Inhibitex, Incorporated
2004 Annual Report

A Year Of Achievements

inhibitex®

Revolutionary Thinking. Evolutionary Medicine.

during the first half of last year. We also completed a $50 million private investment (PIPE) in November. In total, we raised $89 million in gross proceeds during 2004, which puts us in a strong financial position. We closed the year with just over $87 million in cash and short-term investments, an amount that will fund us beyond the availability of data from our ongoing pivotal Veronate® Phase III trial.

OTHER SIGNIFICANT DEVELOPMENTS

In addition to favorable clinical, preclinical and financial developments during 2004, we achieved a number of other key accomplishments, including the following:

- Demonstrated exceptional scientific and clinical leadership by chairing a major session on bacterial infections at the International Congress on Antibiotic and Chemotherapy and giving a major presentation at an international conference on staphylococcal infections.
- Strengthened our intellectual property portfolio through the issuance of nine new patents, as well as having additional claims allowed on five patents.
- Obtained FDA Fast Track status for Aurexis®.
- Positioned ourselves to solve our long-term manufacturing need for Aurexis® by entering into a manufacturing arrangement with Lonza Biologics PLC.

LOOKING AHEAD

2004 was an exciting year for Inhibitex, but the work has just begun. We are focused on completing enrollment in our ongoing Veronate® Phase III clinical trial in the fourth quarter of 2005. Doing so will position us to have data available from this trial in the second quarter of 2006. Also, 2005 will be a critical year for our Aurexis® program. Data from the recently completed Phase II and Phase I trials will be available in the second quarter, and will provide the baseline information we need to appropriately design future efficacy trials for Aurexis®. Early in the second quarter, we will initiate another Phase II trial of Aurexis® in patients with cystic fibrosis.

We are also looking forward to moving into our new headquarters and research facility during the second quarter of 2005. This state-of-the-art facility will allow us to expand our research activities and consolidate all of our employees into one location.

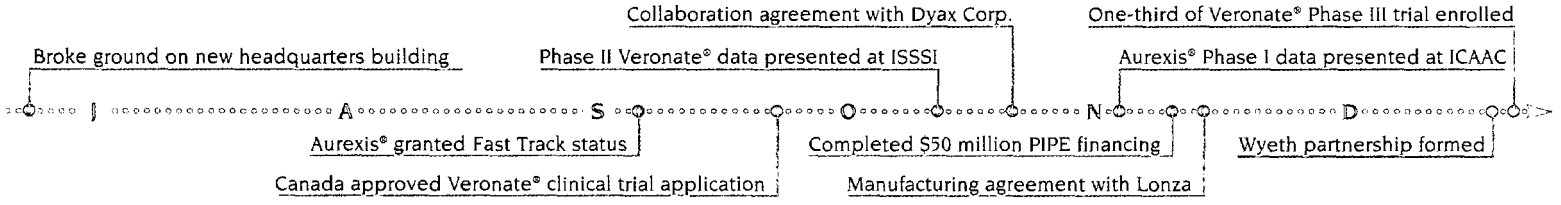
MAKING A DIFFERENCE

At Inhibitex, we have a unified, cohesive and experienced team, highly committed to developing novel, antibody-based products that we believe can save lives and make a difference in the quality of life for many. Our management team has been instrumental in bringing more than 20 drugs through development to market introduction. The strength of this experience, coupled with our talented and capable employees, are key assets to our continued success. Our objectives are clear and the entire organization understands what must be accomplished.

I thank our directors, management and employees for all of their support, effort and commitment to our fine organization. Also, I thank you, our shareholders, for helping us usher in a new era in fighting life threatening infections. We look forward to achieving our goal together.

Sincerely,

William D. Johnston, Ph.D.
President and CEO



William D. Johnston, Ph.D.
President and CEO

Dear Fellow Shareholders:

Since our inception in 1998, we have focused on a single goal – the development of antibody-based products to help prevent and treat serious, life-threatening bacterial and fungal infections. The results of more than a half century of experience with antibiotics and other anti-infectives demonstrates these drugs alone can not, and do not, adequately address these devastating infections. As a result, each year bacterial and fungal infections claim the lives of nearly 100,000 Americans. This figure exceeds the combined number of people who succumb to breast and prostate cancer.

Every day, approximately 250 Americans die from a hospital-associated infection.

Inhibitex was founded on the belief that antibodies can provide a viable solution to this critical, unmet medical need. This belief is stronger today than when the company was created.

This past year was a ***Year of Achievements*** for Inhibitex. We made tremendous progress on multiple fronts including significant advancements in our clinical programs, the expansion of our preclinical pipeline, securing critical manufacturing solutions, and achieving financial stability, all of which move us closer to making our goal a reality.

ADVANCING OUR CLINICAL DEVELOPMENT PROGRAMS

During 2004, we completed a 512-patient Phase II trial of Veronate® for the prevention of hospital associated infections in very low birth weight infants. Based on these results, we obtained the FDA's agreement for a pivotal Phase III trial that we initiated in the spring. By the end of 2004, we had enrolled nearly 700 infants in this 2,000-patient trial, and we recently passed the 1,000 patient mark.

In 2004 we also initiated and completed enrollment in a 60-patient Phase II trial for Aurexis®, our humanized monoclonal antibody for the treatment of *S.aureus* infections. In this trial, patients with confirmed *S.aureus* bloodstream infections were treated with standard of care antibiotics and then adjunctively administered either a placebo or Aurexis®. Additionally, we recently completed enrollment in a small Phase I trial of Aurexis® in patients with end-stage renal disease, or kidney failure, to assess their metabolism rates for Aurexis®.

MOVING OUR PRECLINICAL PIPELINE FORWARD

Our preclinical pipeline continues to advance towards the clinic. In 2004 we completed a number of preclinical studies in support of our staphylococcal vaccine program with Wyeth. We also, entered into a collaboration with Dyax to co-develop monoclonal antibodies for the prevention or treatment of serious enterococcal infections. Entercoccal infections are emerging as one of the most concerning infections in hospitals today. In support of the Veronate® Phase II outcomes, we expanded our understanding of the role of antibodies against MSCRAMM® proteins found on Candida.

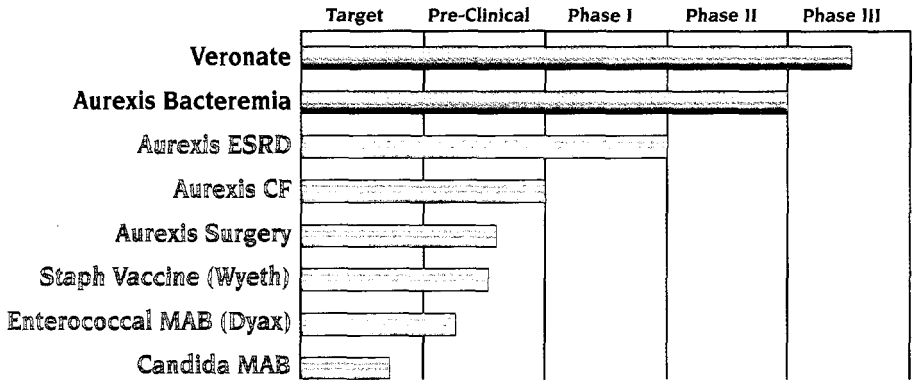
SECURING FINANCIAL STABILITY

A critical success factor for any emerging biopharmaceutical company is the ability to access capital to support its clinical and preclinical development programs. In early June, we completed an initial public offering that was primarily supported by our transition into late-stage clinical development

2004 *Milestones for This Year of Achievements*

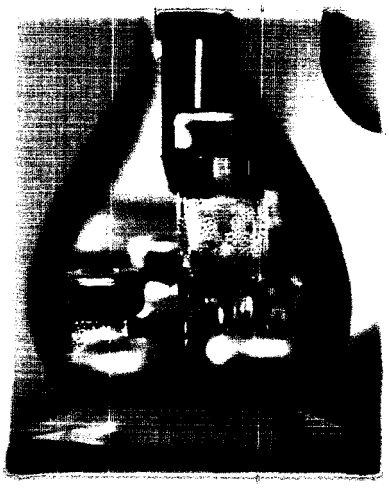
Each year, more than six million people worldwide acquire an infection during a hospital stay.

Deep Pipeline of Innovative Anti-Infectives



Inhibitex is a biopharmaceutical company committed to the discovery, development and commercialization of a pipeline of novel, antibody-based drugs for the treatment and prevention of serious, life - threatening bacterial and fungal infections in hospitalized patients.

Currently, we are focused on a number of drug development programs, all of which are based on our proprietary MSCRAMM® protein platform. MSCRAMM® proteins are a family of cell surface proteins that pathogenic organisms use to adhere or bind to specific sites in human tissue or on implanted biomaterials, such as catheters, vascular grafts or artificial joints, and are the means by which these organisms initiate and cause an infection. We believe the novel mechanisms of action of antibody-based products that target MSCRAMM® proteins can offer many advantages over existing anti-infective therapies, including:



- Improved patient outcomes
- Fewer adverse side effects
- Broad prophylactic utility
- A much lower likelihood of further inducing patterns of drug resistance in virulent pathogens

Our most advanced product candidate, Veronate®, currently is being evaluated in a pivotal Phase III clinical trial for the prevention of hospital-associated infections in very low birth weight infants. Our second product candidate, Aurexis®, is a monoclonal antibody currently being evaluated in several clinical trials, including a Phase II trial for the treatment of patients with documented *S.aureus* bloodstream infections.

Our pre-clinical programs include exciting opportunities; a collaboration with Dyax Corp. to co-develop monoclonal antibodies that target MSCRAMM® proteins on enterococci, and a partnership with Wyeth to develop staphylococcal vaccines.

inhibitex®

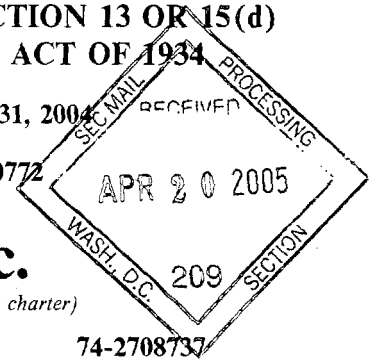
UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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, 2004

Commission file number: 000-50772



Inhibitex, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**74-2708737**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*

1165 Sanctuary Parkway
Suite 400
Alpharetta, GA 30004
(678) 746-1100
(Registrants' telephone number, including area code)

Securities registered pursuant to section 12(b) of the Act:
None

Common Stock, par value $0.001 per share
(Title of Class)

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 an accelerated filer (as defined in Rule 12b-2 of 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, 2004 was $98,654,805

Number of shares of Common Stock outstanding as of March 21, 2005: 25,187,407

Documents incorporated by reference:

Portions of the definitive Proxy Statement with respect to the 2005 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (Part III).

TABLE OF CONTENTS

		Page
	Part I	
Item 1	Business	3
Item 2	Properties	36
Item 3	Legal Proceedings	36
Item 4	Submission of Matters to a Vote of Security Holders	37
	Part II	
Item 5	Market for the Registrant's Common Equity, Related Stockholders Matters, and Issuer Purchases of Equity Securities	37
Item 6	Selected Financial Data	38
Item 7	Management's Discussion and Analysis of Financial Condition and Results of Operations	40
Item 7A	Quantitative and Qualitative Disclosures about Market Risk	49
Item 8	Financial Statements and Supplementary Data	50
Item 9	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	50
Item 9A	Controls and Procedures	50
Item 9B	Other Information	50
	Part III	
Item 10	Directors and Executive Officers of the Registrant	51
Item 11	Executive Compensation	51
Item 12	Security Ownership of Certain Beneficial Owners, Management, and Related Stockholder Matters	51
Item 13	Certain Relationships and Related Transactions	51
Item 14	Principal Accountant Fees and Services	51
	Part IV	
Item 15	Exhibits, Financial Statement Schedule and Reports on Form 8-K	52
Signatures		55

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 *S. aureus* and candida, and reduce overall mortality in very low birth weight infants;
- potential future revenue from collaborative research agreements;
- our ability to 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 number of sites we intend to utilize in our ongoing clinical trials;
- the anticipated length of time to fully enroll and generate data from our Phase III Veronate trial;
- successful results from the ongoing Phase III trial for Veronate being sufficient to support a BLA submission for Veronate;
- the availability of suitable alternative sources of plasma for the manufacture of Veronate;
- the anticipated time frame to generate data from our Phase II Aurexis trial;
- our potential 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;
- our plans to establish partnerships or collaborations with other entities to develop and commercialize our product candidates in other countries;
- the potential benefits of Fast Track and Orphan Drug status;
- increases in our research and development expenses, general and administrative expenses and operating losses in the future;
- the impact that adoption of SFAS No. 123(R) may have on our results of operations;

- our future financing requirements and how we expect to fund them;
- the number of months that our current cash, cash equivalents and short-term investments will allow us to operate; and
- timing of our occupancy into a new facility

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 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 secure and our use of third-party contract clinical research 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; our failure to obtain regulatory approval to 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 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 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.

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 late-stage clinical development. In February 2004, we completed a 512 patient Phase II clinical trial for our lead product candidate, Veronate, which we are developing for the prevention of hospital-associated infections in premature, very low birth weight, or VLBW, infants. In May 2004, we initiated enrollment in a Phase III clinical trial for Veronate. Veronate has been granted Fast Track and Orphan Drug status by the FDA. Our second product candidate, Aurexis, is currently being evaluated in a 60 patient Phase II clinical trial as a first-line therapy, in combination with antibiotics, to treat serious, life-threatening *Staphylococcus aureus,* or *S. aureus,* bloodstream infections in hospitalized patients. We completed the enrollment of this trial in December 2004. Aurexis has also been granted Fast Track status by the FDA. In addition to Veronate and Aurexis, we have three

other preclinical product candidates that are being developed to prevent or treat serious bacteria or fungal infections.

All of our product candidates have been developed based on our expertise in MSCRAMM proteins, for which we own or have licensed numerous patents and patent applications. The development of our product candidates are based on the discovery that MSCRAMM proteins found on the surface of pathogenic organisms play a prominent role in the process of infection. We have demonstrated that antibodies that bind to these MSCRAMM proteins can prevent or reduce the severity of infections by interfering with the attachment of the pathogenic organisms to human tissue or implanted medical devices. We believe our expertise in MSCRAMM proteins and the antibodies that target them will enable us to discover additional novel therapies, as well as to identify, license or acquire products that prevent and treat life-threatening infections.

We have retained all worldwide rights to Veronate and Aurexis. We intend to commercialize Veronate in the United States by establishing a specialized, hospital-based sales force. In markets outside the United States, we intend to enter into collaborations to develop and commercialize our product candidates, including Veronate. While we plan to establish a worldwide collaboration for Aurexis, we intend to retain co-promotion rights to Aurexis in the United States. We currently do not have any commercialization capabilities, and it is possible that we may never be able to successfully commercialize any of our product candidates. We have neither received regulatory approval for, nor derived any commercial revenues from, any of our product candidates.

Hospital-Associated Infections

Hospital-associated infections generally refer to infections that patients acquire while being treated or cared for in a hospital 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 and Decision Resources, a market research firm, there are an estimated six million hospital-associated infections worldwide each year, the vast majority of which are caused by bacteria and fungi. The CDC estimates that approximately two million hospital-associated infections occur in the United States each year, which are implicated in approximately 90,000 deaths per annum. According to the CDC, these infections also result in an estimated $5.0 billion in healthcare costs annually in the United States.

Antibiotics are the predominant agents used to treat hospital-associated infections. Antibiotics are small molecule compounds whose primary mechanisms of action are 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 opsoniszation.

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 patients where 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:

Product Candidate	Intended Use	Stage of Development	Worldwide Commercial Rights
Veronate	Prevention of hospital-associated infections in VLBW infants	Phase III	Inhibitex
Aurexis	First-line therapy for serious *S. aureus* infections in combination with standard of care antibiotics	Phase II	Inhibitex
Enterococcal monoclonal antibodies	Hospital-associated enterococcal infections	Preclinical	Inhibitex/Dyax Corp.
Candida monoclonal antibodies	Hospital-associated candida 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 that 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 May 2004 we initiated enrollment in a 2,000 patient Phase III clinical trial of Veronate. 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 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. Also, as permitted by FDA regulations governing Fast Track status, we intend to submit a "rolling" BLA for Veronate. 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. By utilizing this rolling submission, we intend to file the chemistry, manufacturing and controls, or CMC, section of the BLA for Veronate by the end of 2005. We may also file other sections of the BLA for Veronate prior to the completion of its ongoing Phase III clinical trial. In addition, we anticipate requesting a priority review for this 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 we will receive approval for a rolling BLA submission; we will be granted a priority review; the duration of the approval process for Veronate will be reduced; or 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.

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

According to the National Center for Health Statistics, in 2002 there were 58,544 VLBW infants born in the United States. 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 40,000 of these VLBW infants weighed 1,250 grams or less at birth. 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, and the use of intravenous catheters to deliver nutritional fluids and medication. Various studies indicate that 30-50% of VLBW infants weighing 1,250 grams or less at birth will develop at least up to 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 any 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 hospital when compared to those that do not acquire an infection. A recent study conducted by the NICHD also indicated that those VLBW infants that acquire an infection during their stay in the NICU, also experience significant impairment in their neurological development, including cerebral palsy and mental development as compared to those that did not acquire an infection.

Veronate Clinical Trials

Phase III. Veronate is the subject of an ongoing Phase III clinical trial that we initiated in May 2004. This 2,000 patient trial 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. Patients will be 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, 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 6% infection rate. Secondary endpoints of this Phase III trial include the reduction in the frequency of candidemia, coagulase-negative staphylococcal, or CoNS, infections, from staphylococcal infections and all-cause mortality. If the primary endpoint is achieved, we believe this trial will be sufficient for the submission of a BLA for Veronate.

In January 2005, an independent Data Safety Monitoring Board met to review safety and other data available from the first 500 patients enrolled in this trial and unanimously recommended that the trial proceed as designed without modification. As of March 21, 2005 we have enrolled 962 patients in this trial.

We anticipate that the trial will be conducted in 90-100 neonatal intensive care units in the United States and Canada, approximately 45 of which participated in our Phase II trial for Veronate. We anticipate that full enrollment in this trial will be completed in the fourth quarter of 2005, with data available in the second quarter of 2006. The results of the Phase III trial may not confirm the Phase II results.

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 subjects.

The results of the Phase II clinical trial demonstrated that Veronate was generally safe and well tolerated among treated VLBW infants. The most common adverse events, 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 4 of 1,280 infusions were discontinued or interrupted due to adverse events possibly related to Veronate.

The preliminary efficacy 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 results 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.

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. Results from this trial indicated that Veronate was generally safe and well tolerated in VLBW infants.

Aurexis

Aurexis is a humanized monoclonal antibody currently in a Phase II clinical trial for evaluation as a first-line therapy, in combination with antibiotics, for the treatment of serious, life-threatening *S. aureus* bloodstream infections in hospitalized patients. This trial was initiated in February 2004, and the enrollment phase of the trial was completed in December 2004. We have also completed enrollment in a Phase I trial of Aurexis in patients with end stage renal disease. We anticipate initiating a Phase II clinical trial of Aurexis in patients with cystic fibrosis in the second quarter of 2005, and may initiate additional clinical trials of Aurexis in other patient populations in the future. Aurexis has been granted Fast Track designation by the FDA for the bloodstream infection indication. Aurexis and Veronate target the same MSCRAMM protein on *S. aureus.*

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 Decision Resources, Inc., a market research firm, there were an estimated one million hospital-associated *S. aureus* infections worldwide in 2002, of which approximately 225,000 occurred in the United States. Of the estimated 225,000 *S. aureus* infections that occurred in the United States, we estimate, based on data compiled by Decision Resources, Inc., that approximately 50,000 were 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 are approximately 35%, as compared to the mortality rate associated with methicillin-susceptible *S. aureus* bloodstream infections of approximately

20%. Studies indicate that patients that 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 hospital.

Aurexis Clinical Trials

Phase II. We are currently conducting a 60 patient, multi-center, randomized, double-blind, placebo-controlled Phase II clinical trial for Aurexis, for which we completed the enrollment in December 2004. Patients with documented *S. aureus* bloodstream infections 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 for Aurexis are to evaluate:

- the safety of a single administration of Aurexis;
- the pharmacokinetics of a single dose of Aurexis; and
- the preliminary efficacy of a single dose of Aurexis.

The follow-up period for all patients in this trial has been completed and we expect to have data available during the second quarter of 2005. Results of this Phase II trial may not confirm the Phase I safety and pharmacokinetic results.

Phase I. We recently completed enrollment in an eight patient Phase I trial of Aurexis to evaluate its safety and pharmacokinetics in patients with end stage renal disease, or ESRD. The objective of this trial is to assess the suitability of including these patients in future clinical trials of Aurexis for the treatment of documented *S. aureus* bloodstream infections. We anticipate that data from this trial will be available during the second quarter of 2005.

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. Results from this trial indicate that Aurexis was well tolerated by the healthy volunteers. 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 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 three product candidates in preclinical development, all of which are based on the use of MSCRAMM proteins.

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. In the United States, greater than 24% of confirmed enterococcal infections reported in the June 2000 report of the 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, those with organ transplants or those 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:

Complete the Phase III Trial and Obtain Regulatory Approval for Veronate. We are focused on completing the clinical and regulatory development of Veronate. We intend to complete the ongoing Phase III clinical trial evaluating Veronate for the prevention of hospital-associated infections in VLBW infants. If data from this trial are supportive, we intend to proceed with the filing of a BLA for Veronate. Veronate has been granted Fast Track status, which may allow for an expedited review by the FDA.

Advance the Development of Aurexis and Our Preclinical Product Candidates. We are developing Aurexis as a first-line therapy for the treatment of serious *S. aureus* infections in combination with antibiotics. Aurexis is currently being evaluated 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 and we intend to evaluate it in other indications in the future. We are also advancing the development of our preclinical product candidates focused on enterococcal and candida monoclonal antibodies.

Establish a Specialized, Hospital-Based Sales Force in the United States. We have retained all worldwide rights for Veronate and Aurexis. We intend to establish a specialized hospital-based sales force of approximately 50 individuals 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 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 believe that first-in-class drugs may capture superior market share and have competitive advantages over drugs subsequently introduced. We will 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. 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 sales force of approximately 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 one 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. The 1,000 hospitals that contain NICUs also account for 45% of all hospital beds in the United States, therefore we believe our sales force will be able to effectively market Aurexis and our other product candidates in these hospitals. 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 certain naturally occurring human antibodies that specifically target

MSCRAMM proteins. This plasma is collected 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, Inc., 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.

In January 2005, we entered into a second supply agreement with another supplier of plasma. We currently cannot reasonably predict how much plasma this new supplier may supply us in the future, if any. 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. In addition to DCI and this new supplier, we believe there are additional suppliers of plasma for Veronate and we anticipate entering into supply agreements with other suppliers in the future, as necessary.

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. The manufacturing processes used to manufacture Veronate and Aurexis are vastly different, therefore 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 United States, 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, 2004, our maximum purchase commitments under this agreement through December 31, 2007, were approximately $5.2 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. Because Nabi is developing both a product to prevent *S. aureus* infections in VLBW infants and a staphylococcal vaccine, we consider Nabi to be a potential competitor.

We have also used a contract manufacturer, Avid Bioservices, Inc., or Avid, to produce clinical trial materials for Aurexis for use in our Phase I and II clinical trials. As of December 31, 2004, we have no long-term obligations under any of our prior agreements with Avid.

In November 2004, we entered into an agreement with Lonza Biologics PLC for the manufacture of Aurexis. Under the terms of the agreement, Lonza has agreed to perform numerous process development related services and manufacture two cGMP lots of Aurexis for our use in future clinical trials. As of December 31, 2004, our maximum purchase commitments under this agreement through June 30, 2008, were approximately 3.6 million pounds sterling or $6.7 million. However, prior to June 30, 2005 we can cancel the second cGMP lot without incurring any financial obligations associated with that lot, in which case our purchase commitments to Lonza would be reduced. At this time, we have not contracted with Lonza to manufacture any additional lots of Aurexis. A change in contract manufacturers for commercial lots may require further clinical trials for Aurexis.

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. and Vicuron Pharmaceuticals, 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 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 clinical trials 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.

Biosynexus, Inc. is 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.

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 are licensed under 25 issued United States patents and over 25 pending United States patent applications, as well as corresponding international filings in the field of MSCRAMMs generally. We own seven pending United States patent applications and co-own two issued United States patents and three pending United States patent application, as well as corresponding international and foreign applications. The issued United States patents expire between 2009 and 2018. 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 *S. aureus* and *S. epidermidis* MSCRAMM proteins. 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 and the ClfA MSCRAMM protein of *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 pending United States ClfA monoclonal antibody patent application relates to Aurexis and claims a composition of matter for a monoclonal antibody to the ClfA protein. This US application has been allowed and will issue in the second quarter of 2005. 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 2005. We believe that we do not infringe the corresponding United States patents, which have narrower claims than those issued in Europe. We have filed an opposition proceeding with the EPO to revoke or substantially narrow a patent issued to Montana State University relating in broadly to a therapeutic composition including a pathogen adhesion molecule. This patent has been licensed to Ligocyte Pharmaceuticals, Inc. of Bozeman, MT. No substantive proceedings have occurred to date in this opposition.

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 to 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 the 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 $1.3 million through December 31, 2004. We have no future minimum royalty or milestone obligations pursuant to these agreements, but we currently pay Texas A&M approximately $350,000 in annual sponsored research payments. Our obligation to pay sponsored research payments ends in November 2005. 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 (BRI)/Trinity College Dublin

We have obtained a royalty-bearing license from BioResearch Ireland, or BRI, under the United States SdrG patents and related applications licensed to us from Texas A&M, as described above. Scientists from both Texas A&M and BRI are co-inventors on these applications. We 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 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 are subject to research rights retained by BRI. BRI 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 $382,000 through December 31, 2004. We have no future minimum royalty or milestone obligations pursuant to these agreements, but we currently pay BRI 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 $3.8 million in an upfront license fee and annual research support payments from Wyeth as of December 31, 2004. 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. 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 Corp.

In October 2004, we entered into a collaboration agreement with Dyax Corp. 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 would 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 $693,000 as of December 31, 2004.

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, 2004. 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, 2004. 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, the 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, 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 form 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, and any other monoclonal product candidates that we may develop, are being regulated through CDER.

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. The main purpose of the 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 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 or 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 likely to be effective and has an acceptable safety profile, one or more Phase III trials are generally undertaken to further demonstrate 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 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 the Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, we, the FDA or an IRB 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

Once our clinical trials have been completed, 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. Fast Track status products, such as Veronate and Aurexis are required to conduct Phase IV clinical trials.

Post-Approval Regulations

Even if 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 must be in compliance 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 and additional government regulations may be enacted which 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.

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. Further, an accelerated approval process is potentially available to product candidates that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses. 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 requires as a condition of the approval of an application for certain Fast Track products on additional post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Fast Track status also provides for the potential for a product candidate to have a "Priority Review." A Fast Track status allows for portions of the BLA to be submitted to the FDA for review prior to the completion of the entire application, which could result in a reduction in the length of time it would otherwise take the FDA to complete its review of the BLA. 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.

Employees

As of December 31, 2004, we had 74 full-time employees, 58 of whom were engaged in research and development, clinical, regulatory, and quality assurance and control, and 16 of whom were engaged in administration, accounting, 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 450 Fifth Street, NW, 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 that contains the reports, proxy and information statements, and other information filed electronically. Our website address is 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.

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 and financial condition and our ability to raise additional capital in the future. 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 still 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 ability to generate significant product revenues will depend on the successful development and commercialization of Veronate. We believe we will need to raise additional funds before we can advance Veronate through the regulatory review and approval process and commercialization.

If the data from our ongoing Phase III clinical trial for Veronate are not satisfactory, we will not be able to proceed with the filing of a Biologic License Application, or BLA, for Veronate, or we may be forced to narrow the indication for which we seek marketing approval or perform additional Phase III trials. If we believe the results of our ongoing, or if necessary, an additional Phase III trial are satisfactory and we file a BLA for Veronate, the FDA may not accept our filing, may request additional information, require additional clinical trials, limit the approved use of such product or ultimately not grant marketing approval for Veronate. Veronate has been granted Fast Track status by the FDA. Fast Track status may qualify Veronate for expedited review by the FDA, but does not assure such an expedited review. Fast Track status may be withdrawn if the FDA 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 not yet been used by us or others to successfully develop any approved drugs. We may fail to produce an approved drug that targets MSCRAMM proteins, which could materially harm our business. If Phase III clinical trial results for Veronate are unsatisfactory, this may cast doubt on the viability of our MSCRAMM protein approach and our entire portfolio of product candidates.

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 and complexities present in a development stage biopharmaceutical company. In order to receive regulatory approval for the commercialization of our product candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy. Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Delays, or clinical setbacks or failures may occur at any time. If the enrollment of patients in 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 the desired safety and efficacy traits despite having progressed through earlier clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the submission

of a BLA or to obtain regulatory approval in the United States or elsewhere. We have completed a 512 patient Phase II trial for Veronate and a 19 patient Phase I trial for Aurexis. The results of these trials were not statistically significant. We are also nearing the completion of a 60 patient Phase II trial of Aurexis. There can be no assurance that the results of these trials are predictive of the outcomes of our later-stage trials for Veronate and Aurexis. In addition, we had no control over the antibiotic treatments used by investigators in conjunction with Aurexis in our Phase II trial. This may make our Phase II clinical trial data for Aurexis difficult to interpret, which may require us to conduct additional Phase II clinical trials.

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. 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 that we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, and novelty of, and need for the product, requires the expenditure of substantial resources, involves post-marketing surveillance, and may involve ongoing requirements for post-marketing studies. 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 commercialize any product candidates that we develop;
- diminish any competitive advantages that we may have or attain; and
- adversely affect revenues or receipt of royalties from the sale of our products.

Furthermore, any required regulatory approvals, if granted, may be withdrawn later. If we fail to comply with applicable FDA and other regulatory requirements at any time, we may be subject to restrictions, including:

- delays in clinical trials or commercialization;
- 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.

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.

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, outside 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. Furthermore, 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 the FDA determines that our third-party vendors are not in compliance with applicable regulations, we may be required to delay, repeat or terminate such clinical trials. Any delay, repetition or termination of our clinical trials could 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 plasma, which contains the specific antibodies needed to manufacture Veronate, from DCI Management Group, Inc., or DCI, under a long-term supply contract. While we have also recently entered into a long-term supply arrangement with one other supplier to provide us with plasma for the commercialization of Veronate we expect in the near-term to depend on DCI for the majority of this critical raw material. Although our agreement with this other supplier is 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 cost, as well as our ability, to manufacture Veronate on a timely basis.

The collection and testing of plasma, including screening procedures for plasma donors, is 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 our product candidates for our clinical trials. 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:

- Each of our current product candidates is, and will likely continue to be, made by a single third-party contract manufacturer. We do not have 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.

- Changing our current or future manufacturers may be difficult for us, as the number of potential contract manufacturers that would be able to make our products is limited and a change may interrupt our ability to continue with our clinical trials or supply our products to the marketplace if we obtain approval for a product candidate. In accordance with FDA-mandated current good manufacturing practices, or cGMPs, changing manufacturers will require re-validation of the manufacturing processes and procedures and may require further clinical trials, which may be costly and time consuming.
- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business.
- The manufacture of biologic products requires meeting 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 unusable in our clinical trials or commercially.
- Our manufacturers' plants may be closed as a result of a natural disaster.
- To date, our product candidates have been manufactured in small quantities for preclinical studies and clinical trials. If we are unable to increase the manufacturing scale of, or increase the capacity for, our product candidates, their regulatory approval or commercial launch may be delayed; we may experience a shortage in supply, or the cost to manufacture our products may adversely affect the profitability of our products. We cannot assure you that we can find alternative manufacturers acceptable to us who can do so.

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, including 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.

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 has antibody based product candidates currently being evaluated in various stages of clinical trials that are directed towards preventing staphylococcal infections, one of which could potentially compete with Veronate, if approved. Nabi's other antibody-based product candidate could potentially compete with our staphylococcal vaccine that is the subject of our worldwide license and collaboration agreement with Wyeth. Under our 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.

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, 2004, we have incurred a cumulative deficit of approximately $103.0 million. Our losses to date have resulted principally from:

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

We anticipate incurring substantial and increasing losses for the foreseeable future as we further develop our product candidates, particularly Veronate, 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. We also expect that our general and administrative expenses will increase as we add additional personnel to support our operations. We cannot assure you that we will ever become profitable.

We may be forced to delay or curtail the development or commercialization of our product candidates if we are unable to obtain additional funding.

We expect that our need for additional capital will be substantial 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 commercialize our product candidates;
- the costs associated with protecting and expanding our patent and other intellectual property rights;
- future payments, if any, received or made under existing or possible future collaborative arrangements;
- the timing of regulatory approvals needed to market our product candidates;
- market acceptance of our products; and
- the need to acquire licenses to new products or compounds.

We anticipate that our existing cash, cash equivalents and short-term investments will enable us to operate for a period of approximately 21 months. We have no committed sources of additional capital. We cannot assure you that funds will be available to us in the future on favorable 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 on unattractive terms or relinquish rights to certain technologies or product candidates that we would not otherwise relinquish in order to continue independent operations.

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 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, 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 Corp. 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 necessary for us to fund research and development activities, provide a suitable manufacturer, obtain regulatory approvals and to successfully commercialize any product candidates that result form 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.

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 and the price of our common stock may be adversely affected.

Our success depends in part on our ability to attract and retain highly qualified management and personnel and academic scientists and clinicians as advisors or consultants. We are currently dependent upon the efforts of our executive officers, each of whom is party to an employment agreement with us. In order to pursue our product development and commercialization strategies, 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 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.

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 diseases and develop new technologies and treatments. Our current and potential competitors generally include, among others, major multinational pharmaceutical companies, biotechnology firms, universities and other research institutions. In particular, we are aware that Nabi, Biosynexus, Inc., and NeuTec PLC are developing protein-based product candidates, including antibodies, enzymes and peptides, for the prevention and treatment of staphylococcal infections. 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.

Most of our product candidates 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. 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. Orphan Drug status in the United States is intended to provide, subject to certain limited exceptions,

market exclusivity in the United States for seven years for products that are the first to receive FDA approval for the designated indication. We believe that Nabi and Biosynexus, Inc. have also been granted Orphan Drug status for their antibody-based products that are being evaluated in clinical trials for the prevention of staphylococcal infections in premature infants. If we are not 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 our products 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 and support from third-party payers. The degree of market acceptance for any product that we commercialize will depend on a number of factors, including:

- 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 their 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 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 or adequate remedies for our technology 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 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 any 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. As described under "Competition," we believe Biosynexus is developing a monoclonal antibody against staphylococcal organisms for use in the pediatric market. 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. 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.

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.

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. We currently have no internal sales and marketing capabilities, or an infrastructure to support such activities, and have no 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. 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 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 our sales 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 coverage and adequate reimbursement rates for our products, our revenues and potential for profitability will be harmed.

In both the United States and 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 of these third-party payers.

Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare, including 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 pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we receive for any 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.

Veronate is a blood product derived from human plasma. The administration of blood products could result in the transmission of infectious diseases 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 are 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 transmission of both known and unknown pathogens or impurities to patients being treated with Veronate. If Veronate were known to have transmitted any harmful pathogens or impurities, approval of Veronate may be delayed, suspended or withdrawn, we could be forced to recall the product, and we may be subject to product liability claims. Further, if public concern arises that any blood product other than Veronate may transmit a disease, approval for Veronate may be delayed or withdrawn, or the use of Veronate may be reduced or limited due to these concerns.

If a product liability claim is successfully brought against us for uninsured liabilities or 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 will need to increase our product liability coverage. Such insurance coverage may not protect us against any or all of the product liability claims which may be brought against us in the future. We may not be able to acquire or maintain adequate such 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 under collaborative arrangements. To date, these payments have been in the form of up-front license and research and development support payments. 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 paid. Therefore, our historical and current revenues may not be indicative of our ability to continue 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 be uneconomic to us. As of December 31, 2004, our minimum purchase commitments amounted to an aggregate of $18.3 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 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 through clinical development and regulatory approvals, we will need to add or expand research and clinical development, regulatory, manufacturing, information technology and marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand we will need to hire additional personnel and add corporate functions that we currently do not have. Our ability to manage our operations and 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 existing systems and controls.

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 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 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;
- 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 policies;
- announcements by us 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;

- changes in accounting principles; 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, our stockholders may be unable to sell their shares of common stock at or above the price they paid.

If we raise additional capital in the future, the ownership of our current stockholders could be diluted.

We expect that we will need to raise additional capital in the future. We may not be able to do so on favorable terms, if at all. Additional equity financings we may undertake may be dilutive to the holders of our common stock or cause the price of our common stock to decline. If we obtain funds through a credit facility or through the issuance of debt or preferred securities, these securities would have rights senior to the rights of a common stockholders. If we cannot obtain sufficient capital on commercially acceptable terms, we will not be able to fully carry out our business strategy.

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 deemed appropriate.

Insiders will continue to have substantial control over us after this offering, which could delay or prevent a change in our control.

As of December 31, 2004, our directors and executive officers together with their affiliates, beneficially owned, in the aggregate, approximately 58.7% of our outstanding shares of common stock. As a result, these stockholders, acting together, would 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 election of directors;
- 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 in which we are incorporated, 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*

Our offices and laboratory facilities are currently located in two separate leased properties in Alpharetta, Georgia, a northern suburb of Atlanta. We lease our office space, which is approximately 13,500 square feet, under a lease which expires in June 2005. We lease our laboratory facility, which is approximately 12,500 square feet, under a separate sub-lease, which expires in December 2005. In December 2003, we entered into an agreement to lease a 51,000 square foot facility in Alpharetta, Georgia, which is being built to our specifications, where we will relocate all personnel from both of our existing facilities. We anticipate that we will occupy this new facility during the second quarter of 2005, at which time we expect that our expense, including minimum lease obligations for this facility, and amortization of leasehold improvements paid by the lessor will approximate $1.0 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 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. The court's ruling also indicated that Biosynexus had not shown a substantial likelihood that it will ultimately prevail on the merits of its case at trial. 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.

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*

Not Applicable

PART II

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

The Company's common stock trades on The Nasdaq National Market under the symbol "INHX." At March 21, 2005, the Company had 113 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 June 4, 2004.

	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	

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, 2002, 2003 and 2004 and the balance sheet data as of December 31, 2003 and 2004 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, 2000 and 2001; and the balance sheet data as of December 31, 2000, 2001, and 2002 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, 2004 were derived from our audited financial statements.

	Period from Inception (May 13, 1994) through December 31, 2004	Years Ended December 31,				
		2000	2001	2002	2003	2004
	(In thousands, except per share data)					
Statement of Operations Data:						
Revenue	$ 3,812	$ 634	$ 271	$ 900	$ 1,096	$ 650
Operating expenses:						
Research and development	75,039	5,864	7,099	15,615	18,991	22,581
General and administrative	16,303	1,121	1,847	3,328	4,581	4,040
Amortization of deferred stock compensation	649	—	—	—	176	473
Total operating expenses	91,991	6,985	8,946	18,943	23,748	27,094
Loss from operations	(88,179)	(6,351)	(8,675)	(18,043)	(22,652)	(26,444)
Interest and other income (expense), net	1,606	(112)	568	430	319	532
Net loss	(86,573)	(6,463)	(8,107)	(17,613)	(22,333)	(25,912)
Dividends and accretion to redemption value of redeemable preferred stock	(16,382)	(461)	(1,271)	(5,626)	(6,201)	(2,823)
Net loss attributable to common stockholders	$(102,955)	$ (6,924)	$ (9,378)	$(23,239)	$ (28,534)	$ (28,735)
Basic and diluted net loss attributable to common stockholders per share		$ (16.85)	$ (21.17)	$ (47.83)	$ (54.19)	$ (2.52)
Pro forma basic and diluted net loss attributable to common stockholders per share (unaudited) (1)					$ (2.81)	
Weighted average shares used to compute basic and diluted net loss attributable to common stockholders per share		410,945	442,980	485,842	526,578	11,416,354
Pro forma weighted average shares used to compute basic and diluted net loss attributable to common stockholders per share (unaudited) (1)					10,145,137	

	As of December 31,				
	2000	2001	2002	2003	2004
Balance Sheet Data:					
Cash and cash equivalents	$ 7,982	$ 1,404	$ 28,658	$ 26,649	$ 71,581
Short-term investments	—	—	1,000	1,499	15,624
Working capital (deficit)	5,737	(1,360)	25,838	23,529	79,560
Total assets	9,708	3,622	31,942	30,662	91,239
Long-term debt and capital leases, less current portion	387	572	459	1,795	807
Redeemable convertible preferred stock and warrants	19,276	20,558	70,934	95,608	—
Deficit accumulated during the development stage	(13,070)	(22,448)	(45,686)	(74,220)	(102,955)
Total stockholders' (deficit) equity	(12,304)	(21,666)	(44,886)	(73,226)	80,546

(1) See Note 3 of Notes to Financial Statements for a description of the method used to compute pro forma basic and diluted net loss per common share and number of shares used in computing pro forma basic and diluted net loss per common share.

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 antibody-based products for the prevention and treatment of serious bacterial and fungal infections. We currently have two product candidates in late-stage clinical development. Veronate, our lead product candidate, is the subject of a 2,000 patient Phase III clinical trial, for which we initiated enrollment in May 2004. We are developing Veronate for the prevention of hospital-associated infections in premature, very low birth weight, or VLBW, infants. In February 2004, we completed a 512 patient Phase II clinical trial of Veronate. Veronate has been granted Fast Track and Orphan Drug status by the FDA. Our second product candidate, Aurexis, is currently being evaluated in a 60 patient Phase II clinical trial as a first-line therapy, in combination with antibiotics, to treat serious, life-threatening *Staphylococcus aureus,* or *S. aureus,* bloodstream infections in hospitalized patients. We recently completed the enrollment phase of this trial. In addition, we have three preclinical product candidates that are being developed to prevent and treat serious infections.

We are a development stage company that has generated significant losses since our inception in May 1994. We expect to incur substantial and increasing losses for at least the next several years as we continue the development of our product candidates, particularly Veronate and Aurexis, continue our other research and development activities and establish a commercial infrastructure. We currently do not have any 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, which are based on our expertise in MSCRAMM proteins. As of December 31, 2004 we had an accumulated deficit of $103.0 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 $650,000 related to the amortization of deferred stock compensation. We anticipate that our quarterly and annual results of operations will fluctuate due to several factors, including progress made in our 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. Therefore, meaningful predictions of our future operations are 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, quarterly research and development support payments we have received in connection with a license and collaboration agreement with Wyeth. If our development efforts result in regulatory approval and the successful commercialization of any of our product candidates, we expect the majority of our future revenues will result from product sales. In addition, in the future we may generate revenues from up-front or milestone payments in connection with collaborative or strategic relationships and royalties resulting from the licensing of our intellectual property.

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, 2002, 2003 and 2004. 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,		
	2002	2003	2004
		(In thousands)	
Direct external costs:			
Veronate	$ 6,277	$ 7,620	$ 8,851
Aurexis	1,472	2,586	3,120
Unallocated costs and overhead	7,866	8,785	10,610
Total research and development expenses	$15,615	$18,991	$22,581

We expect our research and development costs to increase in the future. In the near-term, we expect to expend a greater portion of our resources on the development of our two most advanced product candidates, Veronate and Aurexis, than on the development of our preclinical product candidates due to the number of patients we expect to enroll in the clinical trials for these product candidates and the related cost of manufacturing clinical trial materials. Due to the progress and timing of clinical trials, such expenditures are likely to be uneven in future periods. Although we are currently focused primarily on advancing Veronate through an ongoing Phase III clinical trial, and Aurexis through Phase I and Phase II clinical trials, we will make determinations as to how much funding to direct to these programs on an on-going basis in response to their scientific, clinical and regulatory success. From inception through December 31, 2004, we have incurred approximately $75.0 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 clinical and commercial supplies of our product candidates; and
- the effect of competing technological and market developments.

The failure to complete the development of our product candidates in a timely manner 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, business development and human resource functions. Other significant costs include professional fees for legal, accounting , market research and other consulting services, as well as insurance premiums. 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 our product candidates, particularly Veronate. From inception through December 31, 2004, we have incurred approximately $16.3 million in general and administrative expenses.

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 consists 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 IPO, or initial public offering 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.

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:

Revenue Recognition. We recognize revenue primarily 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 where 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*, and SAB No. 104, *Revenue*

Recognition, and Financial Accounting Standards Board or FASB's Emerging Issues Task Force No. 00-21, *Revenue Arrangements with Multiple Deliverables.*

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 costs incurred for such service as of each balance sheet date. Examples of 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 our contract manufacturers in conjunction with the manufacture of materials for our clinical trials.

In connection with these service-related fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. In order to estimate costs incurred to date, but not yet invoiced, we analyze the progress of the clinical trial and related activities, invoices received and budgeted costs when evaluating the adequacy of the accrued liability for these related costs. The majority of our service providers invoice us monthly in arrears for services performed or based upon meeting pre-determined milestones. In the event that we are not notified of or we do not identify certain costs that have been incurred, or we underestimate or overestimate the level or costs of services performed, our reported expenses for such period might be too low or too high. We must sometimes estimate the date on which certain services commence and the level or costs of services performed on or before a given date. We make these estimates based upon the facts and circumstances known to us at the time and in accordance with generally accepted accounting principles.

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 Statement of Financial Accounting Standards, or 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. We continue to follow this method until July 1, 2005 with the adoption of FASB Statement No. 123 (revised 2004), *Share-Based Payment.*

Prior to our IPO 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 our shares of common stock, prior valuations of our common stock and the impact of events or milestones that had occurred since. Upon the completion of our IPO, the determination of the fair market value of our common stock is based upon the trading price of our common stock.

Recent Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123. *"SFAS 123(R)"* supersedes APB Opinion No. 25, and amends SFAS No. 95, *Statement of Cash Flows.* Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on fair values. Pro forma disclosure is no longer an alternative.

SFAS 123(R) must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS 123(R) on July 1, 2005. We anticipate that adoption of this statement could have a material effect on our results of operations.

Currently we use the Black-Scholes formula to estimate the value of stock options granted to employees and expect to continue to use this acceptable option valuation model upon the required adoption of SFAS 123(R) on July 1, 2005. Because SFAS 123(R) must be applied not only to new awards but to previously granted awards that are not fully vested on the effective date, compensation cost for some previously granted awards that were not recognized under SFAS 123 will be recognized under SFAS 123(R). However, had we adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net loss and net loss per share in Note 2 to our consolidated financial statements. SFAS 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 net operating cash flows and increase net financing cash flows in periods after adoption.

Results of Operations

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. We do not expect this amount to decrease any further in the future, however as product development progresses Inhibitex's revenue may decline further.

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 $2,449,000, $725,000, and $426,000, 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 $355,000 of additional purchases of the raw material and manufacturing expenses related to Veronate, and $383,000 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,	
	2004	2003
	(In thousands)	
Clinical and manufacturing related expenses	$12,295	$ 9,846
Personnel-related salaries and expenses	5,308	4,583
License fees and other expenses	3,496	3,070
Depreciation and facility related expenses	1,482	1,492
Total research and development expense	$22,581	$18,991

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 $225,000 associated with an increase in headcount, an increase in directors' and officers' insurance premiums and directors' fees of $121,000 and $68,000, respectively, and an increase of $186,000 for 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 $473,000 in 2004 from $176,000 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 (Expense), net. Interest and other income (expense), net, increased to $533,000 in 2004 from $319,000 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 of $37,000, which was principally the result of the $2.5 million we borrowed in June 2003 under our credit facility; and a decrease of $167,000 in 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.

Fiscal Years Ended December 31, 2003 and 2002

Revenue. Revenue increased to $1.1 million in 2003 from $900,000 in 2002. This increase of $196,000, or 22%, resulted from a $300,000 grant received from the FDA in 2003, offset, in part, by a reduction in quarterly collaborative research and development support fees of $104,000 from Wyeth. The FDA grant was a one year grant covering the period September 30, 2003 through September 29, 2004. The collaborative research and development support fees from Wyeth are based on the number of our employees that support the program, which was reduced in 2003 to the minimum annual level

Research and Development Expense. Research and development expense increased to $19.0 million in 2003 from $15.6 million in 2002. This increase of $3.4 million, or 22%, resulted primarily from expenditures related to the clinical development of our two most advanced product candidates, Veronate and Aurexis. During 2003, we enrolled substantially all 512 patients in a Phase II clinical trial for Veronate and we initiated and completed a 19 patient Phase I clinical trial for Aurexis. During 2002, we initiated and completed a 36 patient Phase I clinical trial for Veronate. Approximately $2.0 million of this increase represented direct clinical trial related costs, including fees paid to third-party vendors that performed clinical monitoring, data accumulation, statistical analysis and evaluation for our clinical trials, as well as costs associated with the manufacture of clinical trial materials. The other significant factor contributing to the increase in 2003 was additional license fees of approximately $540,000 paid to several third parties to secure intellectual property rights related to the manufacture of Aurexis. The remainder of the increase was related to a number of items, including an increase in personnel-related salaries and expenses, sponsored research payments to support our clinical trials and other research and development programs, and an increase in facility-related costs. The following table summarizes the components of our research and development expenses for 2003 and 2002.

	December 31,	
	2003	2002
	(In thousands)	
Clinical and manufacturing related expenses	$ 9,846	$ 7,866
Personnel related expenses	4,583	4,403
License fees and other expenses	3,070	2,080
Depreciation and facility related expenses	1,492	1,266
Total research and development expense	$18,991	$15,615

General and Administrative Expense. General and administrative expense increased to $4.6 million in 2003 from $3.3 million in 2002. This increase of $1.3 million, or 39%, resulted from increased legal fees of $1.4 million related to the Biosynexus litigation. This increase was offset, in part, by $305,000 of costs incurred during 2002 for certain marketing studies that were not conducted in 2003. The remainder of the increase was primarily related to increases in personnel-related salaries and expenses, and the hiring of additional personnel.

Amortization of Deferred Stock Compensation. Amortization of deferred stock compensation increased to $176,000 in 2003 from $0 in 2002. This increase was the result of amortization related to $981,000 of deferred stock compensation that we recorded pursuant to stock options granted during the first nine months of 2003. 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 (Expense), net. Interest and other income (expense), net, decreased to $319,000 in 2003 from $430,000 in 2002. This decrease of $111,000, or 26%, resulted from a decrease in interest income of $343,000, an increase in interest expense of $83,000 and an increase in other income of $315,000 primarily due to the sale of unusable raw materials. The decrease in interest income was primarily due to reduced yields on investments resulting from lower interest rates and lower average cash and cash equivalent balances in 2003.

Dividends and Accretion to Redemption Value of Redeemable Preferred Stock. Dividends and accretion to redemption value of redeemable preferred stock increased to $6.2 million in 2003 from $5.6 million in 2002. This increase of $600,000, or 11%, resulted from the accrual of cumulative dividends and the accretion to redemption value associated with our Series D preferred stock. Our Series D financing was completed in February 2002. Accordingly, 2003 reflected the full-year effect of these items.

Liquidity and Capital Resources

Sources of Liquidity

Since inception in May 1994 through December 31, 2004, we have funded our operations primarily with $173.2 million in gross proceeds raised from a series of five private equity financings, our IPO in June 2004, and a PIPE financing, or private placement of public equity, in November 2004 as follows:

Gross Stock Offerings	Year	Amount
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
Total gross proceeds		$173,164,967

From inception through December 31, 2004, we have also borrowed a total of $5.0 million under notes payable, a credit facility with a commercial bank and capital leases, and received approximately $5.8 million in license fees, collaborative research payments and grants, of which $1.2 million and $1.0 million were recorded as deferred revenue as of December 31, 2003 and December 31, 2004, respectively.

At December 31, 2004, cash, cash equivalents and short-term investments were $87.2 million and we held no investments with a maturity greater than 12 months. 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 and money market accounts.

Cash Flows

For the year ended December 31, 2004, cash and cash equivalents increased by $44.9 million, from $26.6 million to $71.6 million. This increase resulted primarily from net proceeds we received in connection with our IPO in June 2004 and the PIPE financing in November 2004, offset in part by cash used for operating activities, capital expenditures and the repayment of capital lease obligations and notes payable.

Net cash used in operating activities was $21.5 million in 2004, primarily reflecting a net loss in 2004 of $25.9 million, which was partially offset by non-cash charges of $1.5 million and a net increase in current liabilities over current assets of $2.9 million. Our net loss was largely the result of funding our ongoing clinical trials associated with Veronate and Aurexis, research and development activities, and ongoing general and administrative expenses. The net increase in current liabilities over current assets reflected an increase in accounts payable and accrued liabilities of $3.6 million resulting from an increase in accounts payable associated with manufacturing-related expenses, clinical trial expenses, and the development of our new facilities, and an increase in accrued expenses associated with clinical trial expenses, manufacturing-related expenses, personnel-related expenses, and filing expenses related to our PIPE financing. This was offset by an increase in prepaid expenses and receivables of $526,000 associated with our manufacturing agreement with Lonza, and interest receivable from our short-term investments.

We used approximately $15.9 million of cash for investing activities during 2004, which consisted of net purchases of short-term investments of $14.3 million and the purchase of laboratory and computer equipment and software of $1.6 million.

We received net cash of $82.3 million from financing activities during 2004, which consisted of $34.0 million in net proceeds from our IPO; $47.7 million in net proceeds from our PIPE transaction; an additional $1.7 million we received from a subscription receivable related to the issuance of convertible preferred stock and warrants in connection with our Series E financing at the end of 2003; and $256,000 from the exercise of stock options, offset by payments on our capital leases and promissory notes for $1.3 million.

Funding Requirements

Our future funding requirements are difficult to determine and will depend on a number of factors, including the timing and costs involved in conducting clinical trials; obtaining regulatory approvals for our product candidates, 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, if ever, a corporate infrastructure to commercialize 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, products or technologies complementary to our business, although none are currently anticipated.

Based upon our current business and operating plans, we believe that our existing cash, cash equivalents and short-term investments of $87.2 million as of December 31, 2004 will enable us to operate for a period of approximately 21 months. We currently do not have any commitments for future funding, nor do we anticipate that we will generate revenue from the sale of any products for a number of years. Therefore, in order to meet our anticipated liquidity needs beyond 21 months, we will need to raise additional capital. We expect to continue to fund our operations primarily through the sale of additional common stock or other equity securities and to a lesser extent, strategic collaborations or debt financing. These funds may not be available to us on acceptable terms, if at all, and our failure to raise such funds could have a material adverse impact on our business strategy, plans, financial condition and results of operations. If adequate funds are not available to us in the future, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs, delay or curtail our clinical trial or commercialization efforts or obtain funds through collaborative arrangements that may require us to relinquish rights to certain product candidates that we might otherwise choose to develop or commercialize independently. Additional equity financings may be dilutive to holders of our common stock and debt financing, if available, may involve significant payment obligations and restrictive covenants that restrict how we operate our business.

Contractual Obligations

Our material contractual obligations relate primarily to a credit facility and notes payable, capital leases, facility leases and certain minimum purchase obligations we have under third-party supply and manufacturing agreements.

The following table summarizes our contractual obligations as of December 31, 2004 and the effect such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual Obligations	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	More Than 5 Years
			(In thousands)		
Short and long-term debt	$ 1,363	$ 877	$ 486	$ —	$ —
Capital lease obligations	636	315	301	20	—
Operating lease and equipment obligations	9,868	906	2,662	1,885	4,415
Purchase obligations(1)	6,411	5,856	555	—	—
Total contractual cash obligations	$18,278	$7,954	$4,004	$1,905	$4,415

(1) Reflects our minimum purchase obligations, in the form of termination fees and cancellation penalties, assuming the related supply and manufacturing agreements are terminated by us as of the date of this table. If not terminated, our expected purchase commitments under these agreements would be approximately $14.2 million in total; $7.3 million for the period of less than one year, and $6.9 million for the period 1-3 years, from the date of this table.

In December 2003, we entered into an agreement to lease a new facility in Alpharetta, Georgia to be built to our specifications. We anticipate that we will occupy this new facility in the second quarter of 2005. Upon the completion of the facility, we expect that our expense including minimum lease obligations and the amortization of leasehold improvements paid by the lessor for this facility will approximate $1.0 million per annum for the lease term of ten years. We have not taken possession of or control the physical use of the property until January, 2005. The table above includes these estimated operating lease obligations.

The contractual obligations outlined in the table above do not include several potential future milestone obligations we may be subject to in the future under a number of our licensing and collaborative agreements. The aggregate amount of our milestone obligations is approximately $9.0 million. Our milestone obligations are primarily due upon either the submission of a Biologics License Application, or BLA, and/or the marketing approval of Aurexis. At this time, due to the uncertainties associated with the clinical development of Aurexis, we cannot determine when these events may occur, if at all. Further, the license and collaboration agreements to which these milestone obligations relate are cancelable by us without further financial obligations upon not more than 90 days written notice in the event we choose to terminate any of the license agreements for any reason.

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 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, 2004, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. 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 any of 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*

The Report of the Independent Registered Public Accounting Firm, Financial Statements and Selected Quarterly Financial Data are set forth on pages F-1 to F-30.

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. It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2004 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 then April 30, 2005 pursuant to Regulation 14A of the Securities Exchange Act of 1934, except for the information included in Item 4A of this report.

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 then April 30, 2005 pursuant to Regulation 14A of the Securities Exchange Act of 1934

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS, 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 then April 30, 2005 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 then April 30, 2005 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 then April 30, 2005 pursuant to Regulation 14A of the Securities Exchange Act of 1934

PART IV

ITEM 15. ***EXHIBITS, FINANCIAL STATEMENT SCHEDULE AND REPORTS ON FORM 8-K***

(a) The following documents are filed as part of this Annual Report in Form 10-K:

Number	Description
F-1	Index to Financial Statements
F-2	Report of Independent Registered Public Accounting Firm
F-3	Balance Sheets at December 31, 2003 and 2004
F-4	Statements of Operations for the years ended December 31, 2002, 2003 and 2004 and for the period from inception (May 13, 1994) through December 31, 2004
F-5	Statements of Stockholders' (Deficit) Equity for the period from inception to December 31, 2004, and for the years ended December 31, 2002, 2003 and 2004
F-7	Statements of Cash Flows for the years ended December 31, 2002, 2003 and 2004 and for the period from inception to December 31, 2004
F-8	Notes to Financial Statements

(b) Exhibits

Exhibit No.	Description
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 Amendment No. 2).
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).

Exhibit No.	Description
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)
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).

Exhibit No.	Description
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).
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).
10.32	Sublease Agreement, dated January 1, 2001, between the registrant and AtheroGenics, Inc. (incorporated by reference to Exhibit 10.32 of the March 2004 S-1).
10.33	Non-Negotiable Promissory Note, dated January 1, 2002 issued by the registrant to AtheroGenics, Inc. (incorporated by reference to Exhibit 10.33 of the March 2004 S-1)
10.34	Sublease Agreement, dated December 23, 2002, between the registrant and Lucent Technologies, Inc. (incorporated by reference to Exhibit 10.34 of the March 2004 S-1)
10.34.1	Lease Agreement, dated March 23, 2004, between the registrant and Sanctuary Park Realty Holding Company (incorporated by reference to Exhibit 10.34.1 of Amendment No. 2).
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.
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Section 302 Certification of the Chief Executive Officer.
31.2	Section 302 Certification of the Chief Financial Officer.
32.1	Section 1350 Certifications of the Chief Executive Officer and the Chief Financial Officer.

† 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 singed on its behalf by the undersigned, thereunto duly authorized, in the City of Alpharetta, Georgia on this 28th day of March, 2005.

INHIBITEX, INC.

By: /s/ WILLIAM D. JOHNSTON, PH.D.
William D. Johnston, Ph.D.
President and Chief Executive Officer

Signature	Title	Date
/s/ WILLIAM D. JOHNSTON, PH.D. William D. Johnston, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2005
/s/ RUSSELL H. PLUMB Russell H. Plumb	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2005
/s/ MICHAEL A. HENOS Michael A. Henos	Chairman of the Board of Directors	March 28, 2005
/s/ M. JAMES BARRETT, PH.D. M. James Barrett, Ph.D.	Director	March 28, 2005
/s/ CARL E. BROOKS Carl E. Brooks	Director	March 28, 2005
/s/ J. DOUGLAS EPLETT, M.D. J. Douglas Eplett, M.D.	Director	March 28, 2005
/s/ RUSSELL M. MEDFORD, M.D., PH.D. Russell M. Medford, M.D., Ph.D.	Director	March 28, 2005
/s/ ARDA M. MINOCHERHOMJEE, PH.D. Arda M. Minocherhomjee, Ph.D.	Director	March 28, 2005
/s/ JOSEPH M. PATTI, M.S.P.H., PH.D. Joseph M. Patti, M.S.P.H., Ph.D.	Director	March 28, 2005
/s/ MARC L. PREMINGER Marc L. Preminger	Director	March 28, 2005
/s/ LOUIS W. SULLIVAN, M.D. Louis W. Sullivan, M.D.	Director	March 28, 2005

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INHIBITEX, INC.
(A Development Stage Company)

INDEX TO FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets	F-3
Statements of Operations	F-4
Statements of Stockholders' (Deficit) Equity	F-5
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

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, 2003 and 2004, and the related statements of operations, stockholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2004, and for the period from inception (May 13, 1994) through December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Inhibitex, Inc. (a Development Stage Company) at December 31, 2003 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, and for the period from inception (May 13, 1994) through December 31, 2004, in conformity with U.S. generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

Atlanta, Georgia
March 24, 2005

INHIBITEX, INC.
(A Development Stage Company)

Balance Sheets

	December 31, 2003	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,649,150	$ 71,580,823
Short-term investments	1,498,980	15,623,887
Prepaid expenses and other current assets	569,667	1,082,359
Accounts receivable	308,924	322,019
Total current assets	29,026,721	88,609,088
Property and equipment, net	1,635,544	2,629,987
Total assets	$ 30,662,265	$ 91,239,075
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 1,385,972	$ 3,077,636
Accrued expenses	1,700,539	3,587,093
Current portion of notes payable	889,523	877,239
Current portion of capital lease obligations	330,408	315,043
Current portion of deferred revenue	191,667	191,667
Other current liabilities	1,000,000	1,000,000
Total current liabilities	5,498,109	9,048,678
Long-term liabilities:		
Notes payable, net of current portion	1,363,351	486,112
Capital lease obligations, net of current portion	431,853	321,190
Deferred revenue, net of current portion	987,498	837,498
Total long-term liabilities	2,782,702	1,644,800
Redeemable convertible preferred stock, $.001 par value; 37,700,000, and 5,000,0000 shares authorized at December 31, 2003 and 2004, respectively; 24,373,444, and no shares issued and outstanding at December 31, 2003 and 2004, respectively; liquidation preference of $101,556,363, and $0 at December 31, 2003 and 2004, respectively	89,542,242	—
Preferred stock warrants	6,065,467	—
Stockholders' (deficit) equity:		
Series A convertible preferred stock, $.001 par value; 216,000 and no shares authorized, issued and outstanding at December 31, 2003 and 2004, respectively; liquidation preference of $251,424 and $0 at December 31, 2003 and 2004, respectively	216	—
Common stock, $.001 par value; 43,100,000 and 75,000,000 shares authorized at December 31, 2003 and 2004, respectively; 536,066 and 25,133,327 shares issued and outstanding at December 31, 2003 and 2004, respectively	536	25,133
Additional paid-in capital	1,797,798	173,188,745
Warrants	—	11,555,968
Deferred stock compensation	(804,310)	(1,269,099)
Deficit accumulated during the development stage	(74,220,495)	(102,955,150)
Total stockholders' (deficit) equity	(73,226,255)	80,545,597
Total liabilities, redeemable convertible preferred stock and warrants and stockholders' (deficit) equity	$ 30,662,265	$ 91,239,075

INHIBITEX, INC.
(A Development Stage Company)

Statements of Operations

	Period from Inception (May 13, 1994) through December 31, 2004	Year Ended December 31,		
	(Unaudited)	2002	2003	2004
Revenue:				
License fees and Milestones	$ 1,012,500	$ 150,000	$ 150,000	$ 150,000
Collaborative research and development	2,499,455	750,000	645,833	500,000
Grants	300,000	—	300,000	—
Total revenue	3,811,955	900,000	1,095,833	650,000
Operating expense:				
Research and development	75,039,164	15,614,526	18,990,954	22,580,709
General and administrative	16,302,578	3,327,857	4,580,957	4,040,266
Amortization of deferred stock compensation	649,524	—	176,235	473,289
Total operating expense	91,991,266	18,942,383	23,748,146	27,094,264
Loss from operations	(88,179,311)	(18,042,383)	(22,652,313)	(26,444,264)
Other income (expense), net	703,042	(44,180)	271,306	103,684
Interest income (expense), net	903,182	473,840	47,986	429,085
Net loss	(86,573,087)	(17,612,723)	(22,333,021)	(25,911,495)
Dividends and accretion to redemption value of redeemable preferred stock	(16,382,063)	(5,625,804)	(6,201,116)	(2,823,160)
Net loss attributable to common stockholders	$(102,955,150)	$(23,238,527)	$(28,534,137)	$(28,734,655)
Basic and diluted net loss attributable to common stockholders per share		$ (47.83)	$ (54.19)	$ (2.52)
Weighted average shares used to compute basic and diluted net loss attributable to common stockholders per share		485,842	526,578	11,416,354
Pro forma basic and diluted net loss attributable to common stockholders per share (unaudited)			$ (2.81)	
Pro forma weighted average shares used to compute basic and diluted net loss attributable to common stockholders per share (unaudited)			10,145,137	

INHIBITEX, INC.
(A Development Stage Company)

Statements 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	Deficit Accumulated During Development Stage	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 $.005 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 $.005 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	—	—	—	—	—	—	—	—	—	—	(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)

INHIBITEX, INC.
(A Development Stage Company)

Statements of Stockholders' (Deficit) Equity — (Continued)

	Series A Preferred Stock		Common Stock Subscription		Common Stock		Additional Paid-In Capital	Receivable for Purchase of Stock	Common Stock Warrants	Deferred Stock Compensation	Deficit Accumulated During Development Stage	Total Stockholders' (Deficit) Equity
	Shares	Par Value	Shares	Par Value	Shares	Par Value						
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)
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	—	—	—	—	—	—	—	—	—	—	(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

INHIBITEX, INC.
(A Development Stage Company)
Statements of Cash Flows

	Period from Inception (May 13, 1994) Through December 31, 2004	Year Ended December 31, 2002	2003	2004
Cash flows from operating activities				
Net loss	$(86,573,087)	$(17,612,723)	$(22,333,021)	$(25,911,495)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	3,465,054	772,139	768,245	820,298
Amortization of deferred stock compensation	649,524	—	176,235	473,289
Loss on sale of equipment	48,134	48,134	—	—
Amortization of investment premium	200,661	—	45,249	155,412
Forgiveness of receivables from stockholders	28,695	—	—	—
Amortization of warrants and discount on debt	176,477	4,153	—	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	(1,082,359)	(344,888)	(128,304)	(512,692)
Accounts receivable	(322,019)	(26,174)	(273,110)	(13,095)
Accounts payable and other current liabilities	4,077,636	248,573	667,374	1,691,664
Accrued expenses	3,587,093	1,390,736	(320,265)	1,886,554
Deferred revenue	1,029,165	(379,169)	(170,831)	(150,000)
Net cash used in operating activities	(74,488,640)	(15,899,219)	(21,568,428)	(21,504,070)
Cash flows from investing activities				
Purchases of property and equipment	(4,185,336)	(264,034)	(176,208)	(1,573,977)
Purchases of short-term investments	(47,444,232)	(1,000,310)	(15,551,099)	(30,892,823)
Proceeds from maturities of short-term investments	31,607,180	—	15,007,180	16,600,000
Net cash used in investing activities	(20,022,388)	(1,264,344)	(720,127)	(15,866,800)
Cash flows from financing activities				
Proceeds from promissory notes and related warrants	3,013,492	—	2,500,000	—
Payments on promissory notes and capital leases	(2,971,747)	(347,609)	(710,292)	(1,256,315)
Proceeds from bridge loan and related warrants	2,220,000	—	—	—
Net proceeds from the issuance of preferred stock and warrants	81,788,868	44,746,579	18,472,533	1,682,546
Proceeds from the issuance of common Stock	82,041,238	18,306	17,386	81,876,312
Net cash provided by (used in) financing activities	166,091,851	44,417,276	20,279,627	82,302,543
Increase (decrease) in cash and cash equivalents	71,580,823	27,253,713	(2,008,928)	44,931,673
Cash and cash equivalents at beginning of period	—	1,404,365	28,658,078	26,649,150
Cash and cash equivalents at end of Period	$ 71,580,823	$ 28,658,078	$ 26,649,150	$ 71,580,823
Supplemental cash flow information:				
Interest paid	$ 781,341	$ 86,227	$ 163,149	$ 198,164
Supplemental non-cash investing and financing activities:				
Fixed assets capitalized using promissory notes and capital leases	1,957,839	251,379	420,665	240,764
Conversion of bridge loans and interest payable into Series C Preferred Stock	2,124,576	—	—	—
Preferred stock dividends and accretion of preferred stock to redemption value	16,382,063	5,625,804	6,201,116	2,823,160

NOTES TO FINANCIAL STATEMENTS

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 is being developed to prevent hospital-associated infections in very low birth weight infants. Aurexis is being developed to treat, in combination with antibiotics, serious, life-threatening *Staphylococcus aureus (S. aureus)* infections in hospitalized patients. Both Veronate and Aurexis are currently being evaluated in clinical trials. The Company plans to continue to finance its operations with equity and/or other 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 accounting principles generally accepted in the United States 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 Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities* ("SFAS 115"). The Company is required to maintain a cash balance equal to two times the loan balance on deposit with a lender pursuant to a loan and security agreement as discussed in Note 7.

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 with unrealized gains and losses, if any, reported in other comprehensive income. 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 2003 consisted of commercial paper, agency obligations, corporate bonds, and money-market funds.

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:

Asset	Estimated Life
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 capitalizes 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 relate to fees recovered for licensed technology, collaborative research and development 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 104 *Revenue Recognition*, and Emerging Issues Task Force ("EITF") Issue 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF Issue 00-21"). 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 are recognized as these activities are performed pursuant to the terms of the related agreements (see Note 12). 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.

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 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 the SFAS No. 123, 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 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. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 and APB No. 28, *Interim Financial Reporting*, to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to employee stock compensation on reported net loss. 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. No stock compensation expense is reflected in the Company's reported net loss in any period prior to December 31, 2002 as all options granted had an exercise price equal to the fair value of the underlying common stock on the date of grant.

The Company recorded deferred stock compensation of $980,545 and $938,078 for the year ended December 31, 2003 and 2004, respectively, which represents the difference between the exercise price per share and the fair value at the respective grant dates for options granted in 2003 and 2004. 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 $176,235 and $473,289 for the years ended December 31, 2003 and 2004, respectively. The expected future amortization of deferred stock compensation related to the options granted in 2003 and 2004 is $496,755, $473,637, $262,762 and $35,945 for the years ended December 31, 2005, 2006, 2007 and 2008, respectively.

The option valuation models used to value options under 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 common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock-based compensation:

	December 31,		
	2002	2003	2004
Net loss attributable to common stockholders — as reported	$(23,238,527)	$(28,534,137)	$(28,734,655)
Add: Amortization of deferred stock compensation included in net loss — as reported	—	176,235	473,289
Deduct: Stock compensation expense determined under fair value method	(45,046)	(412,845)	(1,055,539)
Net loss attributable to common stockholders — pro forma	$(23,283,573)	$(28,770,747)	$(29,316,905)
Net loss attributable to common stockholders per share (basic and diluted):			
As reported	$ (47.83)	$ (54.19)	$ (2.52)
Pro forma	$ (47.92)	$ (54.64)	$ (2.57)

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

	December 31,		
	2002	2003	2004
Risk-free interest rate	4.01%	3.05%	3.23%
Expected life	4 years	4 years	4 years
Weighted average fair value of options granted	$ 0.12	$ 1.52	$ 2.08
Volatility	—	—	.43

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 materials used in its development process that are procured from a single source supplier as well as certain third-party contract manufacturers that make its product candidates. The failure of its supplier 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 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 valuation allowance is 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.

Reclassifications. Certain reclassifications have been made to prior period amounts to conform to the current year presentation.

Recent Accounting Pronouncements. On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123. *"SFAS No. 123(R)"* supersedes APB Opinion No. 25, and amends SFAS No. 95, *Statement of Cash Flows.* Generally, the approach in SFAS 123(R) is similar to the approach described in Statement 123. However, SFAS 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.

SFAS 123(R) must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS 123(R) on July 1, 2005. We anticipate adoption of this statement on July 1, 2005 could have a material effect on our results of operations.

Currently, the Company uses the Black-Scholes formula to estimate the value of stock options granted to employees and expects to continue to use this acceptable option valuation model upon the required adoption of SFAS 123(R) on July 1, 2005. Because SFAS 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 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 awards that were not recognized under SFAS 123 will be recognized under SFAS 123(R). However, had we adopted SFAS 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to our consolidated financial statements. SFAS 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 net operating cash flows and increase net financing cash flows in periods after adoption.

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 Staff Accounting Bulletin No. 98 ("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 conversion of preferred stock and upon the exercise of stock options, and the conversion of preferred stock upon the exercise of warrants. Dilutive earnings per share is the same as basic earnings per share since common stock equivalents are excluded from the calculation, due to their effect being anti-dilutive.

The unaudited pro forma net loss per share attributable to common stockholders and the shares used to compute basic and diluted pro forma net loss per share attributable to common stockholders are calculated assuming all of the Company's outstanding preferred stock was converted into common stock as of its date of issuance and the conversion of all cumulative preferred stock dividends as of the date they were accrued. This calculation excludes the assumed issuance of shares of common stock subject to the mandatory cashless exercise of warrants that were outstanding at December 31, 2003 and December 31, 2004.

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,		
	2002	2003	2004
Historical			
Numerator:			
Net loss attributable to common stockholders ...	$(23,238,527)	$(28,534,137)	$(28,734,655)
Denominator:			
Weighted average common shares outstanding ..	485,842	526,578	11,416,354
Basic and diluted net loss per share attributable to common stockholders	$ (47.83)	$ (54.19)	$ (2.52)
Pro forma			
Net loss attributable to common stockholders ...		$(28,534,137)	
Pro forma basic and diluted net loss per share attributable to common stockholders (unaudited)		$ (2.81)	
Shares used above		526,578	
Pro forma adjustment to reflect assumed weighted average effect of conversion of preferred stock and cumulative preferred stock dividends (unaudited)		9,618,559	
Shares used to compute pro forma basic and diluted net loss per share (unaudited)		10,145,137	

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,		
	2002	2003	2004
Redeemable convertible preferred stock and related dividends	8,886,205	11,595,232	—
Common stock options	1,085,764	1,338,452	1,283,106
Warrants	1,310,292	1,838,118	3,838,588
Convertible preferred stock	90,758	90,758	—
Total	11,373,019	14,862,560	5,121,694

4. Property and Equipment

	December 31,	
	2003	2004
Laboratory equipment	$ 1,948,952	$ 2,315,142
Leasehold improvements	994,617	1,816,694
Computer software and equipment	735,563	1,362,037
Office furniture and fixtures	198,570	198,570
	3,877,702	5,692,443
Less accumulated depreciation and amortization	(2,242,158)	(3,062,456)
Total property and equipment, net	$ 1,635,544	$ 2,629,987

Included in the property and equipment are assets recorded under capital leases with an accumulated cost of approximately $1,158,000, and $1,383,000 at December 31, 2003 and 2004, respectively. Amortization of the assets recorded under capital leases is included in depreciation expense. The accumulated amortization related to these assets under capital leases was approximately $421,000, and $737,000 at December 31, 2003 and 2004. Depreciation expense was approximately $772,000, $768,000, and $821,000 for the years ended December 31, 2002, 2003 and 2004, respectively.

5. Accrued Expenses

The components of accrued expenses are as follows:

	December 31,	
	2003	2004
Clinical development expenses	$ 476,456	$1,674,259
Payroll and related expenses	481,495	699,902
Manufacturing expenses	83,750	295,533
Professional fees	236,746	414,331
Other operating expenses	222,092	286,394
License fees	200,000	216,674
	$1,700,539	$3,587,093

6. Commitments and Contingencies

Lease Commitments. The Company leases laboratory and office facilities in Alpharetta, Georgia under two operating leases, one of which is with a related party. 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 the 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, 2002, 2003 and 2004, rent expense totaled approximately $270,000, $421,000 and $520,000, respectively.

Future minimum payments under these operating leases at December 31, 2004 are as follows:

Year Ending December 31,	
2005	$ 895,079
2006 to 2009	2,658,628
2010 to 2011	1,885,055
2012 and after	4,415,185
Total minimum lease payments	$9,853,947

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. Under this agreement, the Company had a right to terminate the lease without any further obligation by March 31, 2004. The Company did not exercise this right, and expects to occupy this new facility upon its completion, which is anticipated to occur in the second quarter of 2005. The Company is not obligated to make rent payments related to this facility, and has not taken possession of or controls the physical use of the property until January, 2005. The Company estimates that these expenses including minimum rent payments and the amortization of leasehold improvements paid by the lessor will approximate $1.0 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. The table includes these estimated minimum payments under this operating lease as they are an obligation of the Company at December 31, 2004.

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, 2004, the Company's purchase commitments under this agreement through December 31, 2008 were approximately $5.2 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 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 November 2004, Inhibitex entered into an agreement with Lonza Biologics PLC for the manufacture of Aurexis. Under the terms of the agreement, Lonza has agreed to perform numerous process development related services and manufacture two cGMP lots of Aurexis for our use in future clinical trials. As of December 31, 2004, Inhibitex's maximum purchase commitments under this agreement through June 30, 2008, were approximately 3.6 million pounds sterling or $6.7 million. However, prior to June 30, 2005 Inhibitex can cancel the second cGMP lot without incurring any financial obligations associated with that lot, in which case Inhibitex's purchase commitments to Lonza would be reduced. At this time, Inhibitex has not contracted with Lonza to manufacture any additional lots of Aurexis. A change in contract manufacturers for commercial lots may require further clinical trials for Aurexis.

7. Long-term Debt

Capital Lease Obligations. In 2002, 2003 and 2004, 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 at a rate of 10.2% and expire at various dates from March 2005 to November 2007. In connection with 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.

Future payments under capital lease agreements as of December 31, 2004 are as follows:

Year Ending December 31,	
2005	$ 363,897
2006	243,039
2007	110,832
Total future minimum lease payments	717,768
Less amount representing interest	(81,535)
Present value of future minimum lease payments	636,233
Less current portion of capital lease obligations	(315,043)
Long-term portion of capital lease obligations	$ 321,190

Notes Payable. In January 1999, Inhibitex entered into a loan and security agreement (the "Security Agreement") with a financial institution. Under the terms of the Security Agreement, Inhibitex could borrow up to $1,000,000 through December 31, 1999, evidenced by senior secured promissory notes (the "Senior Notes"). In February and June 1999, Inhibitex executed three Senior Notes in the aggregate amount of $447,584 under the Security Agreement. During 2003, two of the Senior Notes were repaid in

full. The outstanding balance of the Senior Notes at December 31, 2003 and 2004 was $15,244 and $0, respectively. The remaining balance was paid in full in April 2004. In conjunction with the Security Agreement, the financial institution received a warrant to purchase 20,000 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 $0.37 per share, assuming no dividend yield, expected life of four years, risk-free interest rate of 5.64% and volatility of 50%. The principal balance of the related promissory notes was discounted in an amount equal to such value.

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. Remaining monthly payments are $3,799 through December 2005, and the outstanding balance as of December 31, 2003 and 2004 was $84,852 and $43,906, 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, Inhibitex 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, 2003 and 2004 was $2,152,778 and $1,319,445, respectively. The Loan Agreement is secured by all unencumbered tangible assets of the Company.

Future minimum payments due under notes payable as of December 31, 2004 are as follows:

Year Ending December 31,	
2005	$ 877,239
2006 to 2009	486,112
2009 and after	—
Total future payments	$1,363,351

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. As of December 31, 2004 no amounts were outstanding under this facility.

8. Income Taxes

At December 31, 2003 and 2004, Inhibitex had available net operating loss ("NOL") carry forwards of approximately $58.9 million, and $84.9 million, respectively, which will begin to expire in the year 2019. 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. Inhibitex also has approximately $657,000 and $866,000 of research and development ("R&D") tax credit carry forwards as of December 31, 2003 and 2004, respectively. The NOL and R&D tax credit carry forwards are available to offset future income taxes payable, if any. The Tax Reform Act of 1986 contains provisions that may limit NOL and R&D tax credit carry forwards available for use in any given year in the event of significant changes in ownership interests, as defined.

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 Inhibitex's deferred tax asset are as follows:

	December 31,	
	2003	2004
Deferred tax assets:		
Net operating loss carry forwards	$ 22,340,200	$ 32,210,300
Research and development tax credit carry forwards	657,100	865,500
Deferred revenue	447,600	317,900
Other, net	235,200	320,700
Total deferred tax assets	23,680,100	33,714,400
Less valuation allowance	(23,680,100)	(33,714,400)
Net deferred tax assets	$ —	$ —

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. Inhibitex 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 $10,034,300 from December 31, 2003 to December 31, 2004.

9. 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.

The following table outlines redeemable convertible preferred stock and related warrants as of December 31, 2002 and 2004, including its conversion to common stock as of June 3, 2004:

	December 31, 2003	December 31, 2004
Series B redeemable convertible preferred stock, $.001 par value; 2,600,000 and no shares authorized at December 31, 2003 and 2004, respectively; 2,288,670 shares and no issued and outstanding at December 31, 2003 and 2004, respectively	$ 2,911,936	$ —
Series C redeemable convertible preferred stock, $.001 par value; 8,000,000 shares authorized and 5,576,240 shares issued and outstanding at December 31, 2003 and no shares authorized, issued or outstanding at December 31, 2004, respectively	20,073,240	—
Series D redeemable convertible preferred stock, $.001 par value; 17,500,000 shares and no shares authorized at December 31, 2003 and 2004, respectively; 11,420,794 and no shares issued and outstanding at December 31, 2003 and 2004, respectively	49,864,860	—
Series E redeemable convertible preferred stock, $.001 par value; 9,600,000 shares and no shares authorized at December 31, 2003 and 2004, respectively; 5,087,740 shares and no shares issued and outstanding at December 31, 2003 and 2004, respectively	18,192,203	—
Subscription receivable for purchase of Series E redeemable convertible preferred stock	(1,499,997)	—
Warrants	6,065,467	—
Total redeemable convertible preferred stock and Warrants	$95,607,709	$ —

During 1997, the Company issued 644,340 shares of Series B Redeemable Convertible Preferred Stock ("Series B") for $750,012 in cash. During 1998, the Company issued an additional 1,644,330 shares of Series B for $2,250,000 in cash.

In April and June 2000, the Company issued an aggregate of 2,300,329 shares of Series C Redeemable Convertible Preferred Stock ("Series C") for total consideration of $6,555,938, which included the conversion of $2,000,000 in bridge loans, accrued interest of $124,576, and cash proceeds of $4,431,365. In October and November 2000, the Company sold an additional 3,275,911 shares of Series C for total cash consideration of $9,336,346.

In February, March and April 2002, the Company issued an aggregate of 11,420,794 shares of Series D Redeemable Convertible Preferred Stock ("Series D") and warrants to purchase 2,855,200 shares of Series D for total cash consideration of $44,997,928. Net proceeds to the Company, after legal and other issuance costs, were $44,746,579. The total proceeds were allocated between Series D and the related warrants based on their relative fair values. The amount allocated to the warrants was $4,140,040, which was recorded as a discount to Series D. This discount is being accreted to the Series D on a straight-line basis through April 6, 2006, the date that Series D becomes redeemable. The accretion is recorded in the statement of operations to arrive at the net loss attributable to common stockholders.

In connection with the Series D financing, in February 2002 the Board of Directors approved three additional series of preferred stock Series B-1 Convertible Preferred Stock (the "Series B-1"), Series C-1 Convertible Preferred Stock (the "Series C-1"), and Series D-1 Convertible Preferred Stock (the "Series D-1"). The Company is authorized to issue up to 2,600,000 shares of Series B-1, 8,000,000 shares of Series C-1 and 17,500,000 shares of Series D-1. Series B-1, Series C-1 and Series D-1 have the same

rights and preferences as the Series B, Series C and Series D, respectively, except for certain provisions relating to anti-dilution rights and rights of first refusal with respect to additional issuances of equity securities. No shares of this series of preferred stock were outstanding as of December 31, 2002, 2003, and 2004.

In December 2003, the Company issued an aggregate of 5,087,740 shares of Series E Redeemable Convertible Preferred Stock ("Series E") and warrants to purchase 1,271,930 shares of Series E for total cash consideration of $20,045,696. Net proceeds to the Company, after legal and other issuance costs, were $19,972,511. Of this amount, $1,499,997 was recorded as a subscription receivable at December 31, 2003, as these proceeds were not received by the Company until January 5, 2004. The total proceeds were allocated between Series E and the related warrants based on their relative fair values. The amount allocated to the warrants was $1,806,141, which was recorded as a discount to Series E. This discount is being accreted to Series E on a straight-line basis through April 6, 2006, the date the Series E becomes redeemable. The accretion is recorded in the statement of operations to arrive at the net loss attributable to common stockholders.

In connection with the Series E financing, in December 2003 the Board of Directors approved an additional series of preferred stock, Series E-1 Convertible Preferred Stock (the "Series E-1"). The Company is authorized to issue up to 9,600,000 shares of Series E and Series E-1. Series E-1 has the same rights and preferences as Series E, except for certain provisions relating to anti-dilution rights and rights of first refusal with respect to additional issuances of equity securities. No shares of this series of preferred stock were outstanding as of December 31, 2002, 2003 and 2004.

Voting Rights. All holders of redeemable convertible preferred stock have voting rights equal to the number of shares of common stock into which the respective preferred stock is convertible.

Dividends. Dividends on Series B are payable when and as declared by the Board of Directors. Dividends on Series C and D are cumulative and accrue at the rate of 8% per annum from the date of issuance through the earlier of: (i) the date on which the liquidation value is paid in connection with the liquidation of the Company or redemption of such shares; (ii) the date on which such shares are converted, or (iii) the date on which such shares are otherwise acquired by the Company. Dividends on Series C and D are also convertible into shares of Series C and D at their respective liquidation values per share. All dividends have been accrued and included in the carrying value of the respective redeemable convertible preferred stock in the accompanying balance sheets. As of December 31, 2003, the Company had accrued cumulative preferred stock dividends of $11,064,505, which were convertible into 1,354,279 of preferred stock, respectively. As of December 31, 2004 the outstanding shares of preferred stock, and accrued dividends thereon, were converted into common stock upon the initial public offering. No dividends have been declared by the Board of Directors, or paid by the Company.

Liquidation. Upon a liquidation event, which includes a liquidation, dissolution, winding-up of the Company, or a merger, consolidation or reorganization of the Company that results in the transfer of 50% or more of the outstanding voting power of the Company or a sale of substantially all the assets of the Company, the holders of Series B, Series C, Series D and Series E are entitled to, prior and in preference to any other stockholders, a liquidation preference distribution of their respective liquidation values plus all accrued but unpaid dividends or if greater, the amount per share as would have been payable had each share of preferred stock been converted in the Company's common stock prior to a liquidation event. The liquidation value of Series B issued before July 2, 1998 and on or after July 2, 1998 is $1.164 and $1.50 per share, respectively. The liquidation value of Series C issued on or before June 8, 2000 and after June 8, 2000 is $5.70 and $2.85 per share, respectively. The liquidation value of Series D and E is $3.94 per share. The following table summarizes the liquidations preferences of convertible redeemable preferred stock:

	December 31, 2003
Series B	$ 3,000,012
Series C	26,722,817
Series D	51,787,839
Series E	20,045,695
	$101,556,363

Conversion. The holders of Series B, Series C, Series D, and Series E may convert at any time shares of their preferred stock into common stock on a one-for-one basis subject to certain adjustments including dilutive issuances, adjustments or splits, as defined. Upon the effectuation of the 1-for-2.38 reverse stock split, the conversion ratio of Series B, Series C, Series D, and Series E was adjusted to approximately 0.42 shares of common stock for each share of redeemable convertible preferred stock. As of June 3, 2004 the outstanding shares of preferred stock were converted into common stock upon the initial public offering.

Redemption. At any time after April 6, 2006, the holders of Series B, Series C, Series D and Series E have the option to require Inhibitex to redeem any or all of their respective outstanding shares of redeemable preferred stock. If so elected, the redemption price for each share of preferred stock is the original purchase price paid for such stock as adjusted for stock splits, stock dividends, or other recapitalizations, plus all accrued but unpaid dividends. Prior to the Series E financing in December 2003, the holders of Series B, Series C and Series D could redeem their preferred stock at any time after April 6, 2005. As of June 3, 2004 the outstanding shares of preferred stock were converted into common stock upon the initial public offering.

Preferred Stock Warrants. The preferred stock issuable upon the exercise of outstanding warrants to purchase shares of the Company's redeemable convertible preferred stock shall convert into common stock based upon a conversion rate of one to one, adjusted for the 1-for-2.38 reverse stock split. The warrants were converted to common stock warrants upon the Company's initial public offering on June 3, 2004.

The following table outlines outstanding warrants to purchase preferred stock at December 31, 2003.

	Exercise Price per Share	Number of Shares of Preferred Stock
Series B	$ 1.50	222,328
Series C	2.85	5,119
Series D	3.94-5.91	2,860,317
Series E	5.91	1,271,930
Total		4,359,694

Warrants to purchase shares of redeemable preferred stock issued in connection with notes payable and capital leases are described in Note 7.

In connection with bridge loans provided to the Company in March and August 1999, the Company issued warrants to purchase a total of 170,000 shares of Series B at an exercise price of $1.50 per share. The warrants became exercisable on December 31, 1999 and expire on June 19, 2004. Using the Black-Scholes method, the warrants have been recorded at their estimated fair value of $0.53 to $0.59 per share, assuming no dividend yield, risk-free rates ranging from 5.19% to 5.97%, expected life of three years and volatility of 50%.

In connection with another bridge loan provided to the Company in March 2000, the Company issued warrants to purchase a total of 40,000 shares of Series B at an exercise price of $1.50 per share. The warrants became exercisable on May 15, 2000 and expire on June 19, 2004. Using the Black-Scholes method, the warrants have been recorded at their estimated fair value of $0.69 per share, assuming no dividend yield, risk-free interest rate of 6.43%, expected life of four years and volatility of 50%.

In connection with the issuance of shares of Series D in February, March and April 2002, the Company issued warrants to purchase 2,855,200 shares of Series D at an exercise price of $5.91 per share. The warrants may be exercised at any time by the holders through February 7, 2007. The warrants have been recorded at their estimated fair value of $1.45 per share using the Black-Scholes method assuming no dividend yield, risk-free interest rate of 4.3%, expected life of five years, and volatility of 50%. The Series D was discounted by an amount equal to such value.

In connection with the issuance of Series E in December 2003, the Company issued warrants to purchase a total of 1,271,930 shares of Series E at an exercise price of $5.91 per share. The warrants may be exercised at any time through December 19, 2008. The warrants have been recorded at their estimated fair value of $1.42 per share using the Black-Scholes method assuming no dividend yield, risk-free interest rate of 3.7%, expected life of five years, and volatility of 50%. The Series E was discounted by an amount equal to such value.

During the years ended December 31, 2002, 2003 and 2004 the Company recorded aggregate accretion related to warrants and preferred dividends of $5,625,804, $6,201,116 and $2,823,160, respectively.

10. Stockholders' (Deficit) Equity

Convertible Preferred Stock. On January 3, 1996, the Company issued 216,000 shares of Series A Preferred Stock ("Series A") for total consideration of $540,000, which included the conversion of a $220,000 bridge loan and $320,000 in cash consideration (the "Series A Financing").

Series A is convertible into common stock at the option of the holder, or automatically upon the completion of a qualified initial public offering of the Company's common stock. The initial conversion

rate for Series A is one to one, which is to be adjusted in the event of a subdivision or combination of the stock or a reorganization, dividend, consolidation, merger or sale of the Company or sale of additional shares of common stock for consideration less than the original purchase price of the Series A. The Series A conversion rate was adjusted to 0.42 shares of common stock for each share of Series A, upon effectuation of the 1-for-2.38 reverse stock split. Dividends on Series A are payable when and as declared by the Board of Directors. In the event of a liquidation of the Company, the Series A stockholders are entitled to receive, prior to and in preference to the common stockholders, an amount equal to the Series A liquidation value. The liquidation value of Series A shares is $1.164 per share plus all declared and accrued but unpaid dividends. As of December 31, 2003 the liquidation value was $251,424. The holders of Series A have voting rights equal to the number of shares of common stock into which the shares are convertible. The holders of Series A and common stock (voting as a class) may elect one director. As of June 3, 2004, outstanding shares of Series A were converted into common stock upon the initial public offering.

Common Stock. As of December 31, 2003 and 2004, the Company is authorized to issue 43,100,000, and 75,000,0000 shares of common stock, respectively. 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.

Our Board of Directors adopted, and our stockholders approved as of February 20, 2004, our 2004 Employee Stock Purchase Plan, or the Purchase Plan. The purpose of the Purchase Plan is to provide an opportunity for our employees to purchase a proprietary interest in us. The Purchase Plan is administered by a committee appointed by the Board of Directors for such purpose. The Board of Directors has appointed our compensation committee to administer the Purchase Plan. A total of 210,084 shares of common stock are authorized for issuance under the Purchase Plan as of December 31, 2004. 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 our 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 first such purchase period commenced on October 1, 2004 and will end on December 31, 2004. 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 our 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 our 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 us. A participant may not transfer rights to purchase our 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 our common stock. Our Board of Directors has the authority to amend or terminate the Purchase Plan, except 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.

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. 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.

On November 10, 2004, the Company completed a private placement 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 become 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.

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

	December 31, 2003	December 31, 2004
Common stock options	1,338,452	1,283,106
Conversion of Series A	90,758	—
Conversion of Series B	961,635	—
Conversion of Series C	2,342,968	—
Conversion of Series D	4,798,638	—
Conversion of Series E	2,137,712	—
Dividends accrued on Series C and D	1,354,279	—
Warrants to purchase shares of common stock	1,838,118	3,838,588
Total	14,862,560	5,121,694

11. 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 from the grant date, and options generally vest ratably over a period of four years from the grant date. As of December 31, 2003 and 2004, there were 421,023 and 188,262 options 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 options 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 were 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.

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, 2004, an aggregate of 2,476,463 shares of common stock were reserved for issuance under the 2004 Plan and the Director Plan, respectively. 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, 2003, there were 867,007 outstanding options to purchase the Company's common stock and 207,197 options available for grant under the 2004 Plan. 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, 2003 and 2004, there were 50,422 and 66,804 outstanding options to purchase the Company's common stock and 54,622 and no options available for grant under the Director Plan, respectively.

The following is a summary of all stock option activity and related information related to all the Company's stock option plans, and 35,000 shares issued outside these plans, from inception of such plans through the period ended December 31, 2004:

	Number of Shares	Exercise Price per Share	Weighted Average Exercise Price per Share
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	(1,787)	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	(8,301)	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	(16,284)	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	(61,429)	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	(10,010)	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	(31,217)	0.29-9.38	4.99
Balance at December 31, 2004	1,283,106	0.24-9.38	3.18

The following tables summarize information relating to outstanding and exercisable options as of December 31, 2004:

	December 31, 2004				
	Outstanding			Exercisable	
Exercise Prices	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	3.41	$ 0.24	10,731	$0.24
0.29	57,535	4.93	0.29	57,535	0.29
0.36	13,972	4.35	0.36	13,972	0.36
0.68	126,299	5.94	0.68	81,875	0.68
1.90	802,076	3.61	1.90	301,957	1.90
5.75-7.23	37,900	5.42-5.84	5.75-7.23	—	—
9.38	234,593	5.20	9.38	5,967	9.38
	1,283,106	4.26	3.18	472,037	1.50

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

12. Research and License Agreements

As of December 31, 2004 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. Inhibitex 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. Inhibitex 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. Pursuant to these agreements, the Company has paid Texas A&M approximately $1.3 million of sponsored research payments as of December 31, 2004. The Company has no future minimum royalty or milestone obligations pursuant to these agreements. However, if the Company does not continue to pay sponsored research payments to Texas A&M, it will be obligated to pay a minimum royalty of $25,000 annually. The Company's obligation to pay sponsored research payments terminates in November 2005.

BioResearch Ireland (BRI)/Trinity College Dublin. Inhibitex has also obtained a license from BioResearch Ireland ("BRI") under certain patents and related applications licensed to it from Texas A&M, as described above. Scientists from both Texas A&M and BRI are co-inventors on these applications. The license also covers 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, this license 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. BRI is entitled to a royalty on the net sales of products sold utilizing these patents. Pursuant to these agreements, the Company has paid BRI approximately $382,000 through December 31, 2004. The Company has no future minimum royalty or milestone obligations pursuant to these agreements.

Wyeth. In August 2001, Inhibitex 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, Inhibitex 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, Inhibitex has received $3.8 million in an upfront license fee and annual research support payments from Wyeth as of December 31, 2004. The Company is also entitled to receive milestones upon the filing of an 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.

Dyax Corp.

In October 2004, Inhibitex entered into a collaboration agreement with Dyax Corp. to co-develop monoclonal antibodies to prevent or treat serious infections caused by enterococci. Under the terms of the agreement, Inhibitex 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, Inhibitex and Dyax are only responsible 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. Inhibitex'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 Inhibitex 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 five agreements relate to intellectual property associated with the production of monoclonal antibodies that the Company has in-licensed.

In November 2001, Inhibitex 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, Inhibitex agreed to pay an annual fee and a royalty on the net sales of any products that it may sell that utilize this technology. Inhibitex 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 $693,000 as of December 31, 2004.

In June 2003, Inhibitex obtained a non-exclusive, worldwide royalty-bearing license from Genentech for a 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. Inhibitex 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, 2004. 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, Inhibitex 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 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, 2004. 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 the 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 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 $350,000 to the Biostapro AB as of December 31, 2004. The Company's aggregate future payments under this agreement are $800,000.

13. Employee Benefit Plan

Inhibitex 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, $112,000, $108,000 and $138,000 in 2002, 2003 and 2004, 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.

14. 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.

	Revenue	Loss from Operations	Net Loss	Net Loss Attributable to Common Stockholders	Net Loss Attributable to Common Stockholders per Share — Basic and Diluted
Year Ended December 31, 2003					
First Quarter	$225,000	$(4,716,231)	$(4,647,137)	$(6,195,560)	$(11.95)
Second Quarter	225,000	(6,235,947)	(6,206,087)	(7,754,510)	(14.78)
Third Quarter	183,333	(6,055,302)	(6,054,360)	(7,602,782)	(14.35)
Fourth Quarter	462,500	(5,644,833)	(5,425,437)	(6,981,285)	(13.10)
Year Ended December 31, 2004					
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)	(.33)
Fourth Quarter	162,500	(8,555,270)	(8,207,950)	(8,207,950)	(.37)

15. 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. Inhibitex has invested in corporate notes and commercial paper, all of which have a minimum investment rating of A1/P1, and government agency notes. Inhibitex had no realized gains or losses from the sale of investments for the years ended December 31, 2004 and 2003. The cumulative unrealized (loss) gains were $(14,086) and $(1,579) at December 31, 2004 and 2003, respectively. The following table summarizes the estimated fair value of Inhibitex's short-term investments:

	December 31, 2004
	Estimated Fair Market Value
Government agency notes	$ 6,485,115
Corporate notes	8,142,552
Commercial paper	996,220
Total	$15,623,887

All available-for-sale securities held at December 31, 2004 will mature during 2005.

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 Affairs

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

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

Robert T. Schweiger, Vice President of Business Development

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

BOARD OF DIRECTORS

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

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

Carl E. Brooks, President – Brooks & Associates

J. Douglas Eplett, M.D., Managing Director – Essex Woodlands Heathcare Ventures

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

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

Arda M. Minocherhomjee, Ph.D., Partner – Chicago Growth Partners

Joseph M. Patti, Ph.D., Vice President of Pre-Clinical 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

SHAREHOLDER INFORMATION

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Transfer Agents
American Stock Transfer
New York, New York

Independent Public Accountants
Ernst and Young, LLP
Atlanta, Georgia

Legal Counsel
Dechert, LLP
New York, New York

Annual Meeting
The annual meeting for shareholders will take place on May 17, 2005, at 9:00 am at The Four Seasons Hotel Atlanta, located at 75 14th Street in Atlanta, Georgia.

Investor Information Requests
Copies of the Inhibitex, Inc. 2004 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

Email
IR@inhibitex.com

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

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

Firefly Creative, Inc. • Atlanta, GA

[redacted] is a clinical stage biopharmaceutical
[redacted] focused on the development and
[redacted] of first-in-class antibody-based
[redacted] for the treatment and prevention of serious,
[redacted] bacterial and fungal infections.

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