantial legal and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing related product development and commercialization and may be subject to damage awards.

If we become involved in any patent litigation, interference or other administrative proceedings, we will incur substantial expense, and the efforts of our technical and management personnel will be significantly diverted. A detrimental outcome of such litigation or proceedings may expose us to loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidates in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses.

Our current and future product candidates may be covered by third-party patents or other intellectual property rights, in which case we would need to obtain a license or sublicense to these rights in order to

develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we do not obtain the required licenses or sublicenses, we could encounter delays in the development of our product candidates or be prevented from manufacturing and commercializing our products. If it is determined that we have infringed an issued patent, we could be compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

Biosynexus, Inc. filed suit against us in January 2003 in the Superior Court of Fulton County, Georgia, alleging the misappropriation of trade secrets, which we purportedly received through a large, nationally recognized third-party contract research organization and utilized in the design of clinical trials for Veronate. In its suit, Biosynexus is seeking injunctive relief as well as financial damages. In July 2003, the court denied Biosynexus' request for injunctive relief, and further ruled that we made a preliminary showing that we had not misappropriated, converted or benefited from the use of any property, including trade secrets, of Biosynexus. The court's ruling also indicated that Biosynexus had not shown a substantial likelihood that it would ultimately prevail on the merits of its case at trial. In August 2003, Biosynexus filed a notice of appeal of the court's ruling. However, we are unaware of any further action by Biosynexus in this matter. We can provide no assurance that the appeal filed by Biosynexus will not be pursued or be successful or that we will not be subject to similar suits in the future. As described under "Competition," MedImmune, Inc. has licensed intellectual property rights owned by Biosynexus and has indicated it intends to develop a monoclonal antibody against staphylococcal organisms for use in the pediatric market. We cannot determine if this development will have an impact on this litigation.

***If we succeed in implementing our strategy, we may encounter difficulties in managing our growth and expanding our operations successfully.***

If we successfully advance our product candidates, particularly Veronate, through clinical development and regulatory approvals, we will need to add or expand our research and clinical development, regulatory, manufacturing, supply-chain logistics, accounting, information technology and marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we may need to hire additional personnel and add corporate functions or capabilities that we currently do not have. Our ability to manage our operations and rapid growth will require us to continue to improve our operational, financial and management controls, information technology, and reporting systems and procedures. We may not be able to implement such improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in these systems and controls as a result of our assessments pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. In the event we cannot successfully manage our growth, there may be an adverse impact on our business.

***If we are unable to attract and retain key employees, advisors or consultants, we may be unable to successfully develop and commercialize our product candidates or otherwise manage our business effectively.***

Our success depends in part on our ability to attract and retain qualified management and personnel, directors, and academic scientists and clinicians as advisors or consultants. We are currently dependent upon the efforts of our executive officers. In order to pursue our product development and commercialization strategy, we will need to attract and hire additional personnel with experience in a number of disciplines, including clinical testing, government regulation, manufacturing, sales and marketing, drug reimbursement, accounting, finance, human resources and information systems. Although we have not had material difficulties in attracting and retaining key personnel in the past, we may not be able to continue to attract and retain such personnel on acceptable terms, if at all. If we lose any key employees, or are unable to attract and retain qualified personnel or advisors, our business may be harmed.

*We have experienced losses since our inception. We expect to continue to incur such losses for the foreseeable future and we may never become profitable.*

Since inception through December 31, 2005, we have incurred a cumulative deficit of approximately \$141.5 million. Our losses to date have resulted principally from:

- costs related to our research programs and the clinical development of our product candidates; and
- general and administrative costs relating to our operations.

We anticipate incurring losses for at least the foreseeable future as we further develop our product candidates, particularly Veronate and Aurexis, which will require us to conduct significant research and laboratory testing, conduct clinical trials, as well as seek regulatory approvals. In addition, we intend to establish a hospital-based sales force in the United States to market and sell Veronate, and potentially Aurexis and our other product candidates. When and if we implement our commercialization plan we also expect that our general and administrative expenses will increase as we add more personnel to support our operations. We cannot assure you that we will generate direct or royalty revenue from the sale of products or ever become profitable.

*We may be unable to successfully develop or commercialize product candidates that are the subject of collaborations if our collaborators do not perform.*

We expect to enter into and rely on collaborations or other arrangements with third parties to develop and/or commercialize our product candidates outside of the United States and in certain circumstances, in the United States. If we do so, such collaborators may not perform as agreed, or may fail to comply with strict regulations or elect to delay or terminate their efforts in developing or commercializing our product candidates. We currently have collaborations with Dyax to jointly develop a monoclonal antibody that targets MSCRAMM proteins on enterococci and with Wyeth to develop a vaccine to prevent staphylococcal infections in humans. We believe these collaborations are desirable for us to fund research and development activities, provide a suitable manufacturer, and obtain regulatory approvals and to successfully commercialize any product candidates that result from these collaborations. We cannot assure you that any product candidates will emerge from our relationships with Dyax or Wyeth, or other collaborations we may enter into in the future related any of our other product candidates.

*Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative products, which could harm our business.*

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about genetics and develop new technologies and approaches to treating and preventing disease. Our current and potential competitors generally include, among others, major multinational pharmaceutical companies, biotechnology firms, universities and other research institutions, particularly those companies that make antibiotic products. Specifically we are aware that Nabi, MedImmune, Inc., and NeuTec PLC are developing protein-based product candidates, including antibodies, enzymes and peptides, for the prevention and treatment of bacterial and fungal infections. In certain cases these companies have commenced clinical trials for these product candidates. Some of these companies and institutions, either alone or together with their collaborators, have substantially greater financial resources and larger research and development staffs than we do. In addition, many of these competitors, either alone or together with their collaborators, have significantly greater experience than we do in discovering, developing, manufacturing and marketing products. Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We face, and will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions, for attracting investigators and sites capable of conducting our clinical trials and for licenses of proprietary technology. These competitors, either alone or with their collaborators, may succeed in developing technologies or products that are more effective, less expensive or easier to

administer than ours. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for their drug candidates more rapidly than we can. Companies that complete clinical trials, obtain required regulatory approvals and commercialize their drugs before their competitors may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights that could delay the ability of competitors to market certain products. We cannot assure you that product candidates resulting from our research and development efforts, or from joint efforts with our collaborators, will be able to compete successfully with our competitors' existing products or products under development.

*Several of our product candidates may target Orphan Drug indications. If we fail to obtain approval for an Orphan Drug indication before one of our competitors does, we may be prevented from selling our products for a period of time.*

Our lead product candidate, Veronate, has been granted Orphan Drug status by the FDA for the reduction of nosocomial bacteremia caused by staphylococci in very low birth weight, or VLBW, infants. In Europe, the EMEA has granted Veronate Orphan Medicinal Product or OMP designation for the prevention of infections in infants who are 32 weeks or less gestational age. We believe that several of our other product candidates may also target Orphan Drug indications, which are indications where the intended patient population in the United States is less than 200,000 individuals. We believe that Nabi and MedImmune, Inc. have been granted FDA Orphan Drug status and European OMP designation for their antibody-based products that are being developed for the prevention of infections in premature infants. If we are not the first to receive FDA approval for our Orphan Drug indications, we may be prevented from having our product candidates approved in those indications for up to seven years. In addition, even if we are first to obtain approval for our Orphan Drug indications, clinicians may choose to use products that have been approved for other indications.

*If a product liability claim is successfully brought against us for uninsured liabilities or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards.*

The use of any of our product candidates in clinical trials and the sale of any approved products may expose us to product liability claims. We currently have product liability insurance coverage for our clinical trials in the amount of \$5.0 million. In the event any of our product candidates are approved for sale by the FDA, we anticipate that we may need to increase our product liability coverage. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

*Our revenues, expenses and results of operations will be subject to significant fluctuations, which will make it difficult to compare our operating results from period to period.*

Until we have successfully developed and commercialized a product candidate, we expect that substantially all of our revenues will result from payments we receive under collaborative arrangements, or license agreements pursuant to which we grant others the right to our intellectual property. To date, these payments have been in the form of up-front license and ongoing research and development support payments and from time to time, payments under materials transfer agreements. We may not be able to generate additional revenues under existing or future collaborative agreements. Furthermore, payments potentially due to us under our existing and any future collaborative arrangements, including any milestone and up-front payments, are subject to significant fluctuation in both timing and amount, or may never be earned or paid. Therefore, our historical and current revenues may not be indicative of our ability to achieve additional payment-generating milestones. In addition, our supply and manufacturing agreements with respect to Veronate and Aurexis require us to purchase certain minimum amounts that we may not

need and therefore may not be cost effective to us. As of December 31, 2005, our minimum purchase commitments amounted to an aggregate of \$17.3 million, assuming the relevant agreements are not cancelled or terminated by us. We expect that our operating results will vary significantly from quarter to quarter and year to year as a result of the timing of our research and development efforts, the execution or termination of collaborative arrangements, the initiation, success or failure of clinical trials, the timing of the manufacture of our product candidates, or other development related factors. Accordingly, our revenues and results of operations for any period may not be comparable to the revenues or results of operations for any other period.

*If our use of hazardous materials results in contamination or injury, we could suffer significant financial loss.*

Our research and manufacturing activities involve the controlled use of certain hazardous materials and medical waste. Notwithstanding the regulations controlling the use of these materials and the safety procedures we undertake, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge or exposure, we may be held liable for any resulting damages, which may exceed our financial resources.

### **Risks Related to the Ownership of Our Common Stock**

*Our common stock price has been highly volatile, and your investment in us could suffer a decline in value.*

The market price of our common stock has been highly volatile since we completed our initial public offering in June 2004. The market price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors and events, including but not limited to:

- disclosure of our or our competitors' clinical trial status or data;
- the approval or commercialization of new products by us or our competitors, and the disclosure thereof;
- announcements of scientific innovations by us or our competitors;
- rumors relating to us or our competitors;
- public concern about the safety of our product candidates, products or similar classes of products;
- litigation to which we may become subject;
- disclosures of any favorable or unfavorable regulatory developments concerning our clinical trials, manufacturing, or product candidates;
- actual or anticipated variations in our annual and quarterly operating results;
- changes in general conditions or trends in the biotechnology and pharmaceutical industries;
- changes in drug reimbursement rates or government policies related to reimbursement;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- new regulatory legislation adopted in the United States or abroad;
- our failure to achieve or meet equity research analysts' expectations or their estimates of our business, or a change in their recommendations concerning our company, the value of our common stock or our industry in general;
- termination or delay in any of our existing or future collaborative arrangements;
- future sales of equity or debt securities, including large block trades or the sale of shares held by our directors or management;

- changes in accounting principles;
- failure to comply with the periodic reporting requirements of publicly-owned companies, under the Securities Exchange Act of 1934, as amended, and the Sarbanes-Oxley Act of 2002; and
- general economic conditions.

In addition, the stock market in general, and the Nasdaq National Market and the market for biotechnology stocks in particular, have historically experienced significant price and volume fluctuations. Volatility in the market price for a particular company's stock has often been unrelated or disproportionate to the operating performance of that company. Market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Due to this volatility, you may be unable to sell your shares of common stock at or above the price you paid.

In April 2006, we anticipate the availability of top-line data from our pivotal Phase III trial of Veronate. In the event that the trial does not achieve its primary endpoint, or the data are otherwise perceived as unsatisfactory, the price of our common stock could suffer a significant decline.

***If we raise additional capital in the future, your ownership in us could be diluted.***

We anticipate that we will need to raise additional capital in the future to fund our operations. Any additional equity financings we may undertake could cause the price of our common stock to decline, or require us to issue shares at a price that is lower than that paid by holders of our common stock in the past, which would result in those shares being dilutive. If we obtain funds through a credit facility or through the issuance of debt or preferred securities, these securities would have rights senior to your rights as a common stockholder.

***Future sales of shares of our common stock may cause our stock price to decline, even if our business is doing well.***

The sale of a significant number of shares of our common stock, or the perception that such sales could occur, particularly with respect to our directors, executive officers, and other insiders or their affiliates, could materially and adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities at a price we deem appropriate.

***Insiders continue to have substantial control over us, which could delay or prevent a change in our control.***

As of December 31, 2005, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 38% of our outstanding shares of our common stock. As a result, these stockholders, acting together, may have the ability to delay or prevent a change in control that may be favored by other stockholders and otherwise exercise significant influence over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including:

- the appointment of directors;
- the appointment, change or termination of management;
- any amendment of our certificate of incorporation or bylaws;
- the approval of some mergers and other significant corporate transactions, including a sale of substantially all of our assets; or
- the defeat of any non-negotiated takeover attempt that might otherwise benefit the public stockholders.

*Our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law contain provisions that could discourage, delay or prevent a change in our control or our management.*

Provisions of our amended and restated certificate of incorporation, bylaws and the laws of Delaware, the state we are incorporated in, may discourage, delay or prevent a change in control of us or a change in management that stockholders may consider favorable. These provisions:

- establish a classified, or staggered, board of directors, so that not all members of our board may be elected at one time;
- set limitations on the removal of directors;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

These provisions could discourage proxy contests and make it more difficult for you and other stockholders to remove and elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

## **ITEM 2. PROPERTIES**

We lease our 51,000 square foot office and laboratory facility, which is located in Alpharetta, Georgia, a northern suburb of Atlanta. We entered into this lease in December 2003 and occupied this new facility during the second quarter of 2005. Our minimum lease obligations for this facility and the amortization of leasehold improvements paid by the lessor will approximate \$1.0 to \$1.1 million per annum for the lease term of ten years.

## **ITEM 3. LEGAL PROCEEDINGS**

In January 2003, Biosynexus commenced an action against us in the Superior Court of Fulton County, Georgia. The suit seeks injunctive relief and financial damages of \$10.0 million on each of the three claims of (i) obtaining, (ii) converting and (iii) benefiting from alleged trade secrets, which we purportedly received through a large, nationally recognized third-party contract research organization.

In July 2003, the court denied Biosynexus' request for an interlocutory injunction. The court's ruling also stated that we made a preliminary showing that we did not misappropriate any Biosynexus information; that we did not use or are not using the information at issue; that our clinical trial protocol and approach to reporting adverse events, which were the alleged trade secrets, are substantially different than Biosynexus'; and that the alleged trade secrets are in fact not trade secrets but well known, widely-used and widely-reported concepts as applied to premature babies in a NICU. Following this ruling, we notified Biosynexus, and its attorneys, of our intent to pursue an abusive litigation claim, as provided for under Georgia law, against Biosynexus to seek full recovery of all legal fees and expenses related to the suit if they did not drop such claim within 30 days. In August 2003, Biosynexus filed notice in the Superior Court of Fulton County of its intent to appeal the court's ruling. Our motion for summary judgment filed in August 2003 has been stayed pending the appeal to the Georgia Supreme Court. We can provide no assurance that the appeal filed by Biosynexus will not be successful or that we will not be subject to similar suits in the future. In 2005, MedImmune, Inc. in-licensed certain intellectual property owned by Biosynexus. We cannot determine whether this development will have any impact on the status of this action or the appeal. Otherwise, we are not a party to or engaged in any material legal proceedings.

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

None.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES**

The Company's common stock trades on the Nasdaq National Market under the symbol "INHX." At March 1, 2006, the Company had 122 common stockholders of record. This figure does not represent the actual number of beneficial owners of common stock because shares are generally held in "street name" by securities dealers and others for the benefit of individual owners who may vote the shares.

The following table shows the range of high and low prices and year-end closing prices for our common stock for each completed fiscal quarter since January 1, 2005.

	2004	
	High	Low
Second Quarter (From June 4, 2004).....	\$ 7.75	\$7.00
Third Quarter .....	7.66	4.80
Fourth Quarter .....	12.76	4.92
Year End Close .....		8.04
	2005	
	High	Low
First Quarter .....	\$10.30	\$5.94
Second Quarter .....	9.49	5.75
Third Quarter .....	10.82	7.00
Fourth Quarter .....	10.70	7.66
Year End Close .....		8.40

The Company has never declared or paid any cash dividends on its common stock and does not anticipate paying any cash dividends in the foreseeable future. The Company currently intends to retain any earnings to fund future growth, product development and operations.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with, and are qualified by reference to, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our Financial Statements and related Notes included elsewhere in this Form 10-K. The statement of operations data for the years ended December 31, 2003, 2004 and 2005 and the balance sheet data as of December 31, 2004 and 2005 are derived from our audited financial statements, which are included elsewhere in this Form 10-K. The statements of operations data for the years ended December 31, 2001 and 2002 and the balance sheet data as of December 31, 2001, 2002, and 2003 are derived from our audited financial statements that are not included in this Form 10-K. The selected financial data for the period from inception on May 13, 1994 through December 31, 2005 were derived from our audited financial statements.

	Period from Inception (May 13, 1994) through December 31, 2005	Years Ended December 31,				
		2001	2002	2003	2004	2005
(In thousands, except per share data)						
<b>Statement of Operations Data:</b>						
Revenue .....	\$ 4,748	\$ 271	\$ 900	\$ 1,096	\$ 650	\$ 936
Operating expenses:						
Research and development .....	109,268	7,099	15,615	18,991	22,581	34,228
General and administrative .....	23,447	1,847	3,328	4,581	4,040	7,144
Amortization of deferred stock compensation .....	1,146	—	—	176	473	497
Total operating expenses .....	<u>133,861</u>	<u>8,946</u>	<u>18,943</u>	<u>23,748</u>	<u>27,094</u>	<u>41,869</u>
Loss from operations .....	(129,113)	(8,675)	(18,043)	(22,652)	(26,444)	(40,933)
Interest and other income (expense), net ..	<u>3,964</u>	<u>568</u>	<u>430</u>	<u>319</u>	<u>532</u>	<u>2,358</u>
Net loss .....	(125,149)	(8,107)	(17,613)	(22,333)	(25,912)	(38,575)
Dividends and accretion to redemption value of redeemable preferred stock .....	<u>(16,382)</u>	<u>(1,271)</u>	<u>(5,626)</u>	<u>(6,201)</u>	<u>(2,823)</u>	<u>—</u>
Net loss attributable to common stockholders .....	<u><u>\$(141,531)</u></u>	<u><u>\$(9,378)</u></u>	<u><u>\$(23,239)</u></u>	<u><u>\$(28,534)</u></u>	<u><u>\$(28,735)</u></u>	<u><u>\$(38,575)</u></u>
Basic and diluted net loss attributable to common stockholders per share .....		<u><u>\$ (21.17)</u></u>	<u><u>\$ (47.83)</u></u>	<u><u>\$ (54.19)</u></u>	<u><u>\$ (2.52)</u></u>	<u><u>\$ (1.43)</u></u>
Weighted average shares used to compute basic and diluted net loss attributable to common stockholders per share .....		<u><u>442,980</u></u>	<u><u>485,842</u></u>	<u><u>526,578</u></u>	<u><u>11,416,354</u></u>	<u><u>26,987,047</u></u>
As of December 31,						
		<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>
<b>Balance Sheet Data:</b>						
Cash and cash equivalents .....	\$ 1,404	\$ 28,658	\$ 26,649	\$ 71,581	\$ 33,843	
Short-term investments .....	—	1,000	1,499	15,624	53,288	
Working capital (deficit) .....	(1,360)	25,838	23,529	79,560	78,364	
Total assets .....	3,622	31,942	30,662	91,239	97,268	
Long-term debt and capital leases, less current portion	572	459	1,795	807	3,105	
Redeemable convertible preferred stock and warrants ..	20,558	70,934	95,608	—	—	
Deficit accumulated during the development stage .....	(22,448)	(45,686)	(74,220)	(102,955)	(141,531)	
Total stockholders' equity (deficit) .....	(21,666)	(44,886)	(73,226)	80,546	81,453	

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read this discussion together with the Financial Statements, related Notes and other financial information included elsewhere in this Form 10-K. The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," "Special Note on Forward-Looking Statements" and elsewhere in this Form 10-K. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.*

### **Overview**

We are a biopharmaceutical company committed to the discovery, development and commercialization of novel antibody-based products for the prevention and treatment of serious bacterial and fungal infections. We currently have two product candidates in clinical development and four product candidates in preclinical development. In November 2005, we completed enrollment in a 2,018 patient Phase III clinical trial for our lead product candidate, Veronate, which we are developing for the prevention of certain hospital-associated infections in premature, very low birth weight, or VLBW, infants. We anticipate top-line data from this trial will be available in April 2006. Our second product candidate is Aurexis, for which we completed a 60 patient Phase II clinical trial in May 2005 evaluating it as first-line therapy, in combination with antibiotics, to treat serious, life-threatening *S. aureus*, bloodstream infections in hospitalized patients.

Our product candidates have all been developed based on our expertise in MSCRAMM proteins, for which we own or have licensed numerous patents and patent applications. We have retained all worldwide rights to both Veronate and Aurexis and intend to commercialize Veronate, and potentially Aurexis, in the United States by establishing a specialized, hospital-based sales force. Further, we have neither received regulatory approval for, nor derived any commercial revenues from, either of these product candidates or any other product candidate. We currently have four other product candidates in preclinical development, all of which are based on the use of MSCRAMM proteins.

We are a development stage company that has generated significant losses since our inception in May 1994. We expect to incur substantial losses for at least the next several years as we plan to continue the development of our product candidates, particularly Veronate and Aurexis, continue our other research and development activities and establish a corporate and sales and marketing infrastructure in anticipation of the commercialization of Veronate. We currently have limited commercialization capabilities, and it is possible that we may never successfully commercialize any of our product candidates. To date, we have devoted substantially all of our efforts towards research and development activities related to the research and development of our product candidates. As of December 31, 2005 we had an accumulated deficit of \$141.5 million, which includes non-cash expenses of \$16.4 million related to the accrual of cumulative preferred stock dividends and the accretion to the redemption value of redeemable convertible preferred stock and \$1.1 million related to the amortization of deferred stock compensation.

In April 2006 we expect to have top-line data available from our pivotal Phase III Veronate trial. In the event the primary endpoint of this trial is met or achieved and the data are favorable or positive, we anticipate that our quarterly and annual operating expenses will increase over the next several years due primarily to the anticipated commercialization of Veronate. Commercialization-related activities potentially include establishing a sales and marketing infrastructure, building and maintaining sufficient product inventory and other investments in business systems and corporate infrastructure. We also anticipate that we will continue to conduct additional clinical trials for Veronate and other product candidates. In the event the primary endpoint of this trial is not met or achieved or the data are otherwise unfavorable or negative, we will not likely proceed with the commercialization of Veronate and we may delay, curtail, or terminate the development or commercialization of Veronate, or any or all of our product candidates, resulting in potentially smaller quarterly and annual operating expenses. The uncertainty of our impending top-line data, coupled with the timing and progress of our clinical trials and research and development

efforts, the timing and outcome of regulatory approvals, if any, and payments made or received pursuant to existing or future licensing or collaboration agreements make meaningful predictions of our future operations difficult to make.

### Financial Operations Overview

*Revenue.* Since our inception, we have not generated any revenue from the sale of products and do not expect product-related revenues until we obtain regulatory approval for and commercialize a product candidate. Currently, our revenues represent the amortization of an up-front license fee and quarterly research and development support payments we have received in connection with a license and collaboration agreement with Wyeth, and from time to time, grant revenue and proceeds from research activities we perform under a materials transfer agreement not covered by a license or collaboration agreement. We may generate future revenues from up-front or milestone payments in connection with collaborative or strategic relationships and royalties resulting from the licensing of our intellectual property. If our future development efforts result in regulatory approval and the successful commercialization of any of our product candidates, we expect the majority of our future revenues would then result from product sales.

*Research and Development Expense.* Research and development expense consists of the expenses incurred in discovering, developing, testing and manufacturing our product candidates. These costs consist primarily of professional fees paid to third-party service providers in conjunction with treating patients enrolled in our clinical trials and monitoring, accumulating and evaluating the related data, salaries and personnel-related expenses, the cost of raw materials, contract manufacturing services, supplies used in clinical trials and research and development activities, consulting, license and sponsored research fees paid to third parties, and facilities costs. We charge all research and development expenses to operations as incurred.

The following table summarizes our research and development expenses for the years ended December 31, 2003, 2004 and 2005. Direct external costs represent significant expenses paid to third parties that specifically relate to our product candidates in clinical development, such as payments to contract research organizations that monitor, accumulate and analyze data from our clinical trials, investigators who treat the patients enrolled in our clinical trials, and the cost of manufacturing clinical trial material. All remaining research and development expenses not tracked to a specific clinical product development program, such as salaries, supplies and other overhead costs, are included in unallocated costs and overhead. Research and development spending for past periods is not indicative of spending in future periods.

	Years Ended December 31,		
	2003	2004	2005
	(In thousands)		
Direct external costs:			
Veronate .....	\$ 7,620	\$ 8,851	\$17,073
Aurexis .....	2,586	3,120	4,214
Unallocated costs and overhead .....	<u>8,785</u>	<u>10,610</u>	<u>12,941</u>
Total research and development expenses .....	<u>\$18,991</u>	<u>\$22,581</u>	<u>\$34,228</u>

In the event the primary endpoint of our Phase III Veronate trial is met or achieved and the data are favorable or positive, we anticipate that our research and development costs will remain at current levels or increase in the future. However, in the near term we anticipate that our research and development expenses will remain near their current level, or possibly decrease due to the completion of the Phase III Veronate clinical trial. We also expect to expend a significant portion of our research and development resources on the development of our two most advanced product candidates, Veronate and Aurexis, than on the development of our preclinical product candidates. In the event the primary endpoint of our Phase III Veronate trial is not met or achieved and the data are unfavorable or negative, we anticipate that our research and development costs may decrease. Due to the uncertainty regarding the status and

timing of future clinical trials, such expenditures are likely to be uneven in future periods. We are currently focused on completing the Phase III Veronate clinical trial in the near-term, planning additional trials of Veronate, and advancing Aurexis through several clinical trials. From time to time, we will make determinations as to how much funding to direct to these programs in response to their scientific, clinical and regulatory success, and anticipated market opportunity. From inception through December 31, 2005, we have incurred approximately \$109.3 million in research and development expenses.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate the nature, timing and cost of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from any of our product candidates due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials and other research and development programs;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost of establishing and maintaining clinical and commercial supplies of our product candidates;
- the effect of competing technological and market developments;
- the cost of establishing, maintaining, and protecting our patents and intellectual property portfolio;
- the availability of funding to continue clinical trials.

The failure to complete the development of our product candidates in a timely manner, particularly Veronate, could have a material adverse effect on our operations, financial position, and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some of the consequences of failing to do so, are set forth in the “Risk Factors” section of this Form 10-K.

*General and Administrative Expense.* General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance, accounting, information technology, sales and marketing, business development and human resource functions. Other significant costs include professional fees for legal and accounting services, market research and other consulting services, as well as premiums for insurance, including directors and officers insurance. Assuming the primary endpoint of the Phase III Veronate trial is met or achieved, we expect our general and administrative expenses to increase as we add personnel, continue to comply with the reporting obligations and regulations applicable to publicly-held companies and establish an infrastructure in anticipation of the commercialization of Veronate. From inception through December 31, 2005, we have incurred approximately \$23.4 million in general and administrative expenses.

*Deferred Stock Compensation.* Deferred stock compensation for stock options granted to employees has been determined as the difference between the deemed fair value of our common stock for financial reporting purposes on the date such options were granted and the applicable exercise price. This amount is recorded as a reduction of stockholders’ equity and is being amortized on the straight-line basis over the related vesting period, which is generally four years. As of December 31, 2005, we had approximately \$0.8 million of deferred stock compensation that will be amortized over the remaining vesting periods of the related stock options. We will adopt Statement of Financial Accounting Standard (“SFAS”) No. 123(Revised 2004), *Share-Based Payment*, or SFAS No. 123(R), on January 1, 2006. Pursuant to SFAS No. 123(R), we will reverse the balance of deferred stock compensation in stockholder’s equity as of December 31, 2005 in the first quarter of 2006 and incorporate the remaining stock compensation expense into our total SFAS No. 123(R) stock compensation expense going forward.

*Interest and Other Income (Expense), net.* Interest income consists of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest incurred on capital leases and notes payable. Other income and (expense) has historically consisted of the proceeds from the sale of excess raw materials and the gain or loss on the disposal of equipment.

*Dividends and Accretion to Redemption Value of Redeemable Preferred Stock.* Until the completion of our initial public offering, or IPO, in June 2004, when all then-outstanding preferred stock and related dividends were converted into common stock, we accrued for an 8% cumulative annual dividend payable on our Series C Redeemable Convertible Preferred Stock, or Series C, and on our Series D Redeemable Convertible Preferred Stock, or Series D. In addition, since our redeemable preferred stock had been discounted to reflect the value of attached warrants, we accreted, or increased, the book value of our redeemable preferred stock to equal its redemption value by the earliest redemption date. This accretion had the impact of reducing stockholders' equity and increasing the net loss per share attributable to common stockholders.

*Lease Accounting.* In December 2003, we entered into a lease for a new facility we occupied in May 2005. Pursuant to the lease agreement, a portion of the leasehold improvements we made to the facility were paid for by the lessor and included in our rent payment. Leasehold improvements paid by the lessor pursuant to the lease agreement are being amortized over the life of the lease as a discount to rent expense and are being recorded as amortization expense to the related leasehold improvements. The balances of these lessor-paid leasehold improvements and rent discounts are classified in the balance sheet as leasehold improvements and other liabilities.

### **Critical Accounting Policies and Estimates**

This discussion and analysis of our current financial condition and historical results of operations is based on our audited financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. We base our estimates on historical experience and various other assumptions that we believe are reasonable under the circumstances at the time, the results of which form the basis for making judgments about the carrying values of certain assets and liabilities. Actual future results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies are important in understanding our financial statements and operating results:

*Use of Estimates.* The preparation of our financial statements in conformance with generally accepted accounting principles in the United States requires us to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. We base our estimates on historical experience and various other assumptions that we believe are reasonable under the circumstances at the time, the results of which form the basis for making judgments about the carrying values of certain assets and liabilities. Actual future results may differ from these estimates under different assumptions or conditions.

*Revenue Recognition.* We recognize revenue under licensing and other collaborative research and development agreements as we perform services or meet contractual obligations. Accordingly, up-front, non-refundable license fees under agreements in which we have an ongoing research and development commitment are amortized, on a straight-line basis, over the term of our ongoing obligations under the agreement. Revenues received for ongoing research and development activities under collaborative arrangements are recognized as the research and development activities are performed pursuant to the terms of the related agreements. In the event we receive milestone payments in the future, we will recognize such payments when all of the terms of such milestone are achieved. Our revenue recognition policies are in compliance with the Securities and Exchange Commission's, or SEC's, Staff Accounting

Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, SAB No. 104, *Revenue Recognition*.

*Accrued Expenses.* The preparation of our financial statements requires us to estimate expenses that we believe we have incurred, but for which we have not yet received invoices from our vendors. This process involves identifying services and activities that have been performed by third-party vendors on our behalf and estimating the level to which they have been performed and the associated cost incurred for such service as of each balance sheet date. Examples of significant expenses for which we accrue based on estimates include fees for services, such as those provided by certain clinical research and data management organizations and investigators in conjunction with clinical trials and fees owed to contract manufacturers in conjunction with the manufacture of materials for our clinical trials. In order to estimate costs incurred to date, but not yet invoiced, we analyze the progress and related activities, invoices received and budgeted costs when evaluating the adequacy of the accrued liability for these related costs. We make these estimates based upon the facts and circumstances known to us at the time and in accordance with generally accepted accounting principles. We believe that historically, our accruals have been reasonably accurate.

*Stock-Based Compensation.* We have elected to follow Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value accounting method provided for under SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, we have not recorded stock-based compensation expense related to stock options issued to employees if the exercise prices of the options are equal to or greater than the fair value of the underlying common stock on the date of grant. In the notes to our financial statements we provide pro forma disclosures in accordance with SFAS No. 123 and related pronouncements.

Prior to our initial public offering in June 2004, the determination of the fair value of our common stock for purposes of stock option grants involved significant judgment on our part because our shares were not publicly traded. In determining the fair value of our common stock from time to time, our board of directors considered the price at which we sold shares of convertible preferred stock to investors, comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we have issued, prior valuations of our common stock and the impact of events or milestones that had occurred since. As a publicly-held company, the determination of the fair market value of our common stock is based upon its trading price.

On January 1, 2006 we will adopt SFAS No. 123(R). Accordingly, beginning in the first quarter of 2006, we will begin to recognize stock-based compensation pursuant to that pronouncement.

### **Recent Accounting Pronouncements**

On December 16, 2004, the FASB issued 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 fair values. Pro forma disclosure is no longer an alternative. We must adopt SFAS No. 123(R) no later than the beginning of its first fiscal year beginning after June 15, 2005, and will adopt SFAS No. 123(R) on January 1, 2006.

Currently, we use the Black-Scholes formula to estimate the value of stock options granted to employees and expect to continue to use this valuation model when we implement the adoption of SFAS No. 123(R) on January 1, 2006. SFAS No. 123(R) must be applied not only to new awards but to previously granted awards that are not fully vested on the effective date, and because we adopted SFAS No. 123 using the prospective transition method (which applied only to awards granted, modified or settled after the adoption date), compensation cost for some previously granted stock options that were not recognized under SFAS No. 123 will be recognized under SFAS No. 123(R) beginning in 2006. However, had we adopted

SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net loss and loss per share set forth in Note 2 of our financial statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce reported net operating cash flows and increase reported net financing cash flows in the periods after adoption. The future impact of the adoption of SFAS No. 123(R) cannot be reasonably predicted at this time as the impact depends on the level of share-based payments granted in the future. However, we expect that the adoption will have a material impact on our results of operations.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* ("SFAS No. 154"). SFAS No. 154 requires retrospective application of a voluntary change in accounting principle to prior period financial statements unless it is impracticable. SFAS No. 154 also requires that a change in method of depreciation, amortization, or depletion for long-lived, non-financial assets be accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS No. 154 replaces APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. SFAS No. 154 is effective for fiscal years beginning after December 15, 2005. We do not expect the adoption of the provisions of SFAS No. 154 to have a material impact on our results of operations or financial condition.

## **Results of Operations**

### ***Fiscal Years Ended December 31, 2005 and 2004***

**Revenue.** Revenue increased to \$936,000 in 2005 from \$650,000 in 2004. This increase of \$286,000 or 44%, resulted from a \$286,000 increase in proceeds from research activities we performed in 2005 pursuant to a materials transfer agreement that did not exist in 2004. Ongoing revenue consists of quarterly collaborative research and development support fees and license fees from Wyeth. The collaborative research and development support fees and license fees from Wyeth are based on the number of our employees that collaborate on the program.

**Research and Development Expense.** Research and development expense increased to \$34.2 million in 2005 from \$22.6 million in 2004. This increase of \$11.6 million, or 51%, resulted from a \$7.2 million increase in clinical trial expenses, a \$2.1 million increase in expenses related to the manufacturing of clinical trial material, a \$1.4 million increase in salaries and personnel-related expenses, a \$1.0 million increase in depreciation and facility-related expenses, offset by a \$0.1 million decrease in license fees, legal, and other expenses. Clinical trial expenses associated with the Veronate Phase III clinical trial increased by \$7.9 million due to approximately 700 additional patients being enrolled in the trial during 2005 as compared to 2004. This increase was offset by a decrease of \$0.7 million in clinical trial expenses for the Aurexis program primarily related to completion of a 60 patient Phase II trial for treatment of *S. aureus* bloodstream infections in May 2005. Manufacturing expenses increased by \$1.8 million largely due to the manufacture of a large scale run of clinical trial material for the Aurexis program during the second and third quarters of 2005, and \$0.3 million for additional raw materials purchased for the manufacturing of clinical trial material for the Veronate program. Salaries and personnel-related expenses increased due to the hiring of additional personnel needed to support our clinical trials, perform research, and increased salaries for existing employees. Depreciation and facility-related expenses increased due to higher rent and operating expenses related to our new facility.

The following table summarizes the components of our research and development expense for 2005 and 2004.

	December 31,	
	2004	2005
	(In thousands)	
Clinical and manufacturing related expenses .....	\$11,972	\$21,287
Salaries and personnel-related expenses .....	5,308	6,687
License fees, legal and other expenses .....	3,819	3,743
Depreciation and facility related expenses .....	1,482	2,511
Total research and development expense .....	<u>\$22,581</u>	<u>\$34,228</u>

*General and Administrative Expense.* General and administrative expense increased to \$7.1 million in 2005 from \$4.0 million in 2004. The increase of \$3.1 million, or 77%, was primarily due to additional direct expenses of \$1.3 million incurred in 2005 as a result of the Company becoming publicly-traded in June 2004, an increase of \$0.9 million in salaries and personnel-related expenses, a \$0.5 million increase in marketing research, an increase of \$0.3 million in depreciation and facility-related expenses, and a \$0.1 million increase in travel and supplies. The additional expenses of becoming a publicly-traded company included a significant increase in directors' and officers' insurance premiums, expenditures related to recruiting expenses and compensating members of our Board of Directors, consulting fees associated with implementing the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, higher audit and legal fees, and consulting and professional fees related to investor and public relations. Salaries and personnel-related expenses increased due to the hiring of additional personnel to support our public company infrastructure, planned commercialization of Veronate, and higher salaries. Market research expenses increased due to expenditures related to the planning and commercialization of Veronate. Depreciation and facility-related expenses increased due to higher rent and operating expenses related to our new facility.

*Amortization of Deferred Stock Compensation.* Amortization of deferred stock compensation was \$0.5 million in 2005 and 2004. This expense was primarily the result of amortization associated with deferred stock compensation recorded from January 2004 through May 2004. Of the amortization expense for 2005, \$264,000 related to employees in general and administrative positions while \$233,000 related to employees engaged in research and development activities. Of the amortization expense for 2004, \$259,000 related to employees in general and administrative positions while \$214,000 related to employees engaged in research and development activities.

*Interest and Other Income, net.* Interest and other income, net, increased to \$2.4 million for 2005 from \$0.5 million in 2004. The increase of \$1.9 million was principally the result of a \$2.0 million increase in interest income due to significantly higher average cash balances and higher interest rates in 2005, offset in part by a loss on disposal of assets in the third quarter of 2005 and a gain on the sale of plasma that occurred in 2004.

*Dividends and Accretion to Redemption Value of Redeemable Preferred Stock.* Dividends on preferred stock and accretion to redemption value of redeemable preferred stock decreased to zero in 2005 from \$2.8 million in 2004. As of June 9, 2004, the closing date of our initial public offering, all the related redeemable preferred stock was converted to common stock, and therefore, we did not record any dividends or accretion to redemption value after that date.

#### ***Fiscal Years Ended December 31, 2004 and 2003***

*Revenue.* Revenue decreased to \$650,000 in 2004 from \$1,096,000 in 2003. This decrease of \$446,000, or 41%, resulted from a \$146,000 reduction in collaborative research and development support fees from Wyeth and the receipt of a FDA grant of \$300,000 in 2003. The collaborative research and development support fees we receive from Wyeth are based on the number of our employees that support the related program, which during the second half of 2003, were reduced to the minimum annual level.

*Research and Development Expense.* Research and development expense increased to \$22.6 million in 2004 from \$19.0 million in 2003. This increase of \$3.6 million, or 19%, resulted from increases in clinical trials and manufacturing-related costs, personnel-related salaries and expenses, and license fees and other expenses associated with intellectual patents of \$2.5 million, \$0.7 million, and \$0.4 million, respectively. Clinical trial costs increased due to the payments associated with the completion of enrollment in the Aurexis Phase II trial, and the ongoing enrollment in the Veronate Phase III trial. In addition, manufacturing-related costs increased primarily due to \$0.4 million of additional purchases of the raw material and manufacturing expenses related to Veronate, and \$0.4 million of process development and manufacturing expenses related to Aurexis. Personnel-related salaries and expenses increased due to the hiring of additional personnel required to support our two ongoing clinical trials, and increased salaries and relocation expenses. License fees and other expenses increased partly due to legal fees associated with maintaining and obtaining intellectual property and patents, and prosecution and maintenance of patents that had been historically been paid by a third-party partner for which, as of June 2004, we are responsible for on an ongoing basis. License fees also increased due to our in-licensing of additional patent rights related to one of our MSCRAMM targets.

The following table summarizes the components of our research and development expense for 2004 and 2003.

	December 31,	
	2003	2004
	(In thousands)	
Clinical and manufacturing related expenses .....	\$ 9,846	\$11,972
Salaries and personnel-related expenses .....	4,583	5,308
License fees, legal and other expenses .....	3,070	3,819
Depreciation and facility related expenses .....	<u>1,492</u>	<u>1,482</u>
Total research and development expense .....	<u>\$18,991</u>	<u>\$22,581</u>

*General and Administrative Expense.* General and administrative expense decreased to \$4.0 million in 2004 from \$4.6 million in 2003. This decrease of \$0.6 million, or 13%, resulted primarily from a decrease in litigation-related legal fees of approximately \$1.1 million, which was offset, in part, by an increase in personnel-related salaries and expenses of approximately \$0.2 million associated with an increase in headcount, an increase in directors' and officers' insurance premiums, directors' fees, and an increase in franchise taxes and general office expenses related to our initial public offering. Our directors' and officers' insurance premiums increased significantly due to our IPO in June 2004. Directors' fees increased largely due to our adoption of retainers for all non-officer directors subsequent to our IPO in June 2004.

*Amortization of Deferred Stock Compensation.* Amortization of deferred stock compensation increased to \$0.5 million in 2004 from \$0.2 million in 2003. This increase of \$297,000, or 169%, was primarily the result of amortization related to \$938,000 of deferred stock compensation recorded in 2004, and the full effect in 2004 of amortization related to \$981,000 of deferred stock compensation that we recorded pursuant to stock options granted during 2003. Of the amortization expense for 2004, \$259,000 related to employees in general and administrative positions while \$214,000 related to employees engaged in research and development activities. Of the amortization expense for 2003, \$96,000 related to employees in general and administrative positions while \$80,000 related to employees engaged in research and development activities.

*Interest and Other Income, net.* Interest and other income (expense), net, increased to \$0.5 million in 2004 from \$0.3 million in 2003. This increase of \$213,000, or 67%, was primarily due to an increase in interest income of \$417,000, which was the result of generally higher average cash balances and to a lesser extent, higher interest rates, in 2004 as compared to 2003. This increase in interest and other income was offset in part by an increase in interest expense and a decrease of other income related to the sale of excess plasma in 2003.

*Dividends and Accretion to Redemption Value of Redeemable Preferred Stock.* Dividends on preferred stock and accretion to redemption value of redeemable preferred stock decreased to \$2.8 million in 2004 from \$6.2 million in 2003. This decrease of \$3.4 million, or 55%, resulted from dividends and the accretion to redemption value being recorded in 2004 only through June 9, 2004, the closing date of our IPO, when all of the related redeemable preferred stock was converted to common stock. Dividends and accretion to redemption value were recorded for all of 2003, during which the related redeemable preferred stock was outstanding.

## Liquidity and Capital Resources

### Sources of Liquidity

Since our inception in May 1994 through December 31, 2005, we have funded our operations primarily with \$214.4 million in gross proceeds raised from a series of five private equity financings, our IPO in June 2004, and two PIPE financings, or private placement of public equity financings, in November 2004 and August 2005 as follows:

<u>Gross Stock Offerings</u>	<u>Year</u>	<u>Amount</u>
Series A .....	1995	\$ 540,000
Series B		
Round I .....	1997/1998	1,500,012
Round II .....	1998	1,500,000
Series C .....	2000	15,892,284
Series D .....	2002	44,997,928
Series E .....	2003	20,045,696
Initial Public Offering .....	2004	38,689,000
PIPE .....	2004	50,000,047
PIPE .....	2005	41,250,000
Total gross proceeds .....		<u>\$214,414,967</u>

From inception through December 31, 2005, we have also borrowed a total of \$12.2 million under various notes payable, a credit facility with a commercial bank, capital leases, and have received approximately \$6.6 million in license fees, collaborative research payments and grants, of which \$1.0 million and \$0.9 million were recorded as deferred revenue as of December 31, 2004 and December 31, 2005, respectively.

At December 31, 2005, cash, cash equivalents and short-term investments were \$87.1 million and we held no investments with a maturity greater than 12 months. The cumulative unrealized loss on short-term investments based on market values as of December 31, 2005 was \$79,971. Our cash, cash equivalents and short-term investments are generally held in a variety of interest-bearing instruments, consisting of United States government agency securities, high-grade corporate bonds, municipal bonds, asset-backed securities, commercial paper, certificates of deposit, and money market accounts that have a maturity date of less than 12 months.

In April 2006 we expect to have top-line data available from our pivotal Phase III Veronate trial. In the event the primary endpoint of this trial is not met or achieved, or the data is otherwise unfavorable or negative, we may not be able to access additional funding under acceptable terms in the future, if at all.

### Cash Flows

For the year ended December 31, 2005, cash, cash equivalents, and short-term investments decreased by \$0.1 million, from \$87.2 million to \$87.1 million. This slight decrease resulted primarily from cash used for operating activities, capital expenditures, and the repayment of capital lease obligations and notes payable,

offset by net proceeds we received in connection with our PIPE financing in August 2005, and a promissory note related to leasehold improvements at our new facility.

Net cash used in operating activities was \$35.0 million in 2005, primarily reflecting a net loss of \$38.6 million, which was partially offset by non-cash charges of \$2.3 million and a net increase in operating liabilities over operating assets of \$1.3 million. Our net loss was largely the result of funding our ongoing clinical trials associated with Veronate and Aurexis, research and development activities, general and administrative expenses, and expenses associated with the planning for the commercialization of Veronate. The net increase in operating liabilities over operating assets reflected an increase in accounts payable and accrued liabilities of \$2.0 million, which was the result of an increase in both accounts payable and accrued expenses associated largely with clinical trial expenses and manufacturing-related expenses, and an increase in accrued expenses associated with clinical trial expenses, manufacturing-related expenses, and personnel-related expenses. This increase in operating liabilities was partially offset by a net increase in prepaid expenses, receivables, and deferred revenue of \$0.7 million associated with higher prepaid insurance premiums, revenue earned, and interest receivable on our short-term investments.

We used approximately \$42.6 million of cash for investing activities during 2005, which consisted of net purchases of short-term investments of \$38.1 million and \$4.5 million for purchases of leasehold improvements, laboratory and computer equipment, furniture and fixtures, and software.

We received net cash of \$39.9 million from financing activities during 2005, which consisted of \$38.8 million in net proceeds from our PIPE financing in August, \$2.5 million borrowed under a loan agreement with a local development authority, and \$0.3 million through the exercise of exercise of stock options and warrants, offset in part by \$1.7 million of payments on our capital leases and promissory notes.

#### ***Funding Requirements***

Our future funding requirements are difficult to determine and will depend on a number of factors, including:

- the nature of the data from our pivotal Phase III trial for Veronate;
- the length of time the FDA may take to review any of our BLA submissions;
- the timing and the extent of direct expenses related to our planned commercialization of Veronate;
- the timing and costs involved in conducting other clinical trials;
- obtaining regulatory approvals for our product candidates, including Veronate, if ever;
- the number of new product candidates we may advance into clinical development;
- future payments received or made under existing or future license or collaboration agreements;
- our ability and the time and cost it takes for us to develop our products, if ever;
- a corporate infrastructure to support the commercialization of our products;
- the cost of filing, prosecuting and enforcing patent and other intellectual property claims, and
- the need to acquire additional licenses to or acquire new products or compounds.

We may also need additional funds for possible future strategic acquisitions of businesses, and products or technologies complementary to our business.

Based upon our current business and operating plans, we believe that our existing cash, cash equivalents and short-term investments of \$87.1 million as of December 31, 2005 will enable us to operate for a period of at least 12 months from the date of this filing. This estimate assumes that the primary endpoint of our pivotal Phase III clinical trial for Veronate is achieved, we complete the BLA submission for Veronate, and we proceed to commercialize Veronate. In the event that the primary endpoint of the pivotal Phase III Veronate clinical trial is not met, we may delay, curtail, or terminate the development or



improvements paid by the lessor, will approximate \$1.0 to \$1.1 million per annum for the lease term of ten years.

**ITEM 7A. *Quantitative and Qualitative Disclosures about Market Risk***

Our primary exposure to market risk relates to changes in interest rates on our cash, cash equivalents, and short-term investments. The objective of our investment activities is to preserve principal. To achieve this objective, we invest in highly liquid and high-quality investment grade debt instruments of financial institutions, corporations and United States government agency securities with a weighted average maturity of no longer than 12 months. Due to the relatively short-term nature of these investments, we believe that we are not subject to any material market risk exposure, and as a result, the estimated fair value of our cash, cash equivalents and short-term investments approximates their principal amounts. If market interest rates were to increase immediately and uniformly by 10% from levels at December 31, 2005, we estimate that the fair value of our investment portfolio would decline by an immaterial amount, and have no plans to sell investments prior to their maturity. We do not have any foreign currency or other derivative financial instruments and we do not have significant interest rate risk associated with our debt obligations. We have the ability to hold our fixed income investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

**Effects of Inflation**

The majority of our assets are monetary, consisting of cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not generally directly affected by inflation. We also believe that we have significant intangible assets in the value of our technology and product candidates. In accordance with generally accepted accounting principles, we have not recorded the value of any intellectual property or intangible assets that we have developed on our balance sheet. Due to the nature of these intangible assets, we do not believe they are 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.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

**The Board of Directors and Stockholders  
Inhibitex, Inc.**

We have audited the accompanying balance sheets of Inhibitex, Inc. (a Development Stage Company) as of December 31, 2004 and 2005, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2005, and for the period from inception (May 13, 1994) through 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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 financial position of Inhibitex, Inc. (a Development Stage Company) at December 31, 2004 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, and for the period from inception (May 13, 1994) through December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Inhibitex, Inc. (a Development Stage Company)'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2006 expressed an unqualified opinion thereon.

*Ernst & Young LLP*

Atlanta, Georgia  
March 10, 2006

**INHIBITEX, INC.**  
**(A Development Stage Company)**

**Balance Sheets**

	December 31,	
	2004	2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 71,580,823	\$ 33,842,937
Short-term investments .....	15,623,887	53,288,016
Prepaid expenses and other current assets .....	1,082,359	1,917,436
Accounts receivable .....	322,019	44,923
Total current assets .....	88,609,088	89,093,312
Property and equipment, net .....	2,629,987	8,175,074
Total assets .....	\$ 91,239,075	\$ 97,268,386
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 3,077,636	\$ 1,879,191
Accrued expenses .....	3,587,093	5,316,906
Current portion of notes payable .....	877,239	1,319,445
Current portion of capital lease obligations .....	315,043	869,043
Current portion of deferred revenue .....	191,667	191,667
Other current liabilities .....	1,000,000	1,152,702
Total current liabilities .....	9,048,678	10,728,954
Long-term liabilities:		
Notes payable, net of current portion .....	486,112	1,458,333
Capital lease obligations, net of current portion .....	321,190	1,646,323
Deferred revenue, net of current portion .....	837,498	687,500
Other liabilities, net of current portion .....	—	1,294,210
Total long-term liabilities .....	1,644,800	5,086,366
Total liabilities .....	10,693,478	15,815,320
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2005 and 2004, none issued and outstanding at December 31, 2005 and 2004 .....	—	—
Common stock, \$.001 par value; 75,000,000 shares authorized at December 31, 2005 and 2004; 30,219,715 and 25,133,327 shares issued and outstanding at December 31, 2005 and 2004, respectively	25,133	30,220
Additional paid-in capital .....	173,188,745	212,210,931
Warrants .....	11,555,968	11,514,793
Deferred stock compensation .....	(1,269,099)	(772,347)
Deficit accumulated during the development stage .....	(102,955,150)	(141,530,531)
Total stockholders' equity .....	80,545,597	81,453,066
Total liabilities, redeemable convertible preferred stock and warrants and stockholders' equity .....	\$ 91,239,075	\$ 97,268,386

**INHIBITEX, INC.**  
**(A Development Stage Company)**

**Statements of Operations**

	Period from Inception (May 13, 1994) Through December 31, 2005	Year Ended December 31,		
		2003	2004	2005
Revenue:				
License fees and milestones .....	\$ 1,162,500	\$ 150,000	\$ 150,000	\$ 150,000
Collaborative research and development .....	2,999,455	645,833	500,000	500,000
Grants and other revenue .....	586,474	300,000	—	286,474
Total revenue .....	4,748,429	1,095,833	650,000	936,474
Operating expense:				
Research and development .....	109,267,851	18,990,954	22,580,709	34,228,687
General and administrative .....	23,447,112	4,580,957	4,040,266	7,144,534
Amortization of deferred stock compensation .....	1,146,276	176,235	473,289	496,752
Total operating expense .....	133,861,239	23,748,146	27,094,264	41,869,973
Loss from operations .....	(129,112,810)	(22,652,313)	(26,444,264)	(40,933,499)
Other income (expense), net .....	657,665	271,306	103,684	(45,377)
Interest income, net .....	3,306,677	47,986	429,085	2,403,495
Net loss .....	(125,148,468)	(22,333,021)	(25,911,495)	(38,575,381)
Dividends and accretion to redemption value of redeemable preferred stock ..	(16,382,063)	(6,201,116)	(2,823,160)	—
Net loss attributable to common stockholders .....	<u>\$ (141,530,531)</u>	<u>\$ (28,534,137)</u>	<u>\$ (28,734,655)</u>	<u>\$ (38,575,381)</u>
Basic and diluted net loss attributable to common stockholders per share .....		<u>\$ (54.19)</u>	<u>\$ (2.52)</u>	<u>\$ (1.43)</u>
Weighted average shares used to compute basic and diluted net loss attributable to common stockholders per share .....		<u>526,578</u>	<u>11,416,354</u>	<u>26,987,047</u>

**INHIBITEX, INC.**  
(A Development Stage Company)

**Statement of Stockholders' (Deficit) Equity**

	Series A Preferred Stock		Common Stock Subscription		Common Stock		Additional Paid-In Capital	Receivable For Purchase of Stock	Common Stock Warrants	Deferred Stock Compensation	Accumulated During Development Stage	Deficit Total Stockholders' (Deficit) Equity
	Shares	Par Value	Shares	Par Value	Shares	Par Value						
Balance at inception (May 13, 1994)	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	—	\$ —	—
Issuance of subscriptions for common stock to founders at \$0.05 per share	—	—	44,258	44	—	—	483	—	—	—	—	527
Issuance of common stock at \$1.00 per share	—	—	—	—	42,017	42	99,958	—	—	—	—	100,000
Net loss	—	—	—	—	—	—	—	—	—	—	(54,088)	(54,088)
Balance at December 31, 1994	—	—	44,258	44	42,017	42	100,441	—	—	—	(54,088)	46,439
Net loss	—	—	—	—	—	—	—	—	—	—	(266,491)	(266,491)
Balance at December 31, 1995	—	—	44,258	44	42,017	42	100,441	—	—	—	(320,579)	(220,052)
Issuance of Series A Preferred Stock at \$2.50 per share, net of related costs of \$18,641	216,000	216	—	—	—	—	521,143	—	—	—	—	521,359
Issuance of subscribed common stock at \$0.05 per share	—	—	(44,258)	(44)	44,258	44	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(248,510)	(248,510)
Balance at December 31, 1996	216,000	216	—	—	86,275	86	621,584	—	—	—	(569,089)	52,797
Issuance of common stock at \$.05 per share, net of receivable from shareholder	—	—	—	—	129,960	130	15,335	(3,867)	—	—	—	11,598
Net loss	—	—	—	—	—	—	—	(3,867)	—	—	(508,304)	(508,304)
Balance at December 31, 1997	216,000	216	—	—	216,235	216	636,919	(3,867)	—	—	(1,077,393)	(443,909)
Issuance of common stock at \$.05 and \$.075 per share, net of receivable from shareholder	—	—	—	—	191,358	191	26,599	(24,828)	—	—	—	1,962
Net loss	—	—	—	—	—	—	—	—	—	—	(1,725,290)	(1,725,290)
Balance at December 31, 1998	216,000	216	—	—	407,593	407	663,518	(28,695)	—	—	(2,802,683)	(2,167,237)
Issuance of common stock at \$.10 per share	—	—	—	—	1,787	2	423	—	—	—	—	425
Net loss	—	—	—	—	—	—	—	—	—	—	(3,343,509)	(3,343,509)
Balance at December 31, 1999	216,000	216	—	—	409,380	409	663,941	(28,695)	—	—	(6,146,192)	(5,510,321)
Forgiveness of receivable from shareholders	—	—	—	—	—	—	—	28,695	—	—	—	28,695
Issuance of warrant for the purchase of common stock at \$.06 per share	—	—	—	—	—	—	75	—	—	—	—	75
Exercise of stock Options	—	—	—	—	8,199	8	2,240	—	—	—	—	2,248
Cumulative effect of change in accounting principle	—	—	—	—	—	—	99,500	—	—	—	—	99,500
Preferred stock Dividends	—	—	—	—	—	—	—	—	—	—	(460,600)	(460,600)
Net loss	—	—	—	—	—	—	—	—	—	—	(6,463,315)	(6,463,315)
Balance at December 31, 2000	216,000	216	—	—	417,579	417	765,756	—	—	—	(13,070,107)	(12,303,718)
Issuance of warrant for the purchase of common stock at \$.23 per share	—	—	—	—	—	—	3,450	—	—	—	—	3,450
Exercise of stock Options	—	—	—	—	48,181	48	12,426	—	—	—	—	12,474
Preferred stock Dividends	—	—	—	—	—	—	—	—	—	—	(1,271,383)	(1,271,383)
Net loss	—	—	—	—	—	—	—	—	—	—	(8,106,341)	(8,106,341)

**INHIBITEX, INC.**  
**(A Development Stage Company)**

**Statement of Stockholders' (Deficit) Equity**

	Series A Preferred Stock		Common Stock Subscription		Common Stock		Additional Paid-In Capital	Receivable For Purchase of Stock	Common Stock Warrants	Deferred Stock Compensation	Accumulated During Development Stage	Deficit Total Stockholders' (Deficit) Equity
	Shares	Par Value	Shares	Par Value	Shares	Par Value						
Balance at December 31, 2001	216,000	216	—	—	465,760	465	781,632	—	—	—	(22,447,831)	(21,665,518)
Exercise of stock Options	—	—	—	—	47,438	48	18,258	—	—	—	—	18,306
Preferred stock Dividends	—	—	—	—	—	—	—	—	—	—	(4,461,328)	(4,461,328)
Accretion of Series D Preferred Stock to redemption value	—	—	—	—	—	—	—	—	—	—	(1,164,476)	(1,164,476)
Net loss	—	—	—	—	—	—	—	—	—	—	(17,612,723)	(17,612,723)
Balance at December 31, 2002	216,000	216	—	—	513,198	513	799,890	—	—	—	(45,686,358)	(44,885,739)
Exercise of stock Options	—	—	—	—	22,868	23	17,363	—	—	—	—	17,386
Preferred stock Dividends	—	—	—	—	—	—	—	—	—	—	(4,871,217)	(4,871,217)
Accretion of Series D and E Preferred Stock to redemption value	—	—	—	—	—	—	—	—	—	—	(1,329,899)	(1,329,899)
Deferred stock Compensation	—	—	—	—	—	—	980,545	—	(980,545)	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	—	—	—	176,235	—	—	176,235
Net loss	—	—	—	—	—	—	—	—	—	(804,310)	(22,333,021)	(22,333,021)
Balance at December 31, 2003	216,000	216	—	—	536,066	536	1,797,798	—	—	(804,310)	(74,220,495)	(73,226,255)
Exercise of stock options	—	—	—	—	309,965	310	255,657	—	—	—	—	255,967
Preferred stock dividends and accretion to redemption value	—	—	—	—	—	—	—	—	—	—	(2,823,160)	(2,823,160)
Deferred stock compensation	—	—	—	—	—	—	938,078	—	(938,078)	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	—	—	—	473,289	—	—	473,289
Conversion of preferred stock to common including dividends	(216,000)	(216)	—	—	11,936,438	11,936	93,871,724	—	—	—	—	93,883,444
Initial Public Offering of common stock	—	—	—	—	5,527,000	5,527	33,951,407	—	—	—	—	33,956,934
Exercise of warrants	—	—	—	—	46,488	47	207,593	—	(47,927)	—	—	159,713
Common Stock Warrants	—	—	—	—	—	—	—	—	6,113,749	—	—	6,113,749
PIPE Financing	—	—	—	—	6,777,370	6,777	42,166,488	—	5,490,146	—	—	47,663,411
Net loss	—	—	—	—	—	—	—	—	—	—	(25,911,495)	(25,911,495)
Balance at December 31, 2004	—	—	—	—	25,133,327	\$25,133	\$173,188,745	—	11,555,968	(1,269,099)	(102,955,150)	80,545,597
Exercise of stock options and issuances of employee stock purchase plan	—	—	—	—	47,943	49	30,652	—	—	—	—	30,701
Deferred stock compensation	—	—	—	—	—	—	—	—	—	—	—	—
Amortization of deferred stock compensation	—	—	—	—	—	—	—	—	496,752	—	—	496,752
PIPE Financing	—	—	—	—	5,000,000	5,000	38,813,187	—	—	—	—	38,777,012
Exercise of warrants	—	—	—	—	38,445	38	178,347	—	(41,175)	—	—	178,385
Net loss	—	—	—	—	—	—	—	—	—	—	(38,575,381)	(38,575,381)
Balance at December 31, 2005	—	\$ —	—	\$ —	30,219,715	\$30,220	\$212,210,931	\$ —	\$11,514,793	\$ (772,347)	\$ (141,530,531)	\$ 81,453,066

**INHIBITEX, INC.**  
**(A Development Stage Company)**

**Statements of Cash Flows**

	Period from Inception (May 13, 1994) Through December 31, 2005	Year Ended December 31,		
		2003	2004	2005
Cash flows from operating activities				
Net loss	\$(125,148,468)	\$(22,333,021)	\$(25,911,495)	\$ (38,575,381)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	4,903,059	768,245	820,298	1,438,005
Amortization of deferred stock compensation	1,146,276	176,235	473,289	496,752
Loss on disposal of fixed assets	99,991	—	—	51,857
Amortization of investment premium	564,745	45,249	155,412	364,084
Forgiveness of receivables from stockholders	28,695	—	—	—
Amortization of warrants and discount on debt	176,477	—	53,685	—
Stock issued for interest	126,886	—	2,310	—
Cumulative effect of change in accounting principle	99,500	—	—	—
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	(1,917,436)	(128,304)	(512,692)	(835,077)
Accounts receivable	(44,923)	(273,110)	(13,095)	277,096
Accounts payable and other liabilities	4,326,103	667,374	1,691,664	248,467
Accrued expenses	5,316,906	(320,265)	1,886,554	1,729,813
Deferred revenue	879,167	(170,831)	(150,000)	(149,998)
Net cash used in operating activities	(109,443,023)	(21,568,428)	(21,504,070)	(34,954,383)
Cash flows from investing activities				
Purchases of property and equipment	(8,730,178)	(176,208)	(1,573,977)	(4,544,842)
Purchases of short-term investments	(151,708,330)	(15,551,099)	(30,892,823)	(104,264,098)
Proceeds from maturities of short-term investments	97,775,598	15,007,180	16,600,000	66,170,000
Net cash used in investing activities	(62,662,910)	(720,127)	(15,866,800)	(42,638,940)
Cash flows from financing activities				
Proceeds from promissory notes and related warrants	5,513,492	2,500,000	—	2,500,000
Payments on promissory notes and capital leases	(4,668,294)	(710,292)	(1,256,315)	(1,696,547)
Proceeds from bridge loan and related warrants	2,220,000	—	—	—
Net proceeds from the issuance of preferred stock and warrants	81,788,868	18,472,533	1,682,546	—
Proceeds from the issuance of common stock	121,094,803	17,386	81,876,312	39,051,983
Net cash provided by financing activities	205,948,869	20,279,627	82,302,543	39,855,436
Increase (decrease) in cash and cash equivalents	33,842,937	(2,008,928)	44,931,673	(37,737,886)
Cash and cash equivalents at beginning of period	—	28,658,078	26,649,150	71,580,823
Cash and cash equivalents at end of period	<u>\$ 33,842,937</u>	<u>\$ 26,649,150</u>	<u>\$ 71,580,823</u>	<u>\$ 33,842,937</u>
Supplemental cash flow information:				
Interest paid	\$ 984,927	\$ 163,149	\$ 198,164	\$ 203,586
Supplemental non-cash investing and financing activities:				
Fixed assets capitalized using promissory notes and capital leases	4,447,946	420,665	240,764	2,490,107
Conversion of bridge loans and interest payable into preferred stock	2,124,576	—	—	—
Preferred stock dividends and accretion of preferred stock to redemption value	16,382,063	6,201,116	2,823,160	—
Unrealized loss on short-term investments	(79,971)	—	(14,086)	(65,885)

**INHIBITEX, INC.**  
**(A Development Stage Company)**

**1. Operations**

Inhibitex, Inc. (“Inhibitex” or the “Company”) was incorporated in the state of Delaware in May 1994. Inhibitex is a biopharmaceutical company committed to the discovery, development and commercialization of novel antibody-based products for the prevention and treatment of serious bacterial and fungal infections. The Company’s primary activities since incorporation have been establishing its offices, recruiting personnel, conducting research, conducting pre-clinical and clinical trials, performing business and financial planning, and raising capital. Accordingly, the Company is considered to be in the development stage for financial reporting purposes.

The Company has incurred operating losses since inception and expects such losses to continue for the foreseeable future. These losses have largely been the result of research and development expenses related to Veronate, the Company’s lead product candidate, and to a lesser extent, Aurexis, its second product candidate. Veronate, which is currently the subject of a pivotal patient Phase III clinical trial, is being developed to prevent hospital-associated infections in very low birth weight infants. Aurexis is currently being developed to treat, in combination with antibiotics, serious, life-threatening *Staphylococcus aureus* (*S. aureus*) bloodstream infections in hospitalized patients and is also being evaluated in other clinical trials. The Company plans to continue to finance its operations with equity and/or debt financings or proceeds from potential future partnerships. The Company’s ability to continue its operations is dependent, in the near term, upon the successful execution of such financings and ultimately upon achieving profitable operations. There can be no assurance that funds will be available on terms acceptable to the Company or that the Company will become profitable.

**2. Summary of Significant Accounting Policies**

*Use of Estimates.* The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimated.

*Cash, Cash Equivalents and Short-Term Investments.* Cash equivalents consist of short-term, highly liquid investments with original maturities of 90 days or less when purchased. Cash equivalents are carried at cost, which approximates their fair market value. Investments with original maturities beyond 90 days when purchased are considered to be short-term investments. These investments are accounted for in accordance with Statement of Financial Accounting Standard (“SFAS”) No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (“SFAS No. 115”). The Company is required to maintain a cash balance on deposit with a commercial bank equal to two times the loan balance it has with that bank pursuant to a loan and security agreement. The Company has classified its entire investment portfolio as available-for-sale. These securities are recorded as either cash equivalents or short-term investments. Short-term investments are carried at estimated fair value based upon quoted market prices. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest and other income (expense), net. Realized gains and losses are included in interest and other income (expense), net. The cost basis of all securities sold is based on the specific identification method.

Available-for-sale securities as of December 31, 2004 and 2005 consisted of commercial paper, government agency obligations, corporate bonds, and money-market funds.

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*Property and Equipment, Net.* Property and equipment are recorded at cost and depreciated using the straight-line method over the following estimated useful lives of the related assets:

<u>Asset</u>	<u>Estimated Life</u>
Computer software and equipment . . . . .	3 years
Furniture and fixtures . . . . .	7 years
Laboratory equipment . . . . .	5 years
Leasehold improvements . . . . .	Lesser of estimated useful life or life of lease

The Company also includes in property and equipment, net its capitalized costs related to computer software developed for internal use in accordance with Statement of Position 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*. When assets are retired or sold, the assets and accumulated depreciation are removed from the respective accounts and any gain or loss is recognized in interest and other income (expense), net. Expenditures for repairs and maintenance are charged to expense as incurred.

*Revenue Recognition.* To date, the Company has not generated any revenues from the sale of products. Revenues to date relate to fees recovered or paid for licensed technology, collaborative research and development agreements, materials transfer agreements and a grant awarded to the Company by the FDA's Office of Orphan Products Development. The Company follows the revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements* ("SAB No. 101") as amended by SAB No. 104, *Revenue Recognition*. Accordingly, up front, non-refundable license fees under agreements where the Company has an ongoing research and development commitment are amortized, on a straight-line basis, over the term of such commitment. Revenues received for ongoing research and development activities under collaborative arrangements and materials transfer agreements are recognized as these activities are performed pursuant to the terms of the related agreements. Any amounts received in advance of performance are recorded as deferred revenue until earned. Revenue related to grant awards is recognized as related research and development expenses are incurred.

*Accrued Expenses.* As part of the process of preparing its financial statements, management is required to estimate expenses that the Company has incurred but for which it has not been invoiced. This process involves identifying services that have been performed on the Company's behalf and estimating the level of services performed by third parties and the associated cost incurred for such services as of each balance sheet date. Examples of expenses for which the Company accrues based on estimates include fees for services, such as those provided by clinical research and data management organizations, investigators and fees owed to contract manufacturers in conjunction with the manufacture of clinical trial materials. In connection with such service fees, these estimates are most affected by management's understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of the Company's service providers invoice the Company monthly in arrears for services performed. Management makes these estimates based upon the facts and circumstances known to it at the time and in accordance with accounting principles generally accepted in the United States.

*Prepaid Expenses and Other Current Assets.* Prepaid expenses and other current assets consist primarily of license payments, insurance premiums, and payments to clinical research organizations that the Company has made in advance of the services being performed, and interest receivable.

*Stock-based Compensation.* The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and Financial Accounting Standards Board Interpretation ("FIN") No. 44 ("FIN 44"), *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25, and Related Interpretations*, and has adopted the disclosure only provisions of

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SFAS No. 123, *Accounting for Stock-Based Compensation* (“SFAS No. 123”). The Company accounts for equity instruments issued to non-employees in accordance with the provisions of 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*. In December 2002, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure* (“SFAS No. 148”). SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. The Company has adopted the disclosure requirements of SFAS No. 148.

Under APB No. 25, if the exercise price of the Company’s employee and director stock options equals or exceeds the estimated fair value of the underlying stock on the date of grant, no compensation expense is recognized. In the event that stock options are granted with an exercise price below the estimated fair value of the Company’s common stock on the date of such grant, APB No. 25 requires that the difference between the estimated fair value and the exercise price be recorded as deferred compensation and amortized over the related vesting period.

The Company recorded deferred stock compensation of \$938,078 and \$0 for the twelve month periods ended December 31, 2004 and 2005, respectively, which represents the difference between the exercise price per share and the fair value at the respective grant dates for options granted in the respective quarters. Deferred stock compensation is recognized and amortized on a straight-line basis over the vesting period of the related options, which for employees is generally four years. The amortization of deferred stock compensation related to stock options granted to the Company’s employees and directors was \$473,289 and \$496,752 for the twelve months ended December 31, 2004 and 2005, respectively. Upon adoption of SFAS No. 123 (Revised 2004), *Share-Based Payment*, (“SFAS No. 123(R)”), in January 1, 2006, the Company will reverse the balance of deferred stock compensation in stockholders’ equity as of December 31, 2005 and incorporate the remaining stock compensation expense into the total SFAS No. 123(R) stock compensation expense.

The option valuation models used for SFAS No. 123 were developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected volatility. Because the Company’s employee stock options have characteristics significantly different from those of traded options and because changes in the subjective input assumptions can materially affect the fair value estimate, in the Company’s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. As a result, the Company has elected to continue to follow the intrinsic value method of accounting as prescribed by APB No. 25. The information regarding net loss as required by SFAS No. 123 has been determined as if the Company had accounted for its stock-based compensation under the fair value method of that Statement. The following table illustrates the effect on net loss attributable to common stockholders and basic and diluted net loss per share attributable to

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common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock-based compensation:

	December 31,		
	2003	2004	2005
Net loss attributable to common stockholders as reported .....	\$(28,534,137)	\$(28,734,655)	\$(38,575,381)
Add: Amortization of deferred stock compensation included in net loss — as reported .....	176,235	473,289	496,752
Deduct: Stock compensation expense determined under fair value method .....	<u>(412,845)</u>	<u>(1,055,539)</u>	<u>(2,122,739)</u>
Net loss attributable to common stockholders — pro forma .....	<u><u>\$(28,770,747)</u></u>	<u><u>\$(29,316,905)</u></u>	<u><u>\$(40,201,368)</u></u>
Net loss attributable to common stockholders per share (basic and diluted):			
As reported .....	<u><u>\$ (54.19)</u></u>	<u><u>\$ (2.52)</u></u>	<u><u>\$ (1.43)</u></u>
Pro forma .....	<u><u>\$ (54.64)</u></u>	<u><u>\$ (2.57)</u></u>	<u><u>\$ (1.49)</u></u>

The fair value of each stock option was estimated at the date of grant using the minimum value method in 2003 and the Black-Scholes method in 2004 and 2005 with the following assumptions:

	December 31,		
	2003	2004	2005
Weighted average risk-free interest rate .....	3.05%	3.23%	3.76%
Expected life .....	4 years	4 years	4 years
Weighted average fair value of options granted .....	\$ 1.52	\$ 2.08	\$ 3.83
Weighted average volatility .....	N/A	.43	.50

For purposes of pro forma disclosure, the estimated fair value of the options is amortized to expense over the vesting period of the related options.

*Fair Value of Financial Instruments.* The carrying amounts of the Company's financial instruments, which include cash, cash equivalents, short-term investments, accounts payable, accrued expenses, and capital lease and debt obligations, approximate their fair values.

*Concentrations of Credit Risk and Limited Suppliers.* Cash and cash equivalents consist of financial instruments that potentially subject the Company to concentrations of credit risk to the extent recorded on the balance sheets. The Company believes that it has established guidelines for investment of its excess cash that maintains principal and liquidity through its policies on diversification and investment maturity.

The Company relies on certain raw materials and supplies used in its development process that are procured from a small group of suppliers as well as certain single-sourced third-party contract manufacturers that make its product candidates. The failure of these suppliers or a contract manufacturer to deliver on schedule, or at all, could delay or interrupt the development process and adversely affect the Company's operating results.

*Research and Development Expense.* Research and development expense primarily consists of costs incurred in the discovery, development, and manufacturing of the Company's product candidates. These expenses consist primarily of (i) fees paid to third-party service providers to monitor and accumulate data related to the Company's clinical trials, (ii) costs related to obtaining patents and license and research

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agreements, (iii) the costs to procure and manufacture materials used in clinical trials, and (iv) salaries and related expenses for personnel. These costs are charged to expense as incurred.

*Income Taxes.* The Company utilizes the liability method of accounting for income taxes as required by SFAS No. 109, *Accounting for Income Taxes* ("SFAS No. 109"). Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax reporting bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. A full valuation allowance has been recorded to reduce the carrying amounts of net deferred tax assets to an amount the Company expects to realize in the future based upon the available evidence at the time.

*Comprehensive Loss.* The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income* ("SFAS No. 130"). SFAS No. 130 establishes standards for the reporting and display of comprehensive loss and its components for general purpose financial statements. For the periods presented, comprehensive loss did not differ materially from reported net loss.

*Lease Accounting.* The Company has entered into a lease for its new facility where leasehold improvements paid by the lessor pursuant to the lease agreement are being amortized over the life of the lease as a discount to rent expense and as amortization expense to related leasehold improvements. The balances of the lessor paid leasehold improvements and rent discounts are classified in the balance sheet as leasehold improvements and other liabilities, respectively.

*Recent Accounting Pronouncements.* On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, ("SFAS No. 123(R)"). 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 fair values. Pro forma disclosure is no longer an alternative. The Company must adopt SFAS No. 123(R) no later than the beginning of its first fiscal year beginning after June 15, 2005, and expects to adopt SFAS No. 123(R) on January 1, 2006.

Currently, the Company uses the Black-Scholes formula to estimate the value of stock options granted to employees and anticipates continuing to use this method in its implementation for adoption of SFAS No. 123(R) on January 1, 2006. SFAS No. 123(R) must be applied not only to new awards but to previously granted awards that are not fully vested on the effective date, and because the Company adopted SFAS No. 123 using the prospective transition method (which applied only to awards granted, modified or settled after the adoption date), compensation cost for some previously granted stock options that were not recognized under SFAS No. 123 will be recognized under SFAS No. 123(R) beginning in 2006. However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net loss and loss per share set forth above in this note. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce reported net operating cash flows and increase reported net financing cash flows in the periods after adoption. The impact of the adoption of SFAS No. 123(R) cannot be predicted at this time because it depends on the level of share-based payments granted in the future. However, the Company expects that the adoption will have a material impact on its results of operations as evidenced by the pro forma results herein.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* ("SFAS No. 154"). SFAS No. 154 requires retrospective application of a voluntary change in accounting principle to prior period financial statements unless it is impracticable. SFAS No. 154 also requires that a change in method of depreciation, amortization, or depletion for long-lived, non-financial assets be

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accounted for as a change in accounting estimate affected by a change in accounting principle. SFAS No. 154 replaces APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. SFAS No. 154 is effective for fiscal years beginning after December 15, 2005. The Company does not expect the adoption of the provisions of SFAS No. 154 to have a material impact on its results of operations or financial condition.

**3. Net Loss Per Share**

The Company calculates net loss per share in accordance with SFAS No. 128, *Earnings Per Share* ("SFAS No. 128") and SEC SAB No. 98, *Earnings Per Share*, ("SAB No. 98"). Under the provisions of SFAS No. 128 and SAB No. 98, basic net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding for the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares and dilutive common stock equivalents then outstanding. Common stock equivalents consist of common shares issuable upon the exercise of stock options and warrants. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since common stock equivalents are excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is anti-dilutive.

The following table sets forth the computation of historical and pro forma basic and diluted net loss attributable to common stockholders per share:

	Year Ended December 31,		
	2003	2004	2005
<b>Historical</b>			
Numerator:			
Net loss attributable to common stockholders . . .	<u>\$ (28,534,137)</u>	<u>\$ (28,734,655)</u>	<u>\$ (38,575,381)</u>
Denominator:			
Weighted average common shares outstanding . .	<u>526,578</u>	<u>11,416,354</u>	<u>26,987,047</u>
Basic and diluted net loss per share attributable to common stockholders . . . . .	<u>\$ (54.19)</u>	<u>\$ (2.52)</u>	<u>\$ (1.43)</u>

The following table outlines potentially dilutive common stock equivalents outstanding that are not included in the above historical calculations as the effect of their inclusion was anti-dilutive.

	December 31,		
	2003	2004	2005
Redeemable convertible preferred stock and related dividends . . . . .	11,595,232	—	—
Common stock options . . . . .	1,338,452	1,283,106	2,304,242
Warrants . . . . .	1,838,118	3,838,588	3,800,143
Convertible preferred stock . . . . .	<u>90,758</u>	<u>—</u>	<u>—</u>
Total . . . . .	<u>14,862,560</u>	<u>5,121,694</u>	<u>6,104,385</u>

**4. Short-Term Investments**

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days from the date of acquisition. The Company has invested in corporate notes and commercial

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paper, all of which have a minimum investment rating of A1/P1, and government agency notes. Short-term investments are carried at estimated fair value based upon quoted market prices. The Company has had no realized gains or losses from the sale of investments for the years ended December 31, 2003, 2004, and 2005. The cumulative unrealized (loss) or gain on cash equivalents and short-term investments were \$0, \$(14,086) and \$(79,971) at December 31, 2003, 2004, and 2005, respectively. The following table summarizes the estimated fair value of the Company's short-term investments, not including cash equivalents as of December 31, 2005.

	<u>December 31, 2005</u>	<u>December 31, 2005</u>
	Carrying Amount	Estimated Fair Market Value
U.S. agency notes .....	\$ 6,171,500	\$ 6,160,994
Corporate debt notes .....	44,809,824	44,018,000
Commercial paper .....	2,461,605	2,460,215
Certificate of deposit .....	649,183	648,807
Total .....	<u>\$53,372,112</u>	<u>\$53,288,016</u>

All available-for-sale securities held at December 31, 2005 will mature during 2006.

**5. Property and Equipment**

The components of property and equipment are as follows:

	<u>December 31,</u>	
	<u>2004</u>	<u>2005</u>
Laboratory equipment .....	\$ 2,315,142	\$ 4,064,865
Leasehold improvements .....	1,816,694	6,056,536
Computer software and equipment .....	1,362,037	1,384,089
Office furniture and fixtures .....	198,570	659,835
Subtotal .....	5,692,443	12,165,325
Less accumulated depreciation and amortization .....	<u>(3,062,456)</u>	<u>(3,990,251)</u>
Total property and equipment, net .....	<u>\$ 2,629,987</u>	<u>\$ 8,175,074</u>

Included in the property and equipment are assets recorded under capital leases. Amortization of the assets recorded under capital leases is included in depreciation expense. Depreciation expense was approximately \$768,000, \$821,000, and \$1,437,000 for the years ended December 31, 2003, 2004 and 2005, respectively. Un-amortizing computer software that was not placed in production was \$0 and \$242,000 as of December 31, 2004 and 2005.

The Company entered into a lease for its recently-occupied facility. Leasehold improvements paid by the lessor pursuant to the lease agreement are being amortized over the life of the lease, or ten years, as a discount to rent expense and as amortization expense to the related leasehold improvements. The balance of the lessor-paid leasehold improvements and rent discounts are classified in the balance sheet as leasehold improvements and other liabilities, respectively. Capitalized leasehold improvements paid by the lessor were \$0 and \$1,297,000 as of December 31, 2004 and 2005.

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**6. Accrued Expenses**

The components of accrued expenses are as follows:

	December 31,	
	2004	2005
Clinical development expenses .....	\$1,674,259	\$3,434,087
Payroll and related expenses .....	699,902	983,725
Manufacturing expenses .....	295,533	194,685
Professional fees .....	414,331	145,894
Other operating expenses .....	286,394	465,293
License fees and sponsored research .....	216,674	93,222
Total .....	\$3,587,093	\$5,316,906

**7. Commitments and Contingencies**

*Lease Commitments.* The Company leases its laboratory and office facilities in Alpharetta, Georgia under one operating lease. The Company also leases office equipment under various non-cancelable operating leases. Future minimum lease payments under operating leases primarily relate to the laboratory and office facility leases. One of these leases includes annual rent increases based upon increases in the Consumer Price Index, which are considered to be contingent rentals and are charged to expense when incurred. During the years ended December 31, 2003, 2004 and 2005, rent expense totaled approximately \$421,000, \$520,000 and \$1,043,000, respectively. Future minimum payments under these operating leases at December 31, 2005 are as follows:

Year Ending December 31,	
2006 .....	\$ 844,852
2007 .....	858,900
2008 .....	876,898
2009 .....	898,826
2010 and after .....	5,184,401
Total minimum lease payments .....	\$8,663,877

In December 2003, the Company entered into an agreement to lease a new 51,000 square foot research and office facility to be built to its specifications. In January 2005, the Company took possession of or controlled the physical use of the property and occupied the facility in May 2005. The Company estimates that these expenses associated with the new facility including minimum rent payments and the amortization of leasehold improvements paid by the lessor (Note 2-lease accounting) will approximate \$1.0 to \$1.1 million per year on average under this lease. In conjunction with this agreement the Company issued 21,009 common stock warrants at a price of \$9.38 to the lessor.

*Purchase Commitments.* In December 2001, the Company entered into a ten-year contract manufacturing agreement for Veronate with Nabi Pharmaceuticals, Inc. ("Nabi"). Pursuant to the terms of the agreement, the Company is obligated to pay Nabi on a per batch basis. The Company is required to provide Nabi with a three-year rolling forecast that outlines the number of batches it desires to be manufactured in each of the next three years. As of December 31, 2005, the Company's maximum purchase commitments under this agreement through December 31, 2009 were approximately \$6.7 million. However, if the Company cancels or postpones the production of one or more lots of Veronate in accordance with the terms of this agreement, certain cancellation penalties would instead apply, which could be substantially less than the minimum purchase commitments, depending on the length of the

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notice provided to Nabi. The amount of the cancellation penalty payable per batch ranges from \$25,000 per batch if Inhibitex provides notice of cancellation more than twelve months in advance, up to \$425,000 per batch if notice of cancellation is provided less than 90 days in advance of the scheduled production date of the related batch. Specific prices per batch were established at the time of the agreement and are subject to increases based upon increases in certain cost of living indexes. The agreement may be terminated by either party in the event of a default by the other party, or upon mutual agreement.

In October 2002, Inhibitex entered into a ten-year plasma supply agreement with a supplier. Inhibitex is required to purchase a certain number of liters of plasma per year that shall be agreed upon by both parties no later than 90 days prior to the beginning of such calendar year. The Company is generally obligated to purchase 90% of the agreed upon quantity in any given year. A price per liter was established at the time of the agreement and is subject to increases based upon increases in certain cost of living indexes and other adjustments. The agreement may be terminated by either party only in the event of a default by the other party, by the Company upon 30 days written notice if the clinical development of Veronate is halted or terminated, or upon mutual agreement. In the event that the supply agreement is terminated, Inhibitex is obligated to purchase the amount of plasma that the supplier had collected on Inhibitex's behalf, but had not yet shipped, as of the date of termination. The Company has estimated that the amount of plasma subject to this termination obligation approximates 17% of the agreed upon quantity in any given year.

In January 2005, the Company entered into a second supply agreement with another supplier of plasma. This agreement has a ten-year term; however, the Company may terminate the agreement upon mutual agreement of the parties, a material breach by the supplier, or upon 30 days notice that the clinical development of Veronate is terminated by the FDA or the Company.

In September 2005, the Company entered into a third plasma supply agreement with another supplier of plasma for a defined volume of plasma. This agreement has a three-year term; however, the Company may terminate the agreement upon mutual consent of the parties, a material breach by the supplier, or upon 30 days notice that the clinical development of Veronate is terminated by the FDA or Inhibitex.

In March 2002, the Company entered into an agreement with Avid Bioservices, Inc., or Avid, to produce clinical trial material for Aurexis for use in clinical trials. As of December 31, 2005, the Company has no long-term obligations under any prior agreements with Avid.

In November 2004, the Company entered into an agreement with Lonza Biologics PLC for the manufacture of Aurexis. Under the terms of the agreement, Lonza performed numerous process development related services and manufactured one lot of Aurexis for use in future clinical trials. As of December 31, 2005, the Company's maximum purchase commitments under this agreement through December 31, 2009, were approximately \$0.2 million.

## **8. Long-term Debt**

*Capital Lease Obligations.* In 2003, 2004 and 2005, Inhibitex entered into capital lease transactions related to the acquisition of certain laboratory and other equipment. The amortization of assets acquired under these capital leases has been recorded as depreciation expense. These capital leases bear interest rates of 9.62% to 10.38%, and expire at various dates from March 2005 to April 2009. In connection with some of these capital leases the lessor was granted warrants to purchase 5,071 common shares at exercise price ranges of \$6.78 to \$9.38 per share. These warrants were recorded at their weighted average estimated fair value of \$4.86 per share, using the Black-Scholes method. This amount was recorded as interest expense.

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Future payments under capital lease agreements as of December 31, 2005 are as follows:

<u>Year Ending December 31,</u>	
2006 .....	\$1,080,390
2007 .....	946,994
2008 .....	776,615
2009 .....	<u>104,382</u>
Total future minimum lease payments .....	2,908,381
Less amount representing interest .....	<u>(393,015)</u>
Present value of future minimum lease payments .....	2,515,366
Less current portion of capital lease obligations .....	<u>(869,043)</u>
Long-term portion of capital lease obligations .....	<u>\$1,646,323</u>

In April 1999, the Company issued two promissory notes to a related party in connection with certain leasehold improvements. The notes bear interest at 7% per annum. One note was repaid in full in December 1999 and the other in December 2005. Monthly payments were \$3,799 through December 2005, and the outstanding balance as of December 31, 2004 and 2005 was \$43,906 and \$0, respectively. In connection with these promissory notes, the Company issued a warrant to purchase 11,250 shares of Series B Redeemable Convertible Preferred Stock at an exercise price of \$1.50 per share. Using the Black-Scholes method, the warrant was recorded at its estimated fair value of \$0.59 per share, assuming no dividend yield, an expected life of three years, risk-free interest rate 5.97% and volatility of 50%. The principal balance of the related notes was discounted in an amount equal to such value.

In February 2003, the Company entered into a loan and security agreement (the "Loan Agreement") with a commercial bank. In June 2003, the Company borrowed \$2.5 million under the Loan Agreement ("Term Note") and paid two interest-only payments in June and July 2003. Beginning August 2003, the Company began to make the first of 36 equal monthly installments of principal of \$69,444. The Term Note bears interest at 6.5% per year. The outstanding balance of the Term Note at December 31, 2004 and 2005 was \$1,319,445 and \$486,111, respectively. The Loan Agreement is secured by all unencumbered tangible assets of the Company and requires the company to keep a compensating balance of two times the remaining loan amount.

In December 2004, the Company entered into an interest-free \$2.5 million credit facility with a local development authority for laboratory-related leasehold improvements at the Company's new research and headquarters facility. The full amount of the credit facility was outstanding as of August 2005. Beginning in October 2005, the Company made the first of 12 equal quarterly installments of principal of \$208,333. As of December 31, 2004 and December 31, 2005, \$0 and \$2,291,667 were outstanding under this credit facility, respectively.

Future minimum payments due under notes payable as of December 31, 2005 are as follows:

<u>Year Ending December 31,</u>	
2006 .....	\$1,319,445
2007 .....	833,333
2008 .....	<u>625,000</u>
Total future payments .....	<u>\$2,777,778</u>

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**9. Other Liabilities**

The components of other liabilities are as follows:

	December 31,	
	2004	2005
Deferred amortization of leasehold improvements and rent holiday		1,446,912
Other .....	\$ 1,000,000	\$ 1,000,000
Less current portion of other liabilities .....	(1,000,000)	(1,152,702)
Long term portion of other liabilities .....	<u>\$ —</u>	<u>\$ 1,294,210</u>

The Company entered into a lease for its recently-occupied facility. Leasehold improvements paid by the lessor pursuant to the lease agreement are being amortized over the life of the lease, or ten years, as a discount to rent expense and as amortization expense to the related leasehold improvements. The balance of the lessor-paid leasehold improvements and rent discounts are classified in the balance sheet as leasehold improvements and other liabilities, respectively. In addition, the Company took possession, or control of, the physical use of the facility in January 2005, at which time the work was initiated on the leasehold improvements. The leasehold improvements were completed in May 2005. This four month gap constituted a rent holiday. As such, the Company accrued rent for that time period. This accrued rent is being amortized as a discount to rent over the remaining 10 year life of the lease. The balance of this rent accrual is classified in the balance sheet as other liabilities.

**10. Income Taxes**

At December 31, 2004 and 2005, the Company had available net operating loss (“NOL”) carry forwards of approximately \$84.9 million, and \$123.1 million, respectively, which will begin to expire in the year 2019 to 2020. A portion of the Company’s existing NOL carryforwards relates to exercises of non-qualified stock options. The tax benefit of which, when utilized, will be recorded as an increase to shareholder equity. The Company also has approximately \$866,000 and \$1,062,000 of research and development (“R&D”) tax credit carry forwards as of December 31, 2004 and 2005, respectively. The NOL and R&D tax credit carry forwards are available to offset future income taxes payable, if any.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company’s deferred tax asset are as follows:

	December 31,	
	2004	2005
Deferred tax assets:		
Net operating loss carry forwards .....	\$ 32,210,300	\$ 46,741,300
Research and development tax credit carry forwards .....	865,500	1,062,500
Deferred revenue .....	317,900	333,700
Other, net .....	<u>320,700</u>	<u>(47,400)</u>
Total deferred tax assets .....	33,714,400	48,090,100
Less valuation allowance .....	<u>(33,714,400)</u>	<u>(48,090,100)</u>
Net deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

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For financial reporting purposes, SFAS No. 109 requires that a valuation allowance be recorded to reduce the balance of deferred income tax assets if it is more likely than not that some portion or all of the deferred income tax assets will not be realized in the future. The Company has established a full valuation allowance equal to the amount of its deferred tax asset due to uncertainties with respect to the Company's ability to generate sufficient taxable income in the future. The valuation allowance increased by \$14.4 million from December 31, 2004 to December 31, 2005. Income tax expense, as reported, differs from expense as calculated based on the U.S. federal statutory rate, due primarily from the change in valuation allowance during the current year.

The Company's net operating loss carryforwards and research credit carryforwards may be subject to certain Internal Revenue Code ("IRC") Section 382 and 383 limitations on annual utilization in the event of changes in ownership. These limitations could significantly reduce the amount of net operating loss and research credit carryforwards available in the future.

#### **11. Redeemable Convertible Preferred Stock and Warrants**

On June 3, 2004, Inhibitex completed an initial public offering (IPO) of five million shares of its common stock at an initial offering price to the public of \$7.00 per share, resulting in net proceeds of \$30.8 million after deducting underwriters' commissions and related expenses. Upon the closing of the IPO, all outstanding shares of preferred stock, and accrued dividends thereon, were converted into 11,936,438 shares of common stock. During the years ended December 31, 2003, 2004 and 2005 the Company recorded aggregate accretion related to warrants and preferred dividends of \$6,201,116, \$2,823,160 and \$0, respectively.

#### **12. Stockholders' Equity**

*Common Stock.* As of December 31, 2004 and 2005, the Company was authorized to issue 75,000,000 shares of common stock. Each holder of common stock is entitled to one vote for each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

*Employee Stock Purchase Plan.* The Company's Board of Directors adopted, and its stockholders approved as of February 20, 2004, its 2004 Employee Stock Purchase Plan, or the Purchase Plan. The purpose of the Purchase Plan is to provide an opportunity for employees to purchase a proprietary interest in the Company. The Purchase Plan is administered by the Company's Compensation Committee. A total of 210,084 shares of common stock are authorized for issuance under the Purchase Plan as of December 31, 2005. Employees who are customarily employed for more than 20 hours per week and for more than five months in any calendar year and have been so employed for a six-month period are eligible to participate in the Purchase Plan. Employees who would own 5% or more of the total combined voting power or value of all classes of the Company's stock immediately after the grant may not participate in the purchase plan. The Purchase Plan is intended to qualify under Section 423 of the Internal Revenue Code and provides for quarterly purchase periods. The Purchase Plan permits participants to purchase common stock through payroll deductions of up to 25% of their eligible base salary. For any calendar year, a participant may not be granted rights to purchase shares to the extent the fair market value of such shares exceeds \$25,000. Amounts deducted and accumulated by the participant are used to purchase shares of common stock at the end of each quarterly purchase period. The purchase price per share is 85% of the lower of the fair market value of the Company's common stock at the beginning of a purchase period or at the end of a purchase period. An employee's participation ends automatically upon termination of employment with the Company. A participant may not transfer rights to purchase the Company's common stock under the Purchase Plan other than by will or the laws of descent and distribution. In the event of a change of control, no further shares shall be available under the Purchase Plan, but all payroll deductions scheduled for collection in that purchase period will be immediately applied to purchase whole shares of common stock. The Board of Directors has the authority to amend or terminate the Purchase Plan, except

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that, subject to certain exceptions described in the Purchase Plan, no such action may adversely affect any outstanding rights to purchase stock under the Purchase Plan and the Board of Directors may not increase the number of shares available under the Purchase Plan, or amend the requirements as to the eligible class of employees, without stockholder approval. As of December 31, 2005 the Company had 1,287 shares committed-to-be-released to employees. The shares market value was \$11,000 based on a 15% discount to the Company's ending stock price on December 31, 2005.

*Initial Public Offering.* On June 3, 2004, the Company completed an initial public offering ("IPO") of five million shares of its common stock at an initial offering price to the public of \$7.00 per share, resulting in net proceeds of \$30.8 million after deducting underwriters' commissions and related expenses. Upon the closing of the IPO, all outstanding shares of preferred stock, and accrued dividends thereon, were converted into 11,936,438 shares of common stock. On July 8, 2004 in connection with the underwriters' exercise of the over-allotment option on the IPO, an additional 527,000 shares of common stock were issued at an initial offering price to the public of \$7.00 per share, resulting in net proceeds of \$3.0 million after deducting underwriters' commissions and related expenses.

*Private Investment in Public Equity.* On November 10, 2004, the Company completed a private investment in public entity or PIPE financing in which it raised \$47.7 million in net proceeds through the sale, at a price of \$7.3775 per share, of 6,777,370 shares of its common stock and warrants to purchase 2,033,211 shares of its common stock. The warrants, which became exercisable on May 9, 2005 and expire November 10, 2009, have an exercise price of \$8.81 per share. The shares and warrants were offered and sold only to institutional and accredited investors. The Company filed a registration statement with the SEC in order to register the sale and resale of the common stock issued in the PIPE and issuable upon the exercise of the related warrants.

On August 22, 2005, the Company completed a PIPE financing in which it raised \$38.8 million in net proceeds through the sale, at a price of \$8.25 per share, of 5,000,000 shares of its common stock. The shares were offered and sold only to institutional and accredited investors. The Company filed a registration statement with the SEC in order to register the resale of the common stock issued in the PIPE.

The Company had reserved shares of common stock for issuance as follows:

	<b>December 31, 2004</b>	<b>December 31, 2005</b>
Common stock options . . . . .	1,283,106	2,304,242
Warrants to purchase shares of common stock . . . . .	3,838,588	3,800,143
Total . . . . .	5,121,694	6,104,385

*Common Stock Warrants.* As of December 31, 2004 and 2005, there were 3,838,588 and 3,800,143 warrants outstanding, respectively. As of December 31, 2005 all of the warrants are exercisable and expire from February 7, 2007 to May 12, 2010. The weighted average strike price as of December 31, 2005 is \$11.20.

**13. Stock Option Plans**

*1998 Equity Ownership Plan.* In May 1998, the Board of Directors approved the 1998 Equity Ownership Plan (the "Plan"), which provided for the grant of stock options to directors, officers, employees and consultants. Under the Plan, both incentive stock options and non-qualified stock options, among other equity related awards, could be granted. The Board of Directors determined the term and vesting dates of all options at their grant date, provided that such price shall not be less than the fair market value of the Company's stock on the date of grant. Under the Plan, the maximum term for an option grant is 10 years

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from the grant date, and options generally vest ratably over a period of four years from the grant date. As of December 31, 2004 and 2005, there were 188,262 and 175,845 options respectively outstanding under the Plan to purchase the Company's common stock, respectively. Upon the adoption of the 2002 Stock Incentive Plan ("2002 Plan") as discussed below, no additional grants of stock option grants or equity awards were authorized under the 1998 Equity Ownership Plan. All options outstanding under the Plan will remain in full force and effect until they expire or are exercised. However, future forfeitures of any stock options granted under the 1998 Equity Ownership Plan are added to the number of shares available under the 2002 Plan.

*2004 Stock Incentive Plan and 2002 Non-Employee Directors Stock Option Plan.* In February 2002, the Board of Directors approved the 2002 Plan, which provided for the grant of incentive stock options, non-qualified stock options and other equity related awards to employees, contractors and consultants of the Company. At that time, the Company also adopted the 2002 Non-Employee Directors Stock Option Plan (the "Director Plan") which provided for the grant of non-qualified stock options and other equity related awards to non-employee members of the Board of Directors. On February 20, 2004, the Board of Directors amended the 2002 Plan and the Director Plan, whereby the 2002 Plan was renamed the 2004 Stock Incentive Plan (the "2004 Plan"). The 2004 Plan was further modified to provide for option grants to non-employee directors and 1,420,180 shares of common stock have been added to the number of reserved shares. Upon the adoption of the 2004 Plan, no further options were authorized to be granted under the Director Plan. In May 2005, pursuant to a stockholder vote the plan was further modified by adding 1,500,000 shares of common stock to the number of reserved shares available for grant.

The 2004 Plan and the Director Plan are administered by the compensation committee of the Board of Directors, which has the authority to select the individuals to whom awards are to be granted, the number of shares granted, and the vesting schedule. As of December 31, 2005, an aggregate of 3,952,966 shares of common stock were reserved for issuance under the 2004 Plan and the Director Plan. Under the 2004 Plan and Director Plan, the maximum term for an option grant is ten and six years from the grant date, respectively. Options granted under the 2004 Plan and Director Plan generally vest ratably over a period of four years and three years, respectively, from the grant date. As of December 31, 2004, there were 1,080,872 outstanding options to purchase the Company's common stock and 1,395,591 options available for grant under the 2004 Plan. As of December 31, 2005, there were 2,114,425 outstanding options to purchase the Company's common stock and 1,838,541 options available for grant under the 2004 Plan. As of December 31, 2004 and 2005, there were 66,804 and 64,304 outstanding options to purchase the Company's common stock and no options available for grant under the Director Plan, respectively.

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The following is a summary of all stock option activity and related information related to all the Company's stock option plans, and 13,972 shares issued outside these plans, from inception of such plans through the period ended December 31, 2005:

	<u>Number of Shares</u>	<u>Exercise Price per Share</u>	<u>Weighted Average Exercise Price per Share</u>
Granted during 1998 .....	51,666	\$ 0.24	\$0.24
Balance at December 31, 1998 .....	51,666	0.24	0.24
Granted .....	66,814	0.29-0.36	0.31
Exercised .....	<u>(1,787)</u>	0.24	0.24
Balance at December 31, 1999 .....	116,693	0.24-0.36	0.29
Granted .....	306,066	0.29-0.68	0.38
Exercised .....	(7,673)	0.24-0.36	0.29
Cancelled .....	<u>(8,301)</u>	0.29	0.29
Balance at December 31, 2000 .....	406,785	0.24-0.68	0.36
Granted .....	208,959	0.68	0.68
Exercised .....	(44,816)	0.24-0.68	0.29
Cancelled .....	<u>(16,284)</u>	0.24-0.68	0.45
Balance at December 31, 2001 .....	554,644	0.24-0.68	0.48
Granted .....	639,981	0.68-1.90	1.90
Exercised .....	(47,432)	0.24-0.68	0.38
Cancelled .....	<u>(61,429)</u>	0.24-1.90	0.74
Balance at December 31, 2002 .....	1,085,764	0.24-1.90	1.31
Granted .....	285,555	1.90	1.90
Exercised .....	(22,857)	0.24-1.90	0.83
Cancelled .....	<u>(10,010)</u>	0.29-1.90	1.55
Balance at December 31, 2003 .....	1,338,452	0.24-1.90	1.43
Granted .....	285,836	2.86-9.38	8.72
Exercised .....	(309,965)	0.24-1.90	0.83
Cancelled .....	<u>(31,217)</u>	0.29-9.38	4.99
Balance at December 31, 2004 .....	1,283,106	0.24-9.38	3.18
Granted .....	1,094,500	6.82-10.23	8.85
Exercised .....	(35,914)	1.90-0.29	1.45
Cancelled .....	<u>(37,450)</u>	10.25-1.90	8.06
Balance at December 31, 2005 .....	<u>2,304,242</u>	0.24-10.23	5.82

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The following tables summarize information relating to outstanding and exercisable options as of December 31, 2005:

Exercise Prices	December 31, 2005				
	Outstanding			Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$0.24 .....	10,731	2.41	\$0.24	10,731	\$0.24
0.29 .....	55,223	3.92	0.29	55,223	0.29
0.36 .....	13,972	3.35	0.36	13,972	0.36
0.68 .....	116,194	4.94	0.68	116,194	0.68
1.90 .....	774,536	2.61	1.90	500,448	1.90
5.91-8.995 .....	332,930	5.81	8.07	8,551	6.56
9.07 .....	760,570	5.09	9.07	—	—
9.38 .....	231,386	4.30	9.38	74,705	9.38
9.69-10.23 .....	8,700	5.64	9.82	—	—
	<u>2,304,242</u>	4.22	5.82	<u>779,824</u>	2.32

The Company applies the measurement principles of APB No. 25 in accounting for stock options granted to its employees and directors.

#### 14. Research and License Agreements

As of December 31, 2005, the Company has entered into a number of license and collaborative agreements with various institutions to obtain intellectual property rights and patents relating to MSCRAMM proteins, and its product candidates. The Company has also entered into an exclusive worldwide license and collaboration agreement with Wyeth with respect to its use of the MSCRAMM proteins to develop staphylococcal vaccines. The significant arrangements are described further below.

*Texas A&M University Health Science Center.* The Company has licensed, on an exclusive basis, from the Texas A&M University System a number of issued United States patents, related United States divisional applications and foreign counterpart applications directed to one of the MSCRAMM proteins that the Company's lead product candidate, Veronate, targets. Texas A&M may terminate the license if the Company fails to use commercially reasonable efforts to bring product candidates to market. Inhibitex may terminate the license without cause upon 60 days written notice. Otherwise, this agreement will terminate upon the expiration of all of the licensed patents. Currently, the latest to expire of the issued patents under the license agreement expires in 2019. The Company has agreed to pay Texas A&M a royalty based on net sales for any products sold utilizing these patents.

In connection with these license agreements, in 1995 the Company entered into the first of several cooperative research agreements with Texas A&M. Pursuant to these agreements, the Company has the exclusive worldwide right to any discoveries resulting from this collaboration, subject to research rights retained by Texas A&M and certain rights of the United States government. The Company also has a right of first refusal to acquire the rights to and file patents on discoveries made by Texas A&M in the field of MSCRAMM proteins that are made outside of the scope of the collaboration. Texas A&M is entitled to a royalty on revenues that the Company receives for products that incorporate technology developed through the collaboration. The Company may terminate this collaboration upon 90 days written notice if the work is not performed satisfactorily. Pursuant to these agreements, the Company has paid Texas A&M approximately \$1.7 million through December 31, 2005. The Company has no future

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minimum royalty or milestone obligations pursuant to these agreements, but the Company currently pays Texas A&M approximately \$382,000 in annual sponsored research payments. The Company's obligation to pay sponsored research payments ends in November 2006. If the Company does not continue to pay sponsored research payments beyond that time, the Company will be obligated to pay a minimum royalty of \$25,000 annually.

*BioResearch Ireland (BRI)/Trinity College Dublin (TCD).* The Company has obtained numerous licenses from BioResearch Ireland ("BRI") under certain patents and related applications licensed to it from Texas A&M, as described above. Some of the licenses also cover pending international applications. BRI may terminate the license if Inhibitex fails to use commercially reasonable efforts to bring one or more products that use the licensed technology to market. Otherwise, these licenses will terminate upon the expiration of the licensed patents. Currently, the latest to expire of the issued patents under the license agreement expires in 2019. The Company may terminate the license agreement as to any patent or patent application upon 90 days notice. BRI is entitled to a royalty on the net sales of products sold utilizing these patents.

Pursuant to these agreements, the Company has entered into several cooperative research agreements with BRI and Trinity College Dublin ("TCD") for technologies relating to staphylococcus surface proteins. The Company has exclusive worldwide rights to, and is entitled to file patents on, any discoveries resulting from this collaboration. All licenses from BRI and TCD are subject to research rights retained by BRI or TCD. BRI or TCD is entitled to a royalty on any revenues that the Company receives from the sale of products that incorporate technology developed through the collaborative arrangement. The Company may terminate the collaboration agreement on two months written notice and BRI or TCD may terminate in the event of an uncured material breach by the Company. Pursuant to these agreements, the Company has paid BRI approximately \$256,000 and TCD approximately \$105,000 through December 31, 2005. The Company has no future minimum royalty or milestone obligations pursuant to these agreements, but the Company currently pays TCD approximately \$35,000 in annual sponsored research payments.

*Wyeth.* In August 2001, the Company entered into an exclusive worldwide license and development collaboration agreement with Wyeth for the development of staphylococcal vaccines for humans. Under the terms of this agreement, the Company granted Wyeth an exclusive worldwide license to its MSCRAMM protein intellectual property with respect to human vaccines against staphylococcal organisms. The development, manufacture and sale of any products resulting from the collaboration are the responsibility of Wyeth. Inhibitex may terminate the agreement if Wyeth fails to use reasonable commercial efforts to bring related products to market. Wyeth may terminate the agreement, without cause, upon six months notice. Otherwise, this agreement will terminate upon the expiration of all of the licensed patents. Currently, the latest to expire of the issued patents under the license agreement expires in 2019.

Pursuant to this agreement, the Company has received \$4.3 million in an upfront license fee and annual research support payments from Wyeth as of December 31, 2005. The Company is entitled to receive minimum research support payments of \$500,000 per year until the first commercial sale of any product developed under this agreement. The minimum research payment escalates to \$1.0 million in the event that Wyeth does not initiate a Phase I by July 31, 2007. The Company is also entitled to receive milestones upon the filing of an investigational new drug application ("IND"), the commencement of both Phase II and Phase III clinical trials, the filing of a BLA, and FDA approval of a licensed product. If all such milestones are achieved relative to one or more licensed products, the Company would be entitled to receive a minimum of \$10.0 million in milestone payments from Wyeth. The maximum milestone payments the Company could receive with respect to all licensed products are \$15.5 million. Finally, the Company is also entitled to royalties on net sales of licensed products manufactured, sold or distributed by Wyeth.

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*Dyax.* In October 2004, the Company entered into a collaboration agreement with Dyax to co-develop monoclonal antibodies to prevent or treat serious infections caused by enterococci. Under the terms of the agreement, the Company and Dyax have agreed to collaborate and share in the costs to perform preclinical research and development activities intended to identify and select a fully human monoclonal antibody, or antibodies, against MSCRAMM proteins located on the surface of enterococci, that Inhibitex and Dyax would jointly advance into clinical trials. During this preclinical phase, the Company and Dyax are only responsible for its respective internal development costs. Accordingly, neither party is responsible to make any upfront payments to the other party, nor is either party obligated to make future milestone or royalty payments to the other party at this time. The Company's internal development costs are expected to consist largely of salaries and other personnel-related costs associated with existing employees, certain supplies, and other costs, such as travel and entertainment, associated with supporting existing employees. If at the end of the collaborative preclinical development activities, Inhibitex and Dyax mutually agree to advance one or more human monoclonal antibodies into clinical trials, Inhibitex and Dyax will continue to share in the clinical development costs of any such product candidates. The agreement also contemplates that the Company and Dyax would share in the commercialization rights and profits from any approved and marketed products resulting from the collaboration. In the event that the parties mutually agree that the collaboration has been unable to identify a suitable monoclonal antibody to advance into clinical development, the collaboration agreement will immediately and automatically terminate without any further obligations to either party. Otherwise, this agreement can only be terminated during the initial preclinical development phase upon the mutual consent of both parties, or by one party in the event that the other party has committed a material breach, or filed for insolvency or bankruptcy.

*Other Agreements.* The following agreements relate to intellectual property associated with the production of monoclonal antibodies that the Company has in-licensed.

In November 2001, the Company entered into a research evaluation and worldwide non-exclusive license agreement with Lonza Biologics for intellectual property and materials relating to the expression of recombinant monoclonal antibodies to bacterial surface proteins for use in the manufacture of Aurexis. Under the terms of the agreement, the Company agreed to pay an annual fee and a royalty on the net sales of any products that it may sell that utilize this technology. The Company may terminate the agreement upon 60 days notice. The agreement terminates upon the expiration of the last valid patent or 15 years, whichever is longer. Currently, the latest to expire of the issued patents under the license agreement expires in 2016. Pursuant to this agreement, the Company has paid Lonza \$761,000 as of December 31, 2005.

In June 2003, the Company obtained a non-exclusive, worldwide royalty-bearing license from Genentech for a patent, commonly referred to as the Cabilly patent, relating to the production of monoclonal antibodies for use in the manufacture of Aurexis. Under the agreement, the Company agreed to pay Genentech an up-front license fee and it is further obligated to pay a milestone payment upon the approval of Aurexis and a royalty on the sale of any of its products that utilize the underlying technology. The Company may terminate this agreement without cause upon 90 days notice. Otherwise, this license will terminate upon the expiration of the patent, which will occur in 2018 if not extended. Pursuant to this agreement, the Company has paid \$500,000 to Genentech as of December 31, 2005. The Company's aggregate future payments under this agreement are \$5.0 million, of which most is payable if Aurexis is approved for sale by the FDA.

In July 2003, the Company obtained a non-exclusive, worldwide royalty-bearing license from the University of Iowa for patents relating to technology used in the expression of recombinant proteins for use in the manufacture of Aurexis. Under this agreement, the Company has paid the University of Iowa an up-front license fee of \$35,000 and it is obligated to make annual payments of \$35,000 per year. The Company also agreed to pay a milestone payment of \$40,000 for each of the first four license related products to receive FDA approval and a royalty on the sale of any of its products that utilize the

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underlying technology. The Company may terminate this agreement at any time. Otherwise, this license will terminate upon the expiration of the patents, which will be 2009 and 2012, respectively.

In March 2004, the Company obtained a non-exclusive, worldwide royalty bearing license from the National Institutes of Health (NIH) for patent applications relating to the humanization of monoclonal antibodies. Under this agreement, the Company agreed to pay an up-front license fee, a minimum annual royalty of \$25,000 per year, milestone payments and a royalty on the sale of any of its products that would otherwise infringe any patent that may issue from the pending applications. For any product covered by this license, the milestone payments are based upon the filing of an IND, the first subject enrolled in a Phase II and Phase III trial, the filing of a BLA and upon the approval of a BLA by the FDA. The Company may terminate this agreement upon 60 days notice. Otherwise, this agreement terminates upon the expiration of the patent, which will occur in 2011 if not extended. Pursuant to this agreement, the Company has paid \$259,000 to the NIH as of December 31, 2005. If Aurexis is approved for sale by the FDA, the Company's total future payments to the NIH under this agreement related to the up-front license fee and milestone payments would be approximately \$900,000 in the aggregate.

In April 2004, the Company obtained an exclusive, worldwide royalty bearing license from Biostapro AB for patent applications relating to the staphylococcal proteins. Under this agreement, the Company agreed to pay an up-front license fee, a milestone payment, and a royalty on the net sale of products utilizing the underlying technology. The milestone payment is based on the marketing approval of a Biological License Application ("BLA") by the FDA. The Company may terminate this agreement upon 90 days notice. Otherwise, this agreement terminates upon the expiration of the patent. Pursuant to this agreement, the Company has paid \$250,000 to Biostapro AB as of December 31, 2005. The Company's aggregate future payments under this agreement are \$750,000. Pursuant to this license agreement above the Company entered into several cooperative research agreements with Biostapro AB relating to staphylococcal surface proteins. The Company has exclusive worldwide rights to any discoveries resulting from this collaboration. Biostapro AB is entitled to a royalty on any revenues that the Company receives from the sale of products that incorporate technology developed through the collaborative arrangement. The Company may terminate the collaboration agreement on three months written notice and Biostapro AB may terminate in the event of an uncured material breach by the Company. Pursuant to these agreements, the Company has paid Biostapro AB approximately \$200,000 through December 31, 2005. The Company has no future minimum royalty or milestone obligations pursuant to these agreements, but the Company currently pays Biostapro AB approximately \$100,000 in annual sponsored research payments.

**15. Employee Benefit Plan**

The Company sponsors a 401(k) plan for the benefit of its employees that is a defined contribution plan intended to qualify under Section 401(a) of the Internal Revenue Code of 1986, as amended. Eligible employees may make pre-tax contributions to the 401(k) plan of up to 20% of their eligible earnings, subject to the statutorily prescribed annual limit. The 401(k) plan permits the Company to make discretionary matching and profit sharing contributions. The Company's contributions to the plan were approximately, \$108,000, \$138,000 and \$156,000 in 2003, 2004 and 2005, respectively. Under the 401(k) plan, each employee is fully vested in his or her deferred salary contributions. The Company's contributions vest over a three-year period.

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**16. Quarterly Financial Data (Unaudited)**

The following table presents unaudited quarterly financial data of the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results.

	<u>Revenue</u>	<u>Loss from Operations</u>	<u>Net Loss</u>	<u>Net Loss Attributable to Common Stockholders</u>	<u>Net Loss Attributable to Common Stockholders per Share — Basic and Diluted</u>
<b>Year Ended December 31, 2004</b>					
First Quarter .....	\$162,500	\$ (4,824,717)	\$ (4,821,569)	\$ (6,422,907)	\$(10.74)
Second Quarter .....	162,500	(6,836,401)	(6,812,096)	(8,033,918)	(1.72)
Third Quarter .....	162,500	(6,227,876)	(6,069,880)	(6,069,880)	(0.33)
Fourth Quarter .....	162,500	(8,555,270)	(8,207,950)	(8,207,950)	(0.37)
<b>Year Ended December 31, 2005</b>					
First Quarter .....	277,131	(10,385,085)	(9,942,688)	(9,942,688)	(0.40)
Second Quarter .....	168,520	(10,556,215)	(10,069,993)	(10,069,993)	(0.40)
Third Quarter .....	328,323	(9,603,465)	(9,046,379)	(9,046,379)	(0.33)
Fourth Quarter .....	162,500	(10,388,734)	(9,516,321)	(9,516,321)	(0.31)

**ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

There have been no disagreements with our independent accountants on any matter of accounting principles or practices or financial statement disclosure.

**ITEM 9A. *CONTROLS AND PROCEDURES***

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit pursuant to the Securities Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management, under the supervision of the Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

**Management's Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework. Management has concluded that, as of December 31, 2005, its internal control over financial reporting is effective based on these criteria.

Management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2005, has been audited by Ernst & Young LLP, the independent registered public accounting firm who also audited our consolidated financial statements, and their opinion of management's assessment is stated in their report, which is included herein.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
ON INTERNAL CONTROL**

**The Board of Directors and Stockholders of  
Inhibitex, Inc.**

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Inhibitex, Inc. (a Development Stage Company) maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Inhibitex, Inc. (a Development Stage Company)'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, management's assessment that Inhibitex, Inc. (a Development Stage Company) maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Inhibitex, Inc. (a Development Stage Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Inhibitex, Inc. (a Development Stage Company) as of December 31, 2004 and 2005, and the related statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2005, and for the period from inception (May 13, 1994) through December 31, 2005, and our report dated March 10, 2006 expressed an unqualified opinion thereon.

*Ernst + Young LLP*

Atlanta, Georgia  
March 10, 2006

### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fourth quarter of 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting

### **ITEM 9B. OTHER INFORMATION**

None.

## **PART III**

### **ITEM 10. *DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT***

The information required by this item is incorporated by reference from our definite proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2006 pursuant to Regulation 14A of the Securities Exchange Act of 1934.

### **ITEM 11. *EXECUTIVE COMPENSATION***

The information required by this item is incorporated by reference from our definite proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2006 pursuant to Regulation 14A of the Securities Exchange Act of 1934.

### **ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT, AND RELATED STOCKHOLDER MATTERS***

The information required by this item is incorporated by reference from our definite proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2006 pursuant to Regulation 14A of the Securities Exchange Act of 1934.

### **ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS***

The information required by this item is incorporated by reference from our definite proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2006 pursuant to Regulation 14A of the Securities Exchange Act of 1934.

### **ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES***

The information required by this item is incorporated by reference from our definite proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2006 pursuant to Regulation 14A of the Securities Exchange Act of 1934.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (b) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
3.1	Eighth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.4 of the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 3, 2004 (the "March 2004 S-1")).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.5 of the March 2004 S-1).
4.1	Specimen certificate evidencing the common stock (incorporated by reference to Exhibit 10.2 of Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on May 6, 2004 ("Amendment No. 2")).
10.1	Amended and Restated 1998 Equity Ownership Plan and related form of option agreement (incorporated by reference to Exhibit 10.1 of the March 2004 S-1).
10.2	2004 Stock Incentive Plan and related Form of option agreement (incorporated by reference to Exhibit 10.2 of the March 2004 S-1).
10.2.1	Amended and Restated 2004 Stock Incentive Plan (incorporated by reference to Exhibit 99.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2006 (the "February 2006 8-K")).
10.2.2	Non-Employee Directors Stock Option Agreement (incorporated by reference to Exhibit 99.2 of the February 2006 8-K).
10.2.3	Employee Stock Option Agreement (incorporated by reference to Exhibit 99.3 of the February 2006 8-K).
10.3	2002 Non-Employee Directors Stock Option Plan and related form of option agreement (incorporated by reference to Exhibit 10.3 of the March 2004 S-1).
10.4	2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 of the March 2004 S-1).
10.5	Form of Warrant to purchase shares of Series B Preferred Stock (incorporated by reference to Exhibit 10.5 of the March 2004 S-1).
10.6	Form of Warrant to purchase shares of Series D Preferred Stock (incorporated by reference to Exhibit 10.6 of the March 2004 S-1).
10.7	Form of Amendment to Warrant to purchase shares of Series D Preferred Stock, dated February 20, 2004 (incorporated by reference to Exhibit 10.7 of the March 2004 S-1).
10.7.1	Form of Second Amendment to Warrant to purchase shares of Series D Preferred Stock, dated May 4, 2004 (incorporated by reference to Exhibit 10.7.1 of Amendment No. 2).
10.8	Form of Warrant to purchase shares of Series E Preferred Stock (incorporated by reference to Exhibit 10.8 of the March 2004 S-1).
10.9	Form of Amendment to Warrant to purchase shares of Series E Preferred Stock (incorporated by reference to Exhibit 10.9 of the March 2004 S-1).
10.9.1	Form of Second Amendment to Warrant to purchase shares of Series E Preferred Stock, dated May 4, 2004 (incorporated by reference to Exhibit 10.9.1 of Amendment No. 2).
10.10	Amended and Restated Master Rights Agreement, dated December 19, 2003, by and among the registrant and holders of the registrant's capital stock (incorporated by reference to Exhibit 10.10 of the March 2004 S-1).
10.11	Amendment No. 1 to Amended and Restated Master Rights Agreement dated February 20, 2004 (incorporated by reference to Exhibit 10.11 of the March 2004 S-1).
10.11.1	Amendment No. 2 to Amended and Restated Master Rights Agreement dated May 27, 2004 (incorporated by reference to Exhibit 10.1 of the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 16, 2004).

<u>Exhibit No.</u>	<u>Description</u>
10.12	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.12 of the March 2004 S-1).
10.13	Employment Agreement, dated as of February 20, 2004, by and between the registrant and William D. Johnston (incorporated by reference to Exhibit 10.13 of the March 2004 S-1).
10.14	Amended and Restated Employment Agreement, dated as of February 20, 2004, by and between the registrant and Seth V. Hetherington (incorporated by reference to Exhibit 10.14 of the March 2004 S-1).
10.15	Amended and Restated Employment Agreement, dated as of February 20, 2004, by and between the registrant and Joseph M. Patti (incorporated by reference to Exhibit 10.15 of the March 2004 S-1).
10.16	Amended and Restated Employment Agreement, dated as of February 20, 2004, by and between the registrant and Russell H. Plumb (incorporated by reference to Exhibit 10.16 of the March 2004 S-1).
10.17	Amended and Restated Employment Agreement, dated as of February 20, 2004, by and between the registrant and David M. Wonnacott (incorporated by reference to Exhibit 10.17 of the March 2004 S-1).
10.18†	License and Development Collaboration Agreement, dated August 2, 2001, by and between the registrant and American Home Products Corporation, acting through its Wyeth-Ayerst Laboratories Division (incorporated by reference to Exhibit 10.18 of Amendment No. 3 the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on May 25, 2004 (“Amendment No. 3”).
10.19†	License Agreement, dated February 4, 2000, between the registrant and The Texas A&M University System (incorporated by reference to Exhibit 10.19 of Amendment No. 3).
10.20†	Amendment No. 1 to License Agreement, dated April 29, 2002, between the registrant and The Texas A&M University System (incorporated by reference to Exhibit 10.20 of Amendment No. 3).
10.21	Amendment No. 2 to License Agreement, dated April 29, 2002, between the registrant and The Texas A&M University System (incorporated by reference to Exhibit 10.21 of the March 2004 S-1).
10.22†	Exclusive License Agreement, dated April 8, 1999, between the registrant and Enterprise Ireland, trading as BioResearch Ireland (incorporated by reference to Exhibit 10.22 of the March 2004 S-1).
10.23†	License Agreement, dated December 23, 2002, between the registrant and Lonza Biologics PLC (incorporated by reference to Exhibit 10.23 of Amendment No. 3).
10.24†	Non-Exclusive Cabilly License Agreement, dated June 30, 2003, between the registrant and Genentech, Inc (incorporated by reference to Exhibit 10.24 of the March 2004 S-1).
10.25†	Patent License Agreement, dated March 2, 2004, between the registrant and the National Institutes of Health (incorporated by reference to Exhibit 10.25 of Amendment No. 3).
10.26†	License Agreement, dated July 1, 2003, between the registrant and the University of Iowa Research Foundation (incorporated by reference to Exhibit 10.26 of Amendment No. 3).
10.27†	Plasma Supply Agreement, dated October 22, 2002, between the registrant and DCI Management Group, Inc (incorporated by reference to Exhibit 10.27 of the March 2004 S-1).
10.28	Amendment to Plasma Supply Agreement, dated February 3, 2003, between the registrant and DCI Management Group, LLC (incorporated by reference to Exhibit 10.28 of the March 2004 S-1).
10.29	Amendment to Plasma Supply Agreement, dated July 3, 2003, between the registrant and DCI Management Group, LLC (incorporated by reference to Exhibit 10.29 of the March 2004 S-1).
10.30†	Production Agreement, dated December 5, 2001, between the registrant and Nabi (incorporated by reference to Exhibit 10.30 of Amendment No. 4 the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on May 25, 2004).

<u>Exhibit No.</u>	<u>Description</u>
10.31†	First Amendment to Production Agreement, dated December 5, 2001, between the registrant and Nabi Pharmaceuticals (incorporated by reference to Exhibit 10.31 of the March 2004 S-1).
10.35	Lease Agreement, dated December 31, 2003, between the registrant and Cousins Properties Incorporated (incorporated by reference to Exhibit 10.35 of the March 2004 S-1).
10.36	Loan and Security Agreement, dated February 11, 2003, between the registrant and Silicon Valley Bank (incorporated by reference to Exhibit 10.36 of the March 2004 S-1).
10.37†	Agreement, dated March 14, 2002, between the registrant and Avid Bioservices, Inc. (incorporated by reference to Exhibit 10.31 of Amendment No. 2).
10.38	Form of Stock and Warrant Purchase Agreements, dated November 4, 2004, between the registrant and each of the investors signatory thereto (including Form of Warrant to Purchase Common Stock issued in connection therewith) (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2004).
10.39†	Agreement, dated November 5, 2004, between the registrant and Lonza Biologics PLC (incorporated by reference to Exhibit 10.39 of Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on January 19, 2005).
10.40	Loan agreement, dated December 28, 2004 between the registrant and Development Authority of Fulton County (incorporated by reference to Exhibit 10.40 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2005).
10.41	Form of Securities Purchase Agreement dated August 17, 2005 between registrant and each of the investors signatory thereto (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 17, 2005).
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934.

† We have been granted confidential treatment with respect to the omitted portions of this exhibit and such information has been filed separately with the Securities and Exchange Commission.

## SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Alpharetta, Georgia on this 13th day of March, 2006.

INHIBITEX, INC.

By: /s/ WILLIAM D. JOHNSTON, PH.D.

William D. Johnston, Ph.D.  
*President and Chief Executive Officer*

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ WILLIAM D. JOHNSTON, PH.D.</u> William D. Johnston, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2006
<u>/s/ RUSSELL H. PLUMB</u> Russell H. Plumb	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2006
<u>/s/ MICHAEL A. HENOS</u> Michael A. Henos	Chairman of the Board of Directors	March 13, 2006
<u>/s/ M. JAMES BARRETT, PH.D.</u> M. James Barrett, Ph.D.	Director	March 13, 2006
<u>/s/ CARL E. BROOKS</u> Carl E. Brooks	Director	March 13, 2006
<u>/s/ A. KEITH WILLARD</u> A. Keith Willard	Director	March 13, 2006
<u>/s/ RUSSELL M. MEDFORD, M.D., PH.D.</u> Russell M. Medford, M.D., Ph.D.	Director	March 13, 2006
<u>/s/ ROBERT A. HAMM</u> Robert A. Hamm	Director	March 13, 2006
<u>/s/ JOSEPH M. PATTI, M.S.P.H., PH.D.</u> Joseph M. Patti, M.S.P.H., Ph.D.	Director	March 13, 2006
<u>/s/ MARC L. PREMINGER</u> Marc L. Preminger	Director	March 13, 2006
<u>/s/ LOUIS W. SULLIVAN, M.D.</u> Louis W. Sullivan, M.D.	Director	March 13, 2006

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## EXECUTIVE MANAGEMENT TEAM

**William D. Johnston, Ph.D.**, Chief Executive Officer and President

**Seth V. Hetherington, M.D.**, Chief Medical Officer and Vice President of Clinical Development

**Samuel J. Michini**, Vice President of Sales and Marketing

**Joseph M. Patti, Ph.D.**, Chief Scientific Officer, Co-Founder and Vice President of Research and Development

**Russell H. Plumb**, Chief Financial Officer and Vice President of Finance and Administration

**Robert T. Schweiger**, Vice President of Business Development

**David M. Wonnacott, Ph.D.**, Vice President of Quality and Regulatory Affairs

## BOARD OF DIRECTORS

**Michael A. Henos**, (Chairman) Managing General Partner – Alliance Technology Ventures

**M. James Barrett, Ph.D.**, General Partner – New Enterprise Associates

**Carl E. Brooks**, President – Brooks & Associates

**Robert A. Hamm**, Senior Vice President of Neurology Strategic Business Unit – Biogen Idec, Inc.

**William D. Johnston, Ph.D.**, President and Chief Executive Officer

**Russell M. Medford, M.D., Ph.D.**, President and Chief Executive Officer – AtheroGenics Inc.

**Joseph M. Patti, Ph.D.**, Vice President of Research and Development and Chief Scientific Officer

**Marc L. Preminger**, Senior Vice President, Chief Financial Officer (retired) – CIGNA Healthcare

**Louis W. Sullivan, M.D.**, Director and President Emeritus – Morehouse School of Medicine

**A. Keith Willard**, Chairman and Chief Executive Officer (retired) – Zeneca, Inc.



## SHAREHOLDER INFORMATION

### Headquarters

Inhibitex, Inc.  
9005 Westside Parkway  
Alpharetta, Georgia 30004  
Phone: 678.746.1100  
Fax: 678.746.1299

### Legal Counsel

Dechert, LLP  
New York, New York

### Annual Meeting

The annual meeting of shareholders will take place on May 18, 2006, at 9:00 am at The Company headquarters in Alpharetta, Georgia.

### Investor Information

#### Requests

Copies of the Inhibitex, Inc. 2005 Annual Report and Form 10-K and additional information may be obtained through the corporate website, by email or by letter.

#### Website

[www.inhibitex.com](http://www.inhibitex.com)

#### Email

[IR@inhibitex.com](mailto:IR@inhibitex.com)

### Ticker Symbol

Inhibitex, Inc. Common Stock is traded on the NASDAQ National Market under the symbol: INHX.

### Transfer Agents

American Stock Transfer  
New York, New York

### Independent Public

#### Accountants

Ernst and Young, LLP  
Atlanta, Georgia

#### Above Photograph:

**Front Row:** Robert T. Schweiger, William D. Johnston, Ph.D., Joseph M. Patti, Ph.D.  
**Back Row:** Russell H. Plumb, Samuel J. Michini, Seth V. Hetherington, M.D., David M. Wonnacott, Ph.D.

*Inhibitex, Inc. is a clinical stage biopharmaceutical  
company focused on the development and commercialization of first-in-field antibody-based products  
for the treatment and prevention of serious life-  
threatening bacterial and fungal infections.*



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[www.inhibitex.com](http://www.inhibitex.com)