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innibitex, Inc.



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## Dear Fellow Stockholders:

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Over the past year, a successful transformation has taken place at Inhibitex – one that has resulted in a notable shift in our strategic focus, a rationalization of our operating costs, and the creation of an exciting development pipeline that consists primarily of potentially high value, differentiated antiviral therapies that we believe can one day make a meaningful difference in the lives of millions of patients worldwide.

We see tremendous opportunities in developing new and improved antiviral therapies. In particular, HIV/AIDS, chronic hepatitis C and shingles are large and growing infectious diseases that we believe are underserved by currently approved drugs. Accordingly, our near-term strategy is to focus the majority of our financial and organizational resources on advancing FV-100, which we are developing to treat shingles, and our recently in-licensed HIV integrase and HCV polymerase inhibitors through clinical proof of concept.

*FV-100* is our highly potent, orally available, nucleoside analogue that rapidly inhibits the growth of varicella zoster virus (VZV), the virus that causes both chicken pox and shingles. An estimated 2.5 million individuals develop shingles each year. When compared to currently approved antiviral therapies, we believe FV-100 has the potential to be more conveniently dosed and further reduce shingles-related symptoms, including the incidence and severity of a painful condition known as post herpetic neuralgia (PHN).

We obtained FV-100 through our acquisition of FermaVir Pharmaceuticals, Inc. in late 2007. Since then, we have made excellent progress in its clinical development. During the fourth quarter of 2007, we initiated and completed the first clinical trial of FV-100, which produced highly encouraging results. We plan on initiating a second Phase I trial of FV-100 in the very near future with a goal of advancing this compound into a Phase II trial in shingles patients around year end.

*Integrase Inhibitors* are a relatively new and promising class of anti-retroviral agents that block the ability of HIV to insert its DNA into the DNA of the host cell, thereby inhibiting the virus from replicating and infecting other cells. By inhibiting a different molecular target than currently marketed HIV drugs, integrase inhibitors hold the potential to treat patients with drug resistant strains of HIV. In late 2007, we in-licensed a series of integrase inhibitors that in preclinical studies were potent, orally bioavailable, and demonstrated the potential to be active against HIV strains resistant to other known integrase inhibitors. We are currently optimizing these compounds with the goal of selecting a lead clinical candidate near the end of 2008.

*HCV Polymerase Inhibitors* are an emerging class of drugs that can inhibit an enzyme critical to the lifecycle of HCV. An estimated 170 million people worldwide are infected with chronic hepatitis C, which is a leading cause of cirrhosis, liver cancer and liver failure. We recently in-licensed exclusive worldwide rights to a series of nucleoside analogues that have demonstrated exquisite potency against HCV genotype 1b, the most common and hard-to-treat form of HCV. Similar to our integrase inhibitor program, our goal is to select a lead compound from this program around the end of this year.

In 2007 we "set the stage" for an exciting future, anchored by a promising pipeline and a sound business strategy, which we are well positioned to execute. We ended 2007 with \$50 million on hand and are well-financed to support our planned operations well into 2010. We have also built a highly experienced drug development team, adept at the requisite medicinal chemistry, virology, biology, and analytics. Finally, we recently assembled a highly talented scientific advisory board, composed of distinguished scientists and thought leaders with recognized expertise in virology and infectious diseases, whose collective knowledge, expertise and insight will be invaluable as we go forward.

Our Board of Directors, management and employees are committed to carrying out our plan in a disciplined and transparent manner, building shareholder value and firmly establishing Inhibitex as a premier anti-infective drug development company. On behalf of our entire team, I thank you for your support through our recent transition and look forward to keeping you apprised of our achievements throughout 2008.



Sincerely,

A handwritten signature in black ink, which appears to read "R. Plumb". The signature is fluid and cursive, written over a white background.

Russell H. Plumb  
President and Chief Executive Officer

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2007

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the transition period from to

Commission file number: 000-50772

Inhibitex, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

9005 Westside Parkway Alpharetta, GA

(Address of principal executive offices)

74-2708737

(I.R.S. Employer Identification No.)

30004

(Zip Code)

(678) 746-1100

(Registrant's telephone number, including area code)

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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, par value \$.001 per share

Nasdaq Global Market

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

None

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [X] (Do not check if a smaller reporting company)

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

The approximate aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price on June 30, 2007 was \$26,567,965.

Number of shares of Common Stock outstanding as of March 11, 2008: 42,791,779

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive Proxy Statement with respect to the 2007 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (Part III).

SEC Mail Processing Section MAY 05 2008 Washington, DC 101

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## ITEM 1. BUSINESS

### PART I

#### 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, achievements or events to be materially different from any future results, performance, achievements or events 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 successfully advance and develop our preclinical and clinical product candidates;
- the expected timing of certain milestones, events and the development plans associated with our development programs;
- our ability to successfully execute our strategy;
- the expected timing of initiating and/or completing a Phase I trial evaluating single and multiple ascending doses of FV-100 in healthy volunteers;
- our plan, and the length of time it may take to select a lead candidate for our HIV integrase inhibitor program;
- our plan, and the length of time it may take to select a lead candidate for our HCV polymerase inhibitor program and our CMV nucleoside analogue program;
- our intent to further leverage or monetize our MSCRAMM® platform, including Aurexis, through licenses, co-development, collaborations or other transactions;
- our intent to establish new strategic collaborations in the future to accelerate the development and commercialization of our drug candidates;
- our plans to support our existing collaborations;
- the potential for our drug candidates to have improved potency, diminishing efficacy due to resistance, improved safety profiles, less adverse side effects, to be used in combination therapy to improve efficacy, acute pain and complex dosing schedules;
- our plans, and the length of time it may take to enter into a co-development, collaboration or another business transaction for Aurexis;
- the number of months that our current cash, cash equivalents, and short-term investments will allow us to operate;
- our future financing requirements, the factors that may influence the timing and amount of these requirements, and how we expect to fund them;
- potential future revenue from collaborative research agreements, partnerships, license agreements or materials transfer agreements;
- our ability to generate product-related revenue in the future;

- adequacy of our office and lab facility;
- and anticipated future and increased losses from operations and the potential volatility of our quarterly and annual operating costs.

*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: 3M Company or Wyeth not terminating our license and collaborative research agreements; maintaining sufficient resources, including executive management and key employees; our ability to successfully develop current and future product candidates either in collaboration with a partner or independently and through the regulatory process; our ongoing or future preclinical studies or clinical trials not demonstrating the appropriate safety and/or efficacy of our product candidates; our ability to secure and use third-party clinical and preclinical research and data management organization and, manufacturers who may not fulfill their contractual obligations or otherwise perform satisfactorily in the future; manufacturing and maintaining sufficient quantities of preclinical and clinical trial material on hand to complete our preclinical studies or clinical trials on a timely basis; failure to obtain regulatory approval to commence or continue our clinical trials or to market our product candidates; our ability to protect and maintain our proprietary intellectual property rights from unauthorized use by others; our collaborators failing to fulfill their obligations under our agreements with them in the future; our ability to attract suitable organizations to collaborate on the development and commercialization of our product candidates; the condition of the financial equity and debt markets and our ability to raise sufficient funding in such markets; our ability to manage our current cash reserves as planned; our ability to in-license or acquire additional antiviral development programs in the future to expand our emerging antiviral pipeline; changes in general economic business or competitive conditions; and other statements contained elsewhere in this Annual Report on Form 10-K and risk factors described in or referred to in greater detail in the "Risk Factors" section of this Form 10-K. There may be events in the future that we are unable to predict accurately, or over which we have no control. You should read this Form 10-K and the documents that we reference herein and have been filed or incorporated by reference as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. Our business, financial condition, results of operations, and prospects may change. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information. We qualify all of the information presented in this Form 10-K, and particularly our forward-looking statements, by these cautionary statements.*

*Inhibitex<sup>®</sup>, MSCRAMM<sup>®</sup>, Veronate<sup>®</sup>, and Aurexis<sup>®</sup> are registered trademarks of Inhibitex, Inc.*

## **Overview**

We are a biopharmaceutical company focused on the development of differentiated anti-infective products to prevent and treat serious infections. In 2006, we adopted a strategy to pursue pre-clinical or clinical-stage antiviral development programs via in-licensing or acquisition, and postponed the initiation of any additional clinical trials of Aurexis or other preclinical programs based on our MSCRAMM platform, pending the implementation of this new strategic direction. In connection with this strategy, we entered into the following transactions as described below.

On April 9, 2007, we entered into a definitive Agreement and Plan of Merger and Reorganization with FermaVir Pharmaceuticals, Inc., or FermaVir, which was completed on September 19, 2007. FermaVir's pipeline included FV-100, a nucleoside analogue being developed for the treatment of herpes zoster infections (shingles), and a series of preclinical nucleoside analogues with antiviral activity against cytomegalovirus, or CMV.

On September 11, 2007 we entered into an exclusive worldwide license agreement with the University of Georgia Research Foundation, or UGARF, for intellectual property covering a series of compounds for the treatment of human immunodeficiency virus, or HIV, integrase inhibitors, as well as small molecule compounds being developed for the treatment of hepatitis C virus, or HCV, infections in exchange for an upfront license fee, future milestone payments and royalties on future net sales. In connection with this license agreement, we also entered into a sponsored research agreement with UGARF to provide up to three years of

financial support for specified research and development activities related to the licensed compounds and intellectual property.

On November 19, 2007, we entered into an exclusive worldwide license agreement with Cardiff University in Wales, United Kingdom and Katholieke Universiteit in Leuven, Belgium for intellectual property covering a series of HCV polymerase inhibitors in exchange for an upfront license fee, future milestone payments and royalties on future net sales. The licensed compounds include a series of nucleoside analogs that inhibit NS5b, an RNA-dependent RNA polymerase, which is a critical enzyme in the lifecycle of HCV.

As a result of these transactions, we have transitioned our strategic focus with respect to the anti-infective market and are primarily concentrating on the development of small molecule antiviral compounds. We are currently targeting our development efforts on therapies for shingles, HIV infection, chronic hepatitis C and CMV.

Currently available antiviral therapies have various therapeutic limitations, such as inadequate potency, diminishing efficacy due to the emergence of drug resistant viral strains, and patient non-compliance with certain treatment regimens due to toxicity, adverse side effects, complex dosing schedules and inconvenient routes of administration. We believe that our drug candidates may have the potential to address a number of these limitations and unmet needs in their respective, intended indications.

From our inception in 1994 until the middle of 2006, we devoted substantially all of our resources and efforts towards the discovery and development of novel antibody-based products for the prevention and treatment of serious bacterial and fungal infections, all of which were based upon our proprietary MSCRAMM protein platform. In November 2005, we completed enrollment of a pivotal Phase III clinical trial of Veronate, our lead product candidate at that time, which we had been developing for the prevention of hospital-associated *Staphylococcal aureus* infections in premature, very low birth weight infants. On April 3, 2006, we announced that this pivotal Phase III trial did not achieve its primary endpoint, or any of its secondary endpoints. In light of these Phase III trial results, we discontinued the development of Veronate, reduced our work-force and realigned our operations consistent with the status of other then existing development programs.

We believe there may be significant business advantages on focusing on the development of drugs to treat infectious diseases, including the following:

- the emergence of drug resistance creates a continuing need for new drugs to treat viral diseases, thus creating new markets and growing business opportunities;
- infectious disease research and development programs generally have shorter development cycle times when compared to various therapeutic areas such as oncology, cardiovascular and central nervous system disorders; and
- historical data suggest that anti-infective development programs that enter clinical development have a higher clinical success rate as compared to various other therapeutic areas such as oncology, cardiovascular and central nervous system disorders.

We have neither received regulatory approval to sell or market any of our current or past product candidates, nor do we have any commercialization capabilities; therefore, it is possible that we may never successfully derive any commercial revenues from any of our existing or future product candidates.

## **Background**

Infectious diseases are caused by pathogens present in the environment, such as viruses, bacteria and fungi, which enter the body through the skin or mucous membranes and overwhelm its natural defenses. Some infections are systemic, meaning they affect the entire body, while others may be localized in one organ or system within the body. The severity of infectious diseases varies depending on the nature of the infectious agent, as well as the degree to which the body's immune system can fight the infection. The market for anti-infective drugs can be divided into three main categories: antiviral, anti-bacterial and antifungal.

The widespread use of anti-infective drugs has led to a significant reduction in morbidity and mortality associated with infectious diseases. However, for many infectious diseases, current treatment options are associated with suboptimal treatment outcomes, significant drug-related adverse side effects, complex dosing schedules and inconvenient methods of administration, such as injection or infusion. These factors often lead to patients discontinuing treatment or failing to comply fully with treatment dosing schedules. As a result, physicians are often required to modify therapy regimens throughout the course of treatment.

Moreover, in recent years, the increasing prevalence of drug resistance has created ongoing treatment challenges with respect to many infectious diseases. The ability of both viruses and bacteria to adapt rapidly to existing or new treatments through genetic mutations allows new strains to develop that are highly resistant to currently available drugs. In addition, a patient's failure to comply fully with a treatment regimen can both accelerate and exacerbate drug resistance.

### ***Viruses***

Viruses are submicroscopic infectious agents consisting of an outer layer of protein surrounding a core of genetic material comprised of DNA or RNA. Viruses require living host cells in order to grow and multiply. In many cases, the body's immune system can effectively combat an infection caused by a virus. However, with certain viral infections, the body's immune system is unable to destroy the virus, which results in persistent viral replication and the subsequent infection of healthy cells by the virus. This ultimately leads to the deterioration or destruction of the infected cells, resulting in disease. Infections caused by virus can be both acute and chronic. Acute infection is associated with viruses such as influenza, and generally causes disease that lasts for a short period of time and can self-resolve. Chronic infections may either be latent or active. A latent virus, such as varicella zoster, or VZV, or CMV, can remain in the body for long periods of time, and generally only cause disease when the body's immune system weakens, fails or is suppressed. An active virus can cause disease over a long period of time, as seen with both chronic HCV and HIV.

Antiviral drugs are designed to treat and/or prevent viral diseases. Antiviral drugs are generally developed for a specific virus, but some are active against a number of viruses. Antiviral drugs work by stopping viral replication, or by significantly inhibiting viral replication and allowing the body's immune system to eliminate the virus.

Viruses that develop resistance to antiviral drugs are a major challenge in the treatment of viral infections. The ability of viruses to mutate spontaneously during replication allows drug-resistant strains to emerge when patients are on treatment regimens that do not quickly and completely inhibit viral replication. Resistance occurs because viruses continually make millions of copies of themselves every day, some of which will contain mutations in their genetic material. Mutations that confer a replication advantage in the presence of a suppressive antiviral drug will give rise to viral strains that are resistant or partially resistant to that drug. These mutated viruses, while initially found in low numbers, will eventually become the predominant strain in an infected patient. Once this occurs, the treatment benefit of the antiviral drug diminishes or disappears, which may result in treatment failure and create a need for an alternate therapy with different or possibly new drugs or classes of drugs.

### ***Bacteria***

Bacteria are unicellular, self-propagating microorganisms that multiply through growth in bacterial cell size and the subsequent division of the cell. Bacteria can be broadly classified into two categories based upon the composition of their cell walls: gram-positive or gram-negative. Many antibacterial drugs that are effective against gram-positive bacteria are less effective or ineffective against gram-negative bacteria, and vice versa. Antibacterial drugs that are active against a large number of both classes of bacteria are often referred to as "broad-spectrum" anti-bacterials.

Currently marketed antibacterials, or antibiotics, have historically proved highly successful in controlling the morbidity and mortality that accompany many bacterial infections. Due to the widespread use of antibiotics over time and the ability of bacteria to develop drug resistance, many of these antibiotics now have diminished

or limited antibacterial activity. The inability to effectively treat serious infections caused by drug-resistant bacteria has led to increased mortality rates, prolonged hospitalizations and increased health care costs.

### Our Product Candidates

The following table summarizes key information regarding our product candidates:

<u>Drug Candidate</u>	<u>Indication</u>	<u>Stage of Development</u>	<u>Current Status</u>	<u>Current Marketing Rights</u>
<b>Antivirals</b>				
FV-100	<i>Herpes Zoster (shingles)</i>	Clinical	• Plan to initiate Phase I single ascending dose trial	Inhibitex
HIV Integrase Inhibitors	<i>HIV Infection</i>	Preclinical	• Lead optimization studies in progress	Inhibitex
HCV Polymerase Inhibitors	<i>Chronic HCV Infection</i>	Preclinical	• Lead optimization studies in progress	Inhibitex
HCMV	<i>HCMV infection</i>	Preclinical	• Lead optimization studies in progress	Inhibitex
<b>Antibacterials</b>				
Aurexis	<i>Serious S. aureus Infections</i>	Phase IIa	• Completed Phase IIa	Inhibitex
Staphylococcal Vaccines	<i>Active Vaccine</i>	Preclinical	• Preclinical studies in progress	Wyeth
Diagnostics	Various	Pre-market	• Development	3M

#### ***FV-100 for Shingles***

FV-100 is a nucleoside analogue prodrug we are developing for the treatment of herpes zoster, or shingles, caused by varicella zoster virus, or VZV. VZV is also the causative agent for chicken pox. Published preclinical studies demonstrate that FV-100 is significantly more potent than acyclovir, valacyclovir (Valtrex®), and famciclovir (Famvir®), the only FDA approved drugs for the treatment of shingles. Preclinical studies indicate that FV-100 can enter VZV-infected cells and fully inhibit the replication of VZV much more rapidly than acyclovir, and at significantly lower concentration levels. We believe these characteristics may provide the potential for FV-100, and its antivirally active derivative CF-1743, to reduce the incidence, severity, and duration of shingles-related symptoms, including rash, blisters, acute pain and post herpetic neuralgia, or PHN. In addition, preclinical and early clinical pharmacokinetic data suggest that FV-100 may have the potential to be dosed orally once a day. In the fourth quarter of 2007, we initiated and completed a Phase I clinical trial of FV-100 under an exploratory Investigational New Drug Application, or IND, in the United States. This trial evaluated the safety and pharmacokinetics of three doses of FV-100 in 24 healthy volunteers. There were no serious adverse events observed and FV-100 appeared to be generally well tolerated in the trial. We recently completed IND-enabling preclinical studies and we plan to submit a regular IND for FV-100 and initiate a Phase I trial evaluating single ascending doses in healthy volunteers in the first half of 2008.

### *Market Opportunity for the Treatment of Shingles*

VZV, a DNA virus and a member of the herpes virus group, is the virus that causes both chickenpox and herpes zoster, or shingles, in humans. Initial infections with VZV generally occur during childhood and result in chickenpox. After the primary chickenpox infection subsides, VZV remains latent in dorsal root and cranial nerve ganglia. Individuals who have had chickenpox are at risk for reactivation of the VZV virus, known as shingles.

Although shingles can occur in any individual with a previous VZV infection, its incidence varies with age and immune status, which are the key risk factors. In 2006, there were an estimated 1.0 million cases of shingles in the U.S. In Europe and Japan, the estimated number of shingles cases is 1.0 and 0.5 million, respectively. Shingles is largely a disease of the aged or aging, with over 50% of all cases occurring in individuals over the age of 60, and approximately 80% of the cases occurring in individuals over the age of 40. Due to the aging population, the increasing use of immunosuppressive agents in transplant patients, and the increased numbers of immunosuppressed patients from cancer therapy, the incidence of shingles is expected to increase. It is estimated that approximately 15 to 20% of all persons in the U.S. will suffer from shingles during their lifetime.

The symptoms associated with shingles generally include a localized rash, blisters, and acute pain. Shingles generally starts as small blisters with new blisters continuing to form for several days. The blisters generally follow the path of nerves that emanate from the spinal cord around the torso. Eventually, the blisters will burst and the infected areas will begin to ooze and eventually crust over and heal. The course of the infection typically takes two to four weeks to complete. On occasion, blisters may never appear, but pain will be present. Fewer than 20% of patients experience significant systemic symptoms from shingles, such as fever, headache, malaise, or fatigue.

The pain associated with shingles is a result of damage to the nerve fibers caused by the reactivation of VZV. Pain symptoms are commonly described as a burning sensation with bouts of stabbing and shooting pain, often set off by touching the infected area. The majority of shingles patients will experience acute pain in connection with their infection. In some patients, the shingles-related pain does not resolve when the rash heals but, rather, continues for months or possibly years. This persistent pain is referred to as post herpetic neuralgia, or PHN, and it is the most common complication of shingles. Approximately 20% of shingles patients experience PHN, although the incidence of PHN increases dramatically in patients over 60 years of age where approximately half of the patients will experience shingles-related PHN. Previous studies have established that additional risk factors for PHN include greater acute pain intensity, greater severity of the rash, and the presence and greater severity of a painful prodrome preceding the rash.

In 2006, Merck & Co., Inc received approval to market a shingles vaccine called Zostavax to patients 60 years of age and older. Clinical data indicated that the vaccine can reduce the incidence of shingles by approximately 51% in this population. We are not aware of any other vaccine under development for the prevention of shingles.

Acyclovir (Zovirax®), valacyclovir (Valtrex® — a prodrug of acyclovir), and famciclovir (Famvir® — a prodrug of penciclovir) are oral antivirals currently indicated and approved to treat shingles. These drugs are referred to as “pan-herpetic” drugs, in that they were developed, and are currently being used, to treat various infections caused by viruses in the herpes virus group, including herpes simplex 1 and 2. In fact, it is estimated that approximately 70% of the over \$2.0 billion in annual sales these three drugs generate based on current pricing are for non-shingles use. Accordingly, we currently estimate that the size of the market for oral antivirals to treat shingles may exceed \$500 million per year.

Clinical trial data indicate that administration of these pan-herpetic drugs within 48-72 hours of the appearance of a shingles-related rash can lessen the duration of shingles dermatological symptoms. While these drugs are generally well tolerated, side effects include nausea, headache, diarrhea and vomiting, and all of these drugs dosing schedules must be adjusted for certain patients with insufficient renal function. A course of treatment for shingles with the currently approved FDA drugs is generally 7 to 10 days.

### *Limitations of Current Therapies*

Currently approved pan-herpetic drugs used to treat shingles have a number of limitations, including the following:

- *No FDA Approved Label for the Prevention of PHN.* Currently, there are no oral antiviral therapies indicated for the prevention of PHN. There is also no cure for PHN; rather, treatment focuses on pain management. The most commonly prescribed medications are strong pain relievers containing opioids, antidepressants, anticonvulsants and a topical lidocaine patch. Based upon previously published data evaluating the impact of antiviral therapy on PHN, we believe a highly potent, fast acting anti-VZV compound may have the potential to more rapidly inhibit the replication of VZV, thus reducing the potential for shingles-related nerve damage and therefore, PHN. We believe an antiviral therapy that can reduce PHN may have a significant competitive advantage relative to the current oral antiviral shingles therapies.
- *Lack of Convenience.* Due to their pharmacokinetic properties, current pan-herpetic oral antiviral therapies used to treat shingles require patients to take 3-5 oral doses each day for 7 to 10 days. Specifically, current dosing regimens are as follows: Famvir® — 500 mg, 3 times per day; Valtrex® — 800 mg, 3 times per day; and Zovirax® — 800 mg, 5 times per day. Given the fact that many of shingles patients are elderly and are taking other medications, such dosing regimens are inconvenient and can result in non-compliance and hence, less than optimal treatment outcomes. We believe that a convenient, once-a-day oral administration of an effective antiviral therapy may have a competitive advantage relative to current shingles therapies.
- *Antiviral Drug Dosing Must be Adjusted for Patients with Insufficient Renal Function.* Although current antiviral therapies are generally safe and well tolerated, the doses of Valtrex®, Famvir® and Zovirax® need to be adjusted for patients with insufficient renal (kidney) function to avoid potential adverse events. We believe that an oral antiviral therapy that has a similar safety profile to Valtrex®, Zovirax® and Famvir®, but is not required to be adjusted for patients with renal insufficiency, may have a competitive advantage over currently approved shingles therapies.

We believe there is an unmet need for more potent and faster acting antiviral agents such as FV-100 that may have the potential to reduce the incidence, severity, and duration of shingles-related symptoms, including rash, blisters, acute pain and PHN. Due to its potency and its ability to rapidly penetrate infected cells, we also believe that the amount of FV-100 necessary to inhibit viral replication may be significantly lower than that of the current antiviral therapies, resulting in smaller doses and potentially fewer and less severe side effects. We also believe that the pharmacokinetic properties of FV-100, as observed to-date in preclinical studies and in the Phase I trial we conducted under an exploratory IND in late 2007, may provide for less frequent oral dosing than Valtrex®, Zovirax®, and Famvir®.

### *FV-100 Clinical Trials*

*Phase I.* In December 2007, we reported the results from a blinded, placebo-controlled single ascending dose Phase I clinical trial conducted in the United States under an exploratory Investigational New Drug Application (IND) and evaluated the safety and pharmacokinetics of three oral doses of FV-100 (10, 20 and 40 mg) in healthy volunteers. Each of the three dose cohorts consisted of six subjects that received FV-100 and two that received placebo. There were no serious adverse events observed and that the compound appeared to be generally well tolerated in the trial. In addition, pharmacokinetic data demonstrated that all three doses achieved plasma levels of CF-1743 which exceeded the EC50, with the 40 mg dose maintaining such levels for approximately twelve hours. The EC50 represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*.

### *HIV Integrase Inhibitors*

Integrase inhibitors are an emerging class of anti-retroviral agents being developed for the treatment of HIV. This class of compounds blocks or inhibits the insertion of HIV viral DNA into the genome of the host cell, thereby stopping the virus from replicating. By inhibiting a different molecular target than other classes of HIV drugs such as reverse transcriptase or protease inhibitors, integrase inhibitors may have the potential to

treat patients with drug resistant strains of HIV. Preclinical studies of our integrase inhibitors have demonstrated that the compounds are potent and orally available, exhibit multiple mechanisms of integrase inhibition *in vitro* and have the potential to be active against HIV strains that are resistant to other anti-retroviral classes as well as the only integrase inhibitor approved for sale or those currently in clinical development. We are currently performing lead optimization studies with the goal to select a lead clinical candidate from this program in the future.

#### *Market Opportunity for the Treatment of HIV*

HIV destroys the body's ability to fight infections by attacking cells of the immune system. In 1981, the first cases of Acquired Immunodeficiency Syndrome, or AIDS, were documented, and in 1983, HIV was identified as the cause of AIDS. In the United States, the CDC has reported that the HIV mortality rate has steadily declined since the mid-to-late 1990s, while the incidence of infection continues to rise. This decrease in mortality can be attributed, in large part, to the increased availability of anti-retroviral agents used in the long-term treatment of HIV. According to a recent 2007 UNAIDS/WHO report, by the end of 2007, approximately 1.3 million people in North America and 760,000 people in Western and Central Europe were living with HIV and an additional 46,000 new patients in North America and 31,000 new patients in Western and Central Europe are diagnosed each year. The HIV market generated an estimated \$8.2 billion of sales in 2006 (MIDAS Sales Data, IMS Health, May 2007) and experienced a CAGR of 13.3% from 2003 to 2006. It is expected that the HIV market will continue to grow to \$11.5 billion by 2016 (Datamonitor, *Commercial Insight, 2007: HIV*).

To date, the FDA has approved more than 20 single agents from various classes of drugs, including nucleoside reverse transcriptase inhibitors, or NRTIs, non-nucleoside reverse transcriptase inhibitors, or NNRTIs, protease inhibitors, or PIs, entry inhibitors, and recently an integrase inhibitor, as well as multiple fixed-dose combination therapies for the treatment of HIV.

NRTIs mimic natural nucleosides and are commonly referred to as nucleoside analogs. In the body, NRTIs block viral replication by interfering with the ability of reverse transcriptase to make a DNA copy of HIV RNA. This occurs because this enzyme incorporates the nucleoside analogs instead of the natural nucleosides into newly synthesized viral DNA, causing the premature termination of the DNA chain. This impairs either the synthesis or the functionality of the new viral genome, thereby suppressing viral replication. NNRTIs are composed of a diverse group of compounds unrelated to nucleosides that also directly target the reverse transcriptase. These drugs bind to the enzyme, causing a change in the shape of the enzyme that makes it less efficient in producing DNA. Protease inhibitors target an HIV enzyme that is required to make fully mature and infectious virus. This enzyme processes the viral proteins required to create a protective protein shell that surrounds the HIV RNA. The protease inhibitor class of compounds prevents the HIV protease from making mature virus capable of infecting other cells. Entry inhibitors work outside the cell by inhibiting a virus from entering and infecting the cell. Integrase inhibitors represent one of the newest class of HIV drugs to be approved by the FDA, and these drugs prevent the integrase enzyme from integrating the viral genetic material into human chromosomes, a critical step in the pathogenesis of HIV.

The standard treatment for HIV infection, as recommended by the U.S. Department of Health and Human Services, includes two NRTIs combined with a third drug from another class, either an NNRTI or a protease inhibitor, to form a triple combination therapy known as Highly Active Anti-Retroviral Therapy, or HAART. The two NRTIs in HAART are usually analogs of different nucleosides.

NRTIs, NNRTIs, PIs and integrase inhibitors are generally administered orally as a tablet or capsule. Several of the drugs in these classes are effective when taken once each day. In treatment-naïve individuals, a once-daily therapy has been shown to improve compliance with the prescribed treatment regimen, which leads to better treatment outcomes. To provide additional convenience, several companies have developed combination therapies that combine two or more NRTIs into a single tablet or capsule. These fixed-dose combination therapies have become leaders in the HIV marketplace. As patients develop resistance to certain therapies, they are switched to other treatments. Increasingly, potency against drug-resistant virus has become more important than convenience in treatment-experienced patients.

HIV's inherent ability to mutate results in the occurrence of about one mutation in every new virus particle produced. With over ten million virus particles produced within a 24-hour period, it is possible to observe every conceivable genetic mutation each day, although not all mutated viruses are viable. When a drug-resistant form of HIV first arises, it usually comprises a very small percentage of the virus circulating in the blood. As the original or wild-type virus continues to be suppressed by antiviral therapy and the drug-resistant virus continues to replicate, the mutated virus eventually becomes the dominant virus type. To reduce the likelihood of a dominant drug-resistant mutation, patients must strictly comply with their treatment regimens. Each of the HIV therapies is susceptible to a mutation that confers drug resistance. New drug-resistant forms of HIV continue to emerge, and as a result, new NRTI's, NNRTI's, PIs, integrase inhibitors and other new classes of anti-retroviral therapies to fight drug-resistant HIV will continue to be successfully developed and commercialized.

As previously described, HAART, the current standard of care for patients infected with HIV, is comprised of three or more drugs that are ideally directed against different viral targets. This approach is based on two principles. First, the onset of viral resistance can be delayed by using multiple drugs that maximally suppress viral replication, thereby making it more difficult for a virus to generate the mutations that allow for the emergence of dominant drug-resistant virus. Second, based on scientific studies, it is much more difficult for a drug-resistant virus to arise in the presence of drugs that inhibit different viral targets.

#### *Limitations of Current Therapies*

Currently approved anti-retroviral drugs have significant limitations, including the following:

- *Development of Drug Resistance.* Ongoing viral replication in patients on a HAART regimen results in the emergence of viral strains that are no longer susceptible to one or more components of the treatment regimen. If left unchecked, this may lead to treatment failure. In addition, development of resistance to certain drugs can lead to cross-resistance, or resistance to other drugs of the same class, thus rendering a whole class of drugs ineffective. In order to maintain viral suppression, patients failing a HAART regimen are switched to a new regimen comprised of drugs that are not cross-resistant with drugs from previous regimens.
- *Short Half-Lives of Currently Available Therapies.* Many of the currently available drugs have relatively short plasma half-lives, meaning the length of time that the drug remains in the patient's bloodstream or cells. Short half-lives require patients to take their medications more frequently, or in the case of once-daily dosing, to take doses within a certain timeframe. If patients miss this window, or forget entirely to take their medication, the amount of drug in the bloodstream diminishes, creating an opportunity for increased viral replication and the emergence of drug resistance strains.
- *Inadequate Patient Compliance.* A patient's ability to adhere to a HAART regimen will significantly impact the treatment outcome. Virologic failure rates have been found to be inversely correlated to the level of compliance. The chronic nature of AIDS and the long-term adverse side effects associated with certain drugs, such as the loss of subcutaneous fat associated with certain NRTIs, affect the ability of HIV patients to strictly adhere to their dosing schedules.
- *Limited Treatment Options.* Most current HAART regimens include two NRTIs and a protease. Although there are a number of commonly used NRTIs, not all of them can be paired together due to cross-resistance and drug-to-drug interactions. As drug resistance develops and the efficacy of treatment regimens diminishes over time, patients cycle through different HAART regimens, eventually exhausting all the available NRTI pairings. Therefore, we believe that there is a continuing need for compounds from new classes of drugs, including integrase inhibitors.

#### *HCV Polymerase Inhibitor*

Our HCV program consists of a series of nucleoside and non-nucleoside polymerase inhibitors for the treatment of hepatitis C virus, or HCV. Our compounds target NS5b, an RNA-dependent RNA polymerase that is a critical enzyme in the lifecycle of HCV. In vitro studies using a HCV genotype 1b subgenomic replicon

system demonstrate that our nucleoside analogues are among the most potent HCV polymerase inhibitors in development.

### *Market Opportunity for the Treatment of HCV*

HCV is the most common chronic blood-borne viral infection in the United States and a leading cause of liver failure, liver transplants and liver cancer. HCV is often found among hemodialysis patients, hemophiliacs and recipients of blood transfusions before 1990. HCV is now transmitted primarily through injection drug use and by pregnant women infecting their children in utero. The World Health Organization estimates that nearly 180 million people worldwide, or approximately 3% of the world's population, are infected with HCV. Of these individuals, 130 million are chronic HCV carriers with an increased risk of developing liver cirrhosis or liver cancer. HCV is responsible for more than half of all liver cancer cases and two-thirds of all liver transplants in the developed world, and it is estimated that 3 to 4 million people worldwide are newly infected each year, 70% of whom will develop chronic hepatitis C. The CDC estimates that approximately 3.2 million people in the United States are chronically infected with HCV. Because symptoms of this chronic disease do not appear until its later stages, carriers often do not realize they are infected and serve as a source of transmission.

### *Limitations of Current Therapies*

The current standard of care for the treatment of HCV infection is a combination of a once-weekly injection of pegylated interferon and a twice-daily oral administration of ribavirin, an antiviral drug that interferes with viral replication. Pegylated interferon is a modified version of alpha-interferon, a protein that occurs naturally in the human body and stimulates the ability of the immune system to fight viral infections. Both pegylated interferon and ribavirin may cause side effects, the most common of which are flu-like symptoms, muscle pain, and headache for pegylated interferon, and anemia for ribavirin. In addition, the FDA has required that product labels for pegylated interferon and ribavirin include "black box" warnings due to their potential to cause serious side effects. Ribavirin also may cause birth defects or death of the fetus and is therefore not recommended for use in pregnant women. The side effect profile and 48 week duration of therapy associated with the combination therapy of pegylated interferon and ribavirin, together with interferon's administration by injection, may reduce patients' motivation to initiate or continue HCV therapy under this standard of care.

There are several types, or genotypes, of HCV. In the United States, HCV genotypes 1a and 1b are the two predominant strains of HCV and account for approximately 70% of HCV infections. Unfortunately, less than 50% of treated patients with HCV genotypes 1a and 1b respond to current standard of care with a sustained viral response, or SVR, defined as the absence of a detectable amount of the virus in the blood six months after the end of treatment. Despite their limitations, these standard HCV therapies generated worldwide sales of approximately \$2.2 billion in 2005, and are forecasted to increase to more than \$4.0 billion by 2010 and \$8.0 billion by 2015.

There are currently two approaches to inhibiting the activity of the HCV polymerase. One is the use of nucleoside analogues that mimic the nucleotides normally recognized by the enzyme as it builds a new copy of the viral genome. These nucleoside analogues take advantage of the fact that the virus can tolerate few mutations in its active sites. Any amino acid changes that might occur that would reduce the ability of the nucleoside analogue to bind may also reduce the ability of the polymerase to bind the normal nucleotides. The other approach involves non-nucleoside molecules that can bind to various regions on the polymerase away from the active site. This type of binding generally prevents the polymerase from assuming the correct configuration and in turn either reduces or prevents its activity. The activity of non-nucleoside drugs depends on their ability to bind relatively tightly to specific amino acid sequences and often involves multiple molecular interactions. If any of these interactions are missing due to a change in the polymerase sequence then binding can not occur properly. The probability of this happening is much greater with non-nucleoside than with nucleoside analogues.

In response to the limitations of existing treatments for HCV infection, NS5b polymerase inhibitors have emerged as a potential complement or alternative to the standard treatment. Unlike interferons, which work by

stimulating the immune system's response to viral infection, polymerase inhibitors directly target the virus by inhibiting the NS5V polymerase. Accordingly, polymerase inhibitors may significantly improve treatment outcomes when added to the standard of care in difficult-to-treat patients, including patients infected with HCV genotypes 1a and 1b, relative to treatment with the standard of care alone. The addition of polymerase inhibitors to the standard of care could also lead to shorter treatment duration, which could increase patient compliance. It is likely that NS5b polymerase inhibitors will initially be used in combination with pegylated interferon, ribavirin, and potentially HCV protease inhibitors, however, it may be possible to eventually replace the treatment regimen under the current standard of care with a combination of oral therapies directed at HCV, including polymerase inhibitors.

The FDA has not yet approved any NS5b polymerase inhibitors for the treatment of HCV infection, but several pharmaceutical and biotechnology companies are developing product candidates that target the polymerase. The most advanced polymerase inhibitors are currently in Phase II clinical trials.

## **CMV**

We have licensed a series of nucleoside analogues we are developing for the prevention and/or treatment of cytomegalovirus, or CMV. CMV is a member of the herpes virus group, which includes the viruses that cause chicken pox, shingles, and herpes.

### *Market Opportunity for the Treatment of CMV*

CMV is a virus that most adults carry with them day to day and can remain dormant in the body for long periods of time. By 40 years of age, between 50% and 80% of adults in the United States will have had an infection caused by CMV. In most individuals with intact or well functioning immune systems, CMV causes little or no apparent illness. However, in immunocompromised individuals, CMV can lead to serious disease or death. Before the availability of potent anti-HIV therapy, CMV associated retinitis was common in AIDS patients. Currently, patients who are immunosuppressed following hematopoietic stem cell (e.g., bone marrow) or solid organ transplantation remain at very high risk to CMV infection. In these patients, CMV can lead to severe conditions such as pneumonitis or hepatitis, or to complications such as acute or chronic rejection of a transplanted organ.

Certain antiviral drugs are effective for the prophylaxis and pre-emptive therapy of CMV infection and disease, but are less effective for the treatment of established CMV disease. Further, currently used therapies exhibit significant toxicities and side effects that often limit their use in transplant patients who often have severe comorbidities. Maribavir (Camvia™), a drug candidate currently being developed by ViroPharma, is in Phase III clinical trials. Clinical data suggest that maribavir is a potent and selective, orally bioavailable antiviral drug with a unique mechanism of action against CMV and may have a more favorable clinical tolerability profile than current therapies.

We believe that our CMV compounds may have properties that provide for the potential to improve the prevention and treatment of CMV. Preclinical data suggests that the compounds have a novel mechanism of action and good physical properties.

## **Aurexis**

Aurexis is a humanized monoclonal antibody that we had been developing as a first-line therapy, in combination with antibiotics, for the treatment of serious, life-threatening *Staphylococcus aureus*, or *S. aureus* bloodstream infections in hospitalized patients. Aurexis targets ClfA, a protein found on the surface of virtually all strains of *S. aureus*, including methicillin resistant *S. aureus*, or MRSA. In 2005, we completed a 60 patient Phase II trial of Aurexis in patients with confirmed *S. aureus* bloodstream infections. The results suggested that Aurexis was generally safe and well tolerated in these patients. Aurexis has been granted Fast Track designation by the FDA for the adjunctive treatment of *S. aureus* bloodstream infections.

Based upon our newly adopted strategic focus on antivirals and the lengthy developmental time and resources required to complete a well-powered Phase II proof of concept trial of Aurexis, we do not intend to allocate

any additional development resources to advance the clinical development of Aurexis at this time. We do, however, plan to seek licenses, co-development collaborations, or other business arrangements that can provide financial resources and other synergistic capabilities to support the further development of Aurexis.

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

*S. aureus* is one of the leading causes of hospital-associated infections. An estimated 300,000 *S. aureus* infections occur in the United States annually. We estimate, based on compiled data, that approximately 90,000 of these *S. aureus* infections are bloodstream infections, also referred to as *S. aureus* bacteremia. We believe that the degree to which the medical community may adopt the use of Aurexis, if and when it is approved by the FDA, will be based primarily on its ability to reduce the incidence of infection-associated mortality, the relapse rate associated with these infections, unresolved secondary site infections, and the number of days that patients with such infections stay in the intensive care unit or hospital.

#### *Aurexis Clinical Trials*

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

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

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

Favorable trends were observed in the composite primary endpoint of mortality, relapse rate and infection-related complications, and a number of secondary endpoints and ad-hoc analyses, including the progression in the severity of sepsis, the number of days in the intensive care unit, and the resolution of complications associated with *S. aureus* bacteremia. The Phase II trial was not powered or designed to demonstrate statistically significant differences among the treatment arms in measures of efficacy. Accordingly, these preliminary findings were not statistically significant. We cannot guarantee that the results of subsequent clinical trials of Aurexis will confirm the findings of the Phase II trial.

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

#### *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 for the development of human vaccines against staphylococcal organisms. Wyeth has initiated preclinical studies of a vaccine candidate.

## ***Diagnostic Products***

In January 2007, we entered into a license and commercialization agreement with 3M Company, or 3M, for the development of certain diagnostic products using our MSCRAMM protein platform. Under the terms of the agreement, we granted 3M an exclusive global license to use Clumping Factor A (ClfA), an MSCRAMM surface protein, in the development of diagnostic products. We also granted 3M a license to use additional MSCRAMM protein targets for the development of other diagnostic products. In exchange for these licenses, we received an upfront license payment and are entitled to receive future milestone payments, financial support of further research and development activities and royalty payments on product sales.

## **Our Strategy**

Our goal is to become a leading biopharmaceutical company that discovers and develops differentiated products that can prevent and treat serious infections. In order to achieve this goal, we intend to focus on the following strategies:

- *Advance the Development of Our Current Anti-Viral Product Candidates.* We plan to focus our resources on the development of our most advanced clinical antiviral compound, FV-100, for the treatment of shingles, and our three preclinical antiviral development programs: HIV integrase inhibitors, nucleoside and non-nucleoside HCV polymerase inhibitors, as well as a series of compounds for the prevention and/or treatment of CMV. In particular, we plan to:
  - Advance the development of FV-100 through clinical proof of concept, including the initiation of an additional Phase I clinical trial evaluating single ascending and multiple ascending doses of FV-100 in healthy volunteers in the first half of 2008;
  - Select a lead clinical candidate from our HIV integrase inhibitor program and advance this clinical candidate through Phase I clinical trials
  - Select a lead clinical candidate from our HCV polymerase inhibitor program and advance this clinical candidate through Phase I clinical trials
  - Select a lead clinical compound for the prevention and/or treatment of CMV.
- *Leverage or Monetize our MSCRAMM Platform.* We do not plan to allocate any additional development resources to advance the clinical development of programs based upon our MSCRAMM protein platform, but rather intend to further leverage our capabilities and intellectual property associated with our MSCRAMM protein platform by pursuing licenses, co-development, collaborations or other business arrangements that can provide financial and other synergistic capabilities to support the further development and potential of these programs, including Aurexis. We also plan to continue to support our existing MSCRAMM — based license and collaboration agreements with Wyeth for the development of staphylococcal vaccines and 3M for the development of diagnostic products.
- *Accelerate Growth Through New Collaborations.* We intend to establish new strategic collaborations, partnerships and alliances where we believe we can accelerate the development of our development programs and drug candidates beyond preclinical or clinical proof of concept by utilizing the financial, clinical development, manufacturing and commercialization strengths of a leading pharmaceutical company.

## **Sales and Marketing**

We currently have limited, if any, commercialization capabilities. At this time, we anticipate partnering or collaborating with other larger pharmaceutical or biopharmaceutical companies to advance our antiviral product candidates through late-stage clinical development, and if successful, to commercialize our product candidates. We intend to evaluate whether or not we may independently develop and commercialize any existing or future drug development programs on a case-by-case basis.

## **Manufacturing**

We do not own or operate any manufacturing facilities. We currently rely on contract manufacturers to produce drug substances and drug products required to conduct our clinical trials under current good manufacturing practices, or cGMP, with oversight by our management team. We currently rely on a single manufacturer for the preclinical or clinical materials of each of our drug candidates. However, we believe that there are alternate sources of supply and other contract manufacturers that can produce drug substances and drug products for our preclinical studies and clinical trial requirements without significant delay or material additional costs.

We have used a contract manufacturer, Davos Chemical Company, Inc., or Davos, to produce clinical trial material for use in the preclinical studies and clinical trials of FV-100. As of December 31, 2007, we have no long-term obligations under any of our prior agreements with Davos to manufacture additional clinical trial material for our FV-100 program.

## **Competition**

Our industry is highly competitive and characterized by rapid technological change. Significant competitive factors in our industry include, among others, the ability to advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicological, safety, resistance or cross-resistance, and dosing profile of a product or product candidate; the timing and scope of regulatory approvals; 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. If ultimately approved, FV-100, as well as all of compounds in our antiviral development programs, would compete against existing therapies or other product candidates in various stages of clinical development that we believe may become available for the treatment of shingles, HIV, hepatitis C and bacterial infections in the future. Some of the companies that currently market products that would compete with our product candidates include, but are not limited to: GlaxoSmithKline, Novartis and Merck in the shingles market; Pfizer, Merck and Gilead in the HIV market, and Roche and Schering-Plough in the hepatitis C market. In addition there are several other competitors developing other early-stage drug candidates that may compete with our product candidates in the future.

Developing pharmaceutical product candidates is a highly competitive, expensive, time consuming and risky activity. Many organizations, including large pharmaceutical and biopharmaceutical companies, have substantially more capital resources than we have, and much greater capabilities and experience than we have in basic research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, manufacturing drug substance and drug product, marketing and sales. Our competitors may be more successful than we in obtaining FDA approval for their product candidates and achieving broad market acceptance once approved. Our competitors' drugs may be more effective, have fewer negative side effects, have a more favorable drug-resistance profile, or be more effectively marketed and sold than any drug we may commercialize. New competing drug products or new classes of drugs from our competitors may render our drug candidates obsolete or non-competitive before we successfully develop our product candidates or, if approved, before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we or our collaborators will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or drug targets become available. This may cause us or our collaborators to terminate the development or commercialization of our drug candidates at any time in the future.

A number of our product candidates if approved, particularly FV-100, will compete directly or indirectly with existing generic drugs, or drugs that will be generic by the time our product candidate might be approved for sale. Generic drugs are drugs whose patent protection has expired, and generally have an average selling price substantially lower than drugs protected by intellectual property rights. Unless a patented drug can differentiate itself from a generic drug in a meaningful manner, the existence of generic competition in any indication will generally impose significant pricing pressure on competing drugs.

## **Intellectual Property Rights and Patents**

We own or have licensed numerous issued United States patents and pending patent applications, as well as corresponding international filings in the fields of our development programs and product candidates. In addition to our patents and patent applications, we have registered trademarks for Inhibitex, MSCRAMM, Veronate and Aurexis.

Patent and other proprietary rights are crucial 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 be issued to us in the future may be challenged, invalidated or circumvented, and the rights granted there under 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 drug 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.

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our product candidates;
- defend our patents;
- preserve the confidentiality of our trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

We currently own numerous patents and pending patents in the United States and foreign countries. We have issued and pending patents with respect to FV-100. The earliest projected expiration date of those patents in the United States is approximately 2026.

We have several issued patents relating to our HIV integrase inhibitors and the earliest projected expiration date for these patents is 2025. A related U.S. application is also pending, as are national phase international applications. Also, a PCT application is pending. If the pending patents issue, the earliest projected expiration date in the United States is approximately 2026.

We have several pending patents with respect to our HCV polymerase inhibitors. If these pending patents are issued, the earliest projected expiration date in the United States is approximately 2027.

We have three issued U.S. patents directed to the ClfA protein found on *S. aureus*, and antibodies to the protein. These patents will expire in 2016, 2014, and 2017 respectively, if not extended. There are no corresponding foreign rights available for the ClfA protein and nucleic acid sequences. Other issued U.S. patents and international counterparts are related to Aurexis and contain claims to monoclonal antibodies recognizing the ClfA protein. The U.S. patent will expire in 2021 if not extended.

### ***Licensing and Collaborations***

We have entered into an exclusive worldwide license and collaboration agreement with Wyeth with respect to their use of intellectual property associated with our MSCRAMM proteins to develop human staphylococcal

vaccines and a diagnostic license and commercialization agreement with 3M to develop certain diagnostic products using our MSCRAMM protein platform. Our strategy is to pursue other similar collaborations or partnerships in the future with companies that may utilize our intellectual property in their products, or develop, co-develop, market and sell our product candidates, including our antiviral programs.

#### *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 in 2019. Pursuant to this agreement, we have received \$5.3 million in an upfront license fee and annual research support payments from Wyeth as of December 31, 2007. We are entitled to receive minimum research support payments of \$1.0 million 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 biologics license application, or 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.

#### *3M Company*

In January 2007, we entered into an exclusive worldwide license and commercialization agreement with 3M for the development of various diagnostic products using our MSCRAMM protein platform. Under the terms of the agreement, we granted 3M exclusive global licenses to use MSCRAMM protein intellectual property in the development of diagnostic products in exchange for license fees, future milestone payments, financial support of future research and development activities and royalty payments on net product sales. The development, manufacture and sale of any products resulting from the collaboration are the responsibility of 3M. We may terminate this agreement if 3M fails to use certain reasonable commercial efforts to bring related products to the market. 3M may terminate the agreement, without cause upon three months written notice, upon payment of all license fees, development support for the calendar year, reimbursement of certain patent expenses, and any other amounts potentially due upon the termination of the agreement. Either party may terminate the agreement for cause upon providing two months written notice. Otherwise, this agreement will terminate upon the expiration of all licensed patents. Pursuant to this agreement, we have received \$2.25 million in an upfront license fee and annual research support payments from 3M as of December 31, 2007. We are entitled to annual minimum research support payments of \$0.5 million through 2008, and 3M has a future option on continued minimum research support payments. We are also entitled to receive milestone payments on the first commercial sale of each certain *Staphylococcal aureus* (*S. aureus*) diagnostic product and other MSCRAMM targets that detect organisms other than *S. aureus*, a tiered royalty based on net sales of diagnostic products, and reimbursement of certain patent expenses related to licensed MSCRAMM proteins. We are obligated to provide support to 3M pursuant to a mutually agreed-upon development and collaboration plan for a period of at least two years.

#### *Other Licensing Agreements*

In September 2007, we completed the acquisition of FermaVir. As part of the acquisition, we acquired the rights to an exclusive worldwide royalty bearing license from Cardiff University in Wales, United Kingdom, which includes FV-100, a nucleoside analogue for the treatment of VZV infections, and a series of preclinical nucleoside analogues with antiviral activity against cytomegalovirus, or CMV. The license agreement calls for

us to make certain contingent milestone payments and pay a royalty on the sale of any products that utilize the underlying technology. We may terminate this agreement upon 90 days notice.

In September 2007, we obtained an exclusive worldwide royalty bearing license from the University of Georgia Research Foundation, or UGARF, for intellectual property covering a series of HIV integrase inhibitors and other antiviral compounds in exchange for an upfront license fee of \$0.8 million and the fair market value of \$0.3 million shares of our common stock, plus future milestone payments and royalties on future net sales. The license agreement also includes intellectual property related to non-nucleoside HCV polymerase inhibitors. We may terminate this agreement upon 90 days notice. Otherwise, this agreement terminates upon the expiration of any issued patents. Pursuant to this license agreement, we also entered into a cooperative research agreement with UGARF under which we pay approximately \$0.75 million in annual sponsored research payments. We have the right to renew this sponsored research on an annual basis.

In November 2007, we entered into an exclusive royalty-bearing worldwide license agreement with Cardiff University in Wales, United Kingdom and Katholieke Universiteit in Leuven, Belgium for intellectual property covering a series of nucleoside HCV polymerase inhibitors in exchange for an upfront license fee, future milestone payments and royalties on future net sales. The agreement calls for us to make certain milestone payments and pay a royalty on the sale of any products that utilize the underlying technology. We may terminate this agreement upon 90 days notice. Pursuant to this license agreement, we entered into cooperative research agreements with Cardiff University and Katholieke Universiteit under which we collectively pay Cardiff University and Katholieke Universiteit approximately \$0.3 million in annual sponsored research payments.

### **Pharmaceutical Pricing and Reimbursement**

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

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

We or our collaborators intend to obtain coverage and reimbursement from these third-party payers for any of our products that may be approved for sale; 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 drug 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, total or partial suspension of the clinical development of a drug candidate, product manufacturing and marketing, failure of the government to grant marketing approval, withdrawal of marketing approvals, fines, injunctions, seizure of products and criminal prosecution.

### ***United States Regulatory Approval***

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

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

Successfully completing this development 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.

### ***Preclinical Studies***

Preclinical studies generally include laboratory, or *in vitro* 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 studies, 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 product candidates 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 years or months to complete, and there is no guarantee that an IND based on those studies will become effective, allowing human 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 review board, or 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.

Certain preclinical studies must be conducted in compliance with the FDA's good laboratory practice, or GLP regulations and the United States Department of Agriculture's Animal Welfare Act. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be conducted again.

## *Clinical Trials*

The clinical phase of development follows a successful IND submission and involves the activities necessary to demonstrate safety, tolerability, efficacy and dosage of the substance in humans, as well as the ability to produce the substance and finished drug product in accordance with the FDA's current Good Manufacturing Practice, or cGMP, requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in assessing the safety and the efficacy of the drug. Each clinical trial protocol must be submitted to the FDA as part of the IND prior to beginning the trial. Each trial must be reviewed, approved and conducted under the auspices of an IRB, and each trial, with limited exceptions, must include the patient's informed consent. Sponsors, investigators, and IRBs also must satisfy extensive Good Clinical Practice, or GCP, including regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and reporting adverse events timely. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Foreign studies performed under an IND must meet the same requirements that apply to studies conducted in the United States. The FDA may accept a foreign clinical study not conducted under an IND only if the study is well-designed, well-conducted, performed by qualified investigators, and conforms to the ethical principles contained in the Declaration of Helsinki, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. Clinical trials to support an NDA or BLA for marketing approval are typically conducted in three sequential phases, Phases I, II and III, with Phase IV clinical trials conducted after marketing approval has been received. FDA may require sponsors to conduct Phase IV clinical trials to study certain safety issues. Data from these activities are compiled in an NDA or a BLA for submission to the FDA requesting approval to market the drug. These phases may be compressed, may overlap, or may be omitted in some circumstances.

- *Phase I:* After an IND becomes effective, Phase I human clinical trials can begin. A product candidate is typically introduced either into healthy human subjects or in some cases, patients with the medical condition for which the new drug is intended to be used. Generally the main purpose of a Phase I trial is to assess a product candidate's safety and the ability of the human body to tolerate the product candidate. Absorption, metabolism, distribution and pharmacokinetic trials are also generally performed at this stage. Phase I trials typically evaluate these aspects of the investigational drug in both single doses as well as multiple doses.
- *Phase II:* During Phase II trials, a product candidate is generally studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy or biologic activity of the product candidate for specific targeted diseases or medical conditions, and (iii) assess dosage tolerance and determine the optimal dose for a subsequent Phase II or Phase III trial. Phase II trials generally involve patients who are divided into one or more groups that will get one of several dose levels of the product candidate, and a control group that will not be treated with the product candidate and may receive a placebo.
- *Phase III:* If and when one or more Phase II trials demonstrate that a specific dose or range of doses of a product candidate is potentially effective and has an acceptable safety profile, one or more Phase III trials are generally undertaken to further demonstrate or confirm clinical efficacy and to further evaluate the safety of the investigational drug in an expanded patient population with the goal of evaluating its overall risk-benefit relationship. Phase III trials will generally be designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the product candidate's potential clinical efficacy. The successful demonstration of clinical efficacy and safety in one or more Phase III trials is typically a prerequisite to the filing of a NDA or BLA for a product candidate.

In the case of product candidates being developed for life-threatening diseases, such as HIV and HCV, the initial Phase I human testing is often conducted in patients with the respective disease rather than in healthy volunteers. These studies may provide initial evidence of efficacy traditionally obtained in Phase II clinical trials, and so these trials are frequently referred to as Phase I/II clinical trials. In addition, a company may

hold an "end-of-Phase II Meeting" with the FDA to assess the safety of the drug regimen to be tested in the Phase III clinical trial, to evaluate the Phase III plan, and to identify any additional information that will be needed to support an NDA. If the Phase III clinical trials had been the subject of discussion at an "End-of-Phase 2 Meeting," the company is eligible for a Special Protocol Assessment, or SPA, by the FDA, a process by which the FDA, at the request of the sponsor, will evaluate the trial protocol and issues relating to the protocol within 45 days to assess whether it is adequate to meet scientific and regulatory requirements identified by the sponsor. If the FDA and the sponsor reach agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in an NDA, the FDA will reduce the understanding to writing. The SPA, however, is not a guarantee of product approval by FDA or approval of any permissible claims about the product.

Throughout the clinical phases of development, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed.

Phase I, II, and III testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate further evaluation or trials based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA or the sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, IRBs, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

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

Certain information about clinical trials, including a description of the study, participation criteria, location of study sites, and contact information, shall be sent to the National Institutes of Health ("NIH") for inclusion in a publicly-accessible database that is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Sponsors also are subject to certain state laws imposing requirements to make publicly available certain information on clinical trial results. In addition, the Food and Drug Administration Amendments Act of 2007 directs the FDA to issue regulations that will require sponsors to submit to the NIH the results of all controlled clinical studies, other than Phase I studies.

#### *New Drug and Biologics License Applications*

If and when our human clinical trials are completed with satisfactory clinical data, we must submit a NDA or BLA to the FDA in order to obtain approval for the marketing and sale of a product candidate. Among many other items, a NDA or BLA typically includes the results of preclinical and toxicology studies and human clinical trials and a description of the manufacturing process and quality control methods. The FDA must approve the NDA or BLA prior to the marketing and sale of the related product. The FDA may deny a NDA or BLA if all applicable regulatory criteria are not satisfied or may require additional data, including clinical, toxicology, safety or manufacturing data. The FDA has 60 days from its receipt of the NDA or BLA to review the application to ensure that it is sufficiently complete for substantive review before accepting it for filing. The FDA may request additional information rather than accept a NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a

recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee.

A NDA or BLA can receive either standard or priority review. A drug candidate representing a potential significant improvement in the treatment, prevention or diagnosis of disease may receive priority review. In addition, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing Phase IV clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

If the FDA evaluation of the NDA or BLA and inspection of manufacturing facilities are favorable, the FDA may issue an approval letter or an approvable letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA or BLA. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication. As a condition of NDA or BLA approval, the FDA may require post approval testing, including Phase IV trials, and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling or distribution restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

If the FDA's evaluation of the NDA or BLA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or BLA and issue a not approvable letter. The not approvable letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of a NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

It can take several years for the FDA to approve a NDA or 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 clinical trials, may be required that would add additional product development costs beyond those incurred through Phase III testing. The FDA generally requires products with Fast Track status, such as Aurexis, to be further evaluated for safety in additional clinical trials.

#### *Post-Approval Regulations*

If and when a product candidate receives regulatory approval, the approval is typically limited to specific clinical indications. Further, even after regulatory approval is obtained, subsequent discovery of previously unknown safety problems with a product may result in restrictions on its use, or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Further, drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with cGMP, which impose rigorous procedural and documentation requirements upon us and our

contract manufacturers. 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 or our collaborators 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. We rely, and expect to continue to rely, on third parties for the production and manufacture of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

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

The FDA's policies may change in the future and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad, or the impact such changes could have on our business.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and in some circumstances the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

#### *Fast Track Drug Status*

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

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

### ***Foreign Regulatory Approval***

Outside of the United States, our ability to market any of our existing or future 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 to the FDA approval process 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.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by certain biotechnological processes and optional for those which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for a member state, known as the reference member state, to assess an application, with one or more other member states subsequently approving that assessment. Under this procedure, an applicant submits an application, or dossier, and related materials, including a draft summary of product characteristics, draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

### **Employees**

As of December 31, 2007, we had 32 full-time employees, 23 of whom were engaged in research and development, clinical, regulatory, chemistry and manufacturing, and 9 of whom were engaged in administration, finance, and business development. All of our employees have entered into non-disclosure agreements with us regarding our intellectual property, trade secrets and other confidential information. None of our employees is represented by a labor union or covered by a collective bargaining agreement, nor have we experienced any work stoppages. We believe that we maintain satisfactory relations with our employees.

### **Available Information**

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

## ITEM 1A. RISK FACTORS

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

### **Risks Relating to our Development of our Product Candidates**

*All of our product candidates are still in the early stages of development and remain subject to numerous preclinical studies, clinical testing and regulatory approval. If we are unable to successfully develop our product candidates, our business will be materially harmed.*

Our failure to successfully develop one or more of our product candidates may have a material adverse effect on us, and possibly cause us to cease operations. To date, we have not commercially marketed, distributed or sold any product candidates. The success of our business depends primarily upon our ability to develop our product candidates through early-stages of development and ultimately later commercialize our product candidates successfully. We plan to initiate a Phase I clinical trial evaluating single and multiple ascending doses of FV-100 in healthy volunteers in the first half of 2008. We also plan to select a lead clinical candidate for our HIV integrase and HCV polymerase inhibitor programs in 2008.

Our product candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical testing and obtain regulatory approval of our product candidates. Despite our efforts, our product candidates may not:

- offer therapeutic or other benefits over existing, comparable drugs;
- be proven safe and effective in clinical trials;
- have the desired effects or may include undesirable effects or the drug candidates may have other unexpected characteristics;
- meet applicable regulatory standards;
- be capable of being produced in commercial quantities at acceptable costs; or
- be successfully commercialized by us or by partners.

Even if we achieve success in earlier stage clinical trials, there can be no assurance that later-stage trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing or early clinical trials. Accordingly, the results from our programs that have completed preclinical studies and clinical trials may not be predictive of the results we may obtain in later-stage trials.

Our product candidates will require significant additional research and development efforts, substantial financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. We cannot be certain that any of our product candidates will successfully progress through the drug development process or will result in clinically or commercially viable products. We do not expect any of our drug candidates to be commercially available to us or collaborators for at least several years. If we are unable to successfully develop our product candidates, our business will be materially harmed.

*If preclinical studies or clinical trials for our product candidates, including those that are subject to collaboration agreements, are unsuccessful or delayed, we could be delayed or precluded from further developing or ultimately commercialization of our product candidates.*

In order to further advance the development of and ultimately receive regulatory approval to sell our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or other regulatory authorities. Preclinical studies and clinical testing

are expensive, complex, may take many years to complete, and its outcome is highly uncertain. Delays, setbacks or failures may occur at any time, or in any phase of preclinical studies or clinical development process for a number of reasons, including concerns about safety or toxicity, a lack of demonstrated efficacy or superior efficacy over other similar products that have been approved for sale or are in more advanced stages of development, poor trial design, and issues related to the manufacturing process of the materials used to conduct the clinical trials. The results of preclinical studies and prior clinical trials of our product candidates are not necessarily predictive of the results we may see in later-stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety and efficacy traits despite having successfully demonstrated so in preclinical studies or earlier stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including: regulators or IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site; enrollment in our clinical trials may be delayed or proceed at a slower pace than we expected or participants may drop out of our clinical trials at a higher rate than we anticipated, resulting in significant delays; our third party contractors whom we rely on for conducting preclinical studies and clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner; we might have to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health risks; IRBs or regulators may require that we hold, suspend or terminate preclinical studies or clinical trials for various reasons, including noncompliance with regulatory requirements; and the supply or quality of our product candidates necessary to conduct our preclinical studies or clinical trials may be insufficient or inadequate.

Even if the data collected from preclinical studies or clinical trials involving our product candidates satisfactorily demonstrate safety and efficacy, such results may not be sufficient to support the submission of an IND application to support the initiation of clinical trials in humans or a NDA, or BLA to obtain regulatory approval from the FDA in the United States, to sell the product.

***We must comply with extensive government regulations in order to advance our product candidates through the clinical development process and ultimately obtain and maintain marketing approval for our products in the United States and abroad.***

Our product candidates and any products for which we receive FDA approval to advance through clinical development and ultimately sell 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 similarly extensive regulation by foreign governments to the extent we seek to develop them in those countries. We or our collaborators must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data that appropriately demonstrate our product candidates' safety and efficacy before they can be approved for the targeted indications. None of our product candidates have been approved for sale in the United States or any foreign market, and we cannot predict whether we will obtain regulatory approval for any product candidate we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product, requires the expenditure of substantial resources, involves post-marketing surveillance and vigilance, and generally involves ongoing requirements for post-marketing studies or Phase IV clinical trials. In addition, we or our collaborators 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 approval to advance our product candidates through clinical development and ultimately commercialize them may:

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

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

- delays, suspension or termination of the clinical trials related to our products;
- refusal by the FDA to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

Additionally, we or our collaborators may voluntarily halt the development of any product candidate or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives.

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

***We have limited experience in the development of antiviral product candidates and therefore may encounter difficulties developing our product candidates or managing our operations in the future.***

We recently acquired or licensed several antiviral drug development programs that are based upon chemical compounds, also referred to as small molecules. Historically, we have focused our resources on the development and commercialization of antibody-based product candidates, which are composed of biologic materials and are generally considered to be large molecules. Therefore, we have limited experience in the discovery, development and manufacturing of antiviral small molecule compounds. In order to successfully develop our antiviral pipeline and manage this shift in operational focus, we have begun to expand and supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing functions through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we currently do not possess, including but not limited to virology, medicinal chemistry, drug formulation and pharmacology. We cannot assure you that we will attract or retain such qualified employees, consultants or third-party contractors with the appropriate antiviral small molecule drug development experience. In the event we cannot attract such capabilities or successfully develop our antiviral pipeline or manage these operational changes, our business will be materially harmed.

***In order to develop our product candidates, we expect that we will need to raise additional capital in the future, which may not be available to us on acceptable terms, if at all.***

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

- our ability to successfully advance the development of our drug candidates and programs, most of which we have recently obtained;
- the time and cost to complete the requisite preclinical studies and clinical trials and receive regulatory approval to advance our product candidates through the various phases of clinical development;
- the amount of future payments, if any, received or made under existing or future license, collaboration or similar arrangements;
- the costs associated with protecting or expanding our patent and other intellectual property rights; and

- whether we acquire licenses to new products, development programs or compounds in the future through in-licensing, acquisition or merger, and the stage of development of any such development programs.

If any of our product development efforts are successful, we may receive licensing fees, milestone payments and royalties pursuant to licensing and collaboration agreements we may enter into, which could lessen the need for additional capital, but there can be no assurance that we will be successful in our product development efforts or that we will be able to enter such agreements.

We anticipate that our existing cash and cash equivalents and short-term investments, together with proceeds we expect to receive from existing license and collaboration agreements will enable us to operate for a period of at least 24 months from the date of this filing. We have no other committed sources of additional capital at this time. We cannot assure you that funds will be available to us in the future on acceptable terms, if at all. If adequate funds are not available to us at all or, on terms that we find acceptable 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 licensees, collaborators or partners on unattractive terms, or sell or relinquish rights to certain technologies, product candidates or our intellectual property that we would not otherwise sell or relinquish in order to continue our operations.

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

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

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

We have limited experience in conducting and managing preclinical studies and clinical trials. We have historically relied and intend to continue to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in managing, monitoring and conducting our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the development process, including IND-enabling studies, 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 pre-clinical studies and clinical trials of our product candidates may be delayed or prove unsuccessful. Further, the FDA may inspect some of the clinical sites participating in our clinical trials, or our third-party vendors' sites, to determine if our clinical trials are being conducted according to current good clinical practices. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to delay, repeat or terminate such clinical trials. Any delay, repetition or termination of our pre-clinical studies and clinical trials could be very costly, result in the elimination of a development program, and materially harm our business.

***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 preclinical studies or clinical trials and the development of our product candidates could be terminated, delayed, or adversely affected.***

We do not own or operate any manufacturing facilities. We have historically contracted with third-party contract manufacturers to produce the preclinical and clinical trial materials we use to test our product candidates in development, and we intend to continue to rely on third-party contract manufacturers, at least for the foreseeable future, to manufacture these preclinical and clinical trial materials. Our reliance on third-party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of preclinical studies or clinical trials, the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- the manufacture of products requires compliance with numerous and strict safety, quality and regulatory standards. Our contract manufacturers may not produce our product candidates according to their own standards, our specifications, current good manufacturing procedures, or cGMP, or may otherwise manufacture material that we or the FDA may deem to be unusable in our clinical trials;
- our contract manufacturers may be unable to increase the scale of, or increase the capacity for, our product candidates, we may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our products. We cannot assure you that our contract manufacturers will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our third-party contract manufacturers may place a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers may fail to perform as agreed or may not remain in the contract manufacturing business;
- our manufacturers' plants may be closed as a result of regulatory sanctions or a natural disaster.

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 FDA-mandated current good manufacturing practices, or 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 contract manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party products. These sanctions include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

***In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials and the development of our products could be delayed, adversely affected or terminated, or such a change may result in higher costs.***

Due to regulatory restrictions inherent in an IND, NDA or BLA, the manufacture of our product candidates may be sole-sourced. In accordance with cGMPs, changing manufacturers may require the re-validation of the manufacturing processes and procedures and may require further preclinical studies or clinical trials. Changing our current or future contract manufacturers may be difficult for us and could be costly and take years to complete, which could result in our inability to manufacture our products or product candidates for an extended period of time or possibly additional clinical trials.

***Our product candidates may have undesirable side effects when used alone or in combination with other products that may prevent their regulatory approval or limit their use if approved.***

We must demonstrate the safety of our product candidates to obtain regulatory approval to advance their clinical development or to market them. In preclinical studies and clinical trials conducted to-date our product candidates have generally been well tolerated, however these studies and trials involved a small number of subjects or patients. We may observe adverse or significant adverse events in future preclinical studies or clinical trials of these product candidates. Any side effects associated with our product candidates in development may outweigh their potential benefit and result in the termination the development program, prevent regulatory approval or limit their market acceptance if they are ultimately approved.

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about genetics and develop new technologies and scientific approaches to treating and preventing disease. Our current and potential competitors generally include, among others, major multi-national pharmaceutical companies, large, medium and small biotechnology firms, universities and other research institutions. Some of the companies that currently market products that would compete with our product candidates include, but are not limited to: GlaxoSmithKline, Novartis and Merck in the shingles market; Pfizer, Merck and Gilead in the HIV market, and Roche and Schering-Plough in the hepatitis C market. In addition, there are several other competitors developing early-stage drug candidates that may compete with our product candidates in the future. Most of these companies and institutions, either alone or together with their collaborators, have substantially greater financial or corporate 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, particularly those based upon small molecules. Future successful developments by others may render our product candidates or technologies obsolete or noncompetitive.

We also face, and will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for in-licensing technology from or otherwise establishing relationships with academic and research institutions and for attracting investigators and clinical sites capable of conducting our clinical trials. These competitors, either alone or with their collaborators, may succeed in developing technologies or products that are safer, more effective, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than we can. Companies that complete clinical trials, obtain required regulatory approvals and commercialize their products 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.

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

Since inception (May 13, 1994) through December 31, 2007, we have incurred a cumulative deficit of approximately \$214 million. Our losses to date have resulted principally from:

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

We anticipate incurring losses for the foreseeable future assuming we further develop our product candidates, which will generally require us to conduct significant research and laboratory testing, conduct extensive and expensive clinical trials, and seek regulatory approvals. We cannot assure you that we will ever generate direct or royalty revenue from the sale of products, or ever become profitable. Based on our current strategy, our

quarterly and annual operating costs and revenues may become highly volatile, and comparisons to previous periods will be difficult to make.

***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 a product candidate, we expect that substantially all of our revenue will result from payments we receive under collaborative arrangements or license agreements where we grant others the right to use our intellectual property or know-how. 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 intermittent in nature and are subject to significant fluctuation in both timing and amount, or may never be earned or paid. Further some of our collaboration arrangements allow our partner to terminate the agreement on relatively short notice. Therefore, our historical and current revenues may not be indicative of our ability to achieve additional payment-generating milestones in the future. We expect that our operating results will also vary significantly from quarter to quarter and year to year as a result of newly entered into in-licensing agreements and the acquisition of FermaVir, our re-focused research and development efforts, the execution or termination of collaborative arrangements, the initiation, success or failure of preclinical and 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.

***We do not have drug discovery capabilities, and therefore, we are dependent on third parties to discover additional product candidates for our pipeline.***

We do not have significant internal discovery capabilities, particularly with respect to chemical small molecules, and at this time, we do not intend to build such capabilities. Accordingly, we have relied and will continue to rely on third parties to discover new technologies and compounds through sponsored research or in-licensing arrangements. We will face substantial competition for in-licensing or sponsored research opportunities from others, many of which may have greater resources than we have. Additional opportunities may not be available to us, or if available, the terms may not be acceptable. In addition, many compounds that appear promising in discovery or early preclinical studies fail to progress to become lead product candidates, or ever advance into clinical trials. Our research and development efforts may not lead to the discovery of any additional product candidates that would be suitable for further preclinical or clinical development. The discovery of additional product candidates requires significant time, research and preclinical studies, as well as a substantial commitment of resources. There is a great deal of uncertainty inherent in our research efforts and, as a consequence, our ability to fill our product pipeline with additional product candidates may not be successful.

***The requirements of being a publicly-traded company may strain our corporate infrastructure and increase our overall operating costs.***

As a publicly-traded company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 and the listing requirements of the NASDAQ Stock Market LLC. Section 404 of the Sarbanes-Oxley Act requires that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to assess the effectiveness of our internal control over financial reporting, which is expensive and requires the attention of our limited management resources. The various financial reporting, legal, corporate governance and other obligations associated with being a publicly-traded company require us to incur significant expenditures and place additional demands on our management, administrative, operational, and finance resources. If we are unable to comply with these requirements in a timely and effective manner, our ability to raise additional funds in the future may be impaired and ultimately affect our business. We will continue to incur, or we may experience substantial increases in, additional expenses as a result of being a public company.

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

The use of any of our existing or future 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 and commercialized, we may need to increase our product liability coverage. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

***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 Relating to the Commercialization of our Product Candidates**

***We may delay or terminate the development of a product candidate if the perceived market size or commercial opportunity does not justify further investment, which could materially harm our business.***

Even though the results of preclinical studies and clinical trials that we conduct may support further development of one or more of our drug candidates, we may delay or terminate the future development of a drug candidate at any time for strategic, business, or financial reasons, including the determination or belief that the emerging profile of the drug candidate is such that it may not gain meaningful acceptance or otherwise provide any competitive advantages in its intended indication or market.

***If the actual or perceived therapeutic benefits of FV-100 are not different from competing generic drugs, we may terminate the development of FV-100, or our ability to generate significant revenue may be limited and our potential profitability could be harmed.***

Valtrex®, Famvir® and Zovirax® are existing drugs use to treat shingles patients. Zovirax is a generic drug and Valtrex and Famvir will both be generic drugs by 2010. Accordingly, if FV-100 does not provide meaningful therapeutic benefits over these existing comparable drugs, then we terminate or delay the future development of a FV-100 at any time. We cannot provide any assurance that later stage clinical trials will demonstrate therapeutic benefits over existing therapies, as perceived in our early stage preclinical studies and clinical trials.

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

We currently have no infrastructure to support the commercialization of any of our product candidates, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, our future profitability will depend in part on our ability to access or develop a capable sales force and suitable marketing capabilities. We anticipate that we will need to establish relationships with other companies to commercialize some or all of our products in North America and in other countries around the world. To the extent that we enter into license and collaboration agreements, or marketing and sales arrangements with other

companies to sell, promote or market our products in the United States or abroad, our product revenues, which may be in the form of indirect revenue, a royalty, or a split of profits, will depend largely on their efforts, which may not be successful. The development of a third party sales force and marketing capabilities may 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 third parties or marketing or sales personnel, or be able to establish an effective sales force.

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

We have in the past and expect to continue to enter into and rely on collaborations or other business arrangements with third parties to develop and/or commercialize our existing and future product candidates. Such collaborators or partners 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, even though we have performed our obligations under the arrangement. We cannot assure you that any product candidates will emerge from our relationships with Wyeth or 3M Company or any other new license or collaboration agreements we may enter into in the future related to any of our other product candidates.

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

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

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

***If any product candidates that we develop independently or through collaborations are approved but do not gain meaningful acceptance in their intended markets, we are not likely to generate significant revenues or become profitable.***

Even if our product candidates are successfully developed and we or a partner or collaborator obtain the requisite regulatory approvals to sell our products in the future, they may not gain market acceptance or utilization among physicians and patients. The degree of market acceptance for any of our product candidates that may be commercialized will depend on a number of factors, including:

- the therapeutic efficacy or perceived benefit of the product;
- the level of reimbursement available to cover the cost of the product;
- the cost of the product to the user or payer;

- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA.

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

***Even if we or our collaborator achieve market acceptance for our products, we may experience downward pricing pressure on the price of our products due to generic competition and social or political pressure to lower the cost of drugs .***

Several FDA-approved products are already available in generic form or face patent expiration in the next several years in certain markets and indications we are pursuing, including therapies for the treatment of shingles and HIV. We expect to face competition from these generic drugs, including significant price-based competition. Further, pressure from AIDS awareness and other social activist groups whose goal it is to reduce the cost of HIV drugs, particularly in less developed nations, may also put downward pressure on the prices of HIV drugs, including our integrase program. Similar trends of generic competition or social or political pressure may occur for our HCV program, which could result in downward pressure on those prices as well.

***If conflicts arise between our collaborators and us, our collaborators may act in their best interest and not in our best interest, which could adversely affect our business.***

Conflicts may arise with our collaborators if they pursue alternative therapies for the same diseases that are targeted by intellectual property rights we have licensed to them. Competing products, either developed by our existing or future collaborators, may result in development delays or the withdrawal of their support for our product candidates. Additionally, conflicts may arise if there is a dispute about the progress of, or other activities related to, the clinical development of a product candidate, the achievement and payment of a milestone amount or the ownership of intellectual property that is developed during the course of the collaborative arrangement. Similarly, we may disagree with a collaborator as to which party owns newly developed products. Should an agreement be terminated as a result of a dispute and before we have realized the benefits of the collaboration, we may not be able to obtain revenues that we anticipated receiving.

***If patent applications that we, or our licensors, have filed or may file in the future with respect to our development programs are not issued or the claims are restricted, our business prospects could be harmed.***

Many patents that we expect to rely upon to protect our intellectual property rights, particularly with respect to our antiviral drug development programs, have been filed but not yet issued. These pending patent applications, or those we may file or license from third parties in the future, may not result in patents being issued. Further, until a patent is issued, any or all claims covered by the patent may be narrowed or removed entirely, and therefore we may ultimately not obtain the full patent protection we sought, if at all. As a result, we may conclude that without certain patent rights, the risk and cost of further developing and commercializing certain product candidates is too great, thus adversely affecting our business prospects.

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

Our success depends in part on our ability to:

- obtain and maintain intellectual property rights and patents, or rights to intellectual property and patents, and maintain their validity;
- protect our trade secrets; 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 drug and 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. Therefore, any issued patents that we own or have rights to may be challenged, invalidated or circumvented, and may not provide us with the protection against competitors that we anticipate.

The degree of future protection for our proprietary intellectual property rights is uncertain because issued patents and other legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we, or our licensors might not have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to engage in expensive and protracted interference proceedings to determine priority of invention;
- our, or our licensors' pending patent applications may not result in issued patents;
- our, or our licensors' issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;
- third parties may design around our or our licensors' patent claims to produce competitive products which fall outside the scope of our or our licensors' patents; or

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 such patent rights may 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 and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on or restricts the prices of life-saving drugs. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property.

We may not develop or obtain rights to products or processes that are patentable. Even if we or our licensors do obtain patents, such patents may not adequately protect the products or technologies we own or have licensed. In addition, we may not have total control over the patent prosecution of subject matter that we license from others. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any pending or issued patents we own or license, and rights we receive under those issued patents may not provide competitive advantages to us. We cannot assure you as to the degree of protection that will be afforded by any of our issued or pending patents, or those licensed by us.

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

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

Our success will largely depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the "freedom to operate". 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 highly uncertain. We may become involved in litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the United States are, in most cases, maintained in secrecy until 18 months after the patent application is filed. 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 fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

If we become involved in any patent litigation, interference or other legal proceedings, we will incur substantial expense, and the efforts of our technical and management personnel will be significantly diverted. A negative 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 have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we do not obtain the required licenses or sublicenses, we could encounter delays in the development of our product candidates, or be prevented from developing, manufacturing and commercializing our product candidates at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and/or 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.

***We may be unable to enter into future license, collaborations or other transactions with respect to our Aurexis program, which could harm our business.***

Currently, we do not intend to continue to independently advance the clinical development of Aurexis. We plan to leverage our capabilities and intellectual property associated with our Aurexis program by pursuing licenses, corporate collaborations or other business arrangements that could provide financial and other synergistic capabilities to support the further development and potential of the Aurexis program. We have several existing license and collaboration agreements based upon our MSCRAMM protein platform. These include an agreement with Wyeth for the development of staphylococcal vaccines and with 3M Company for the development of diagnostics products. We cannot assure you that we will be able to successfully enter into any additional licenses, collaborations, or other transactions related to Aurexis on terms acceptable to us or at all.

## Risks Related to Owning Our Common Stock

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

The market price of our common stock has been highly volatile since the completion of 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:

- our ability to successfully advance our drug development programs through preclinical and clinical development activities;
- disclosure of any favorable or unfavorable data from our preclinical studies or clinical trials, or other regulatory developments concerning our clinical trials, manufacturing or product candidates or those of our competitors;
- our ability to manage our cash burn rate at an acceptable or planned level;
- 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 government policies related to reimbursement;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- new regulatory legislation adopted in the United States or abroad;
- changes in patent legislation in the United States or abroad
- our failure to achieve or meet equity research analysts' expectations or their estimates of our business or prospects, or a change in their recommendations concerning us, 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 in connection with raising capital;
- the sale of shares held by our directors or management;
- the loss of our eligibility to have shares of our common stock traded on the NASDAQ Global or Capital Market due to our failure to maintain minimum listing standards;
- changes in accounting principles;
- failure to comply with the periodic reporting requirements of publicly-owned companies, under the Securities Exchange Act of 1934, as amended, and the Sarbanes-Oxley Act of 2002; and
- general economic conditions.

In addition, the stock market in general, and more specifically the NASDAQ Global and Capital Markets and the market for biotechnology stocks in particular, have historically experienced significant price and volume fluctuations. Volatility in the market price for a particular biotechnology 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, investors may be unable to sell their shares of our common stock at or above the price they paid.

***We currently do not meet the standards for continued listing on The NASDAQ Global Market, and we cannot provide any assurance that we will meet these standards in the future. If we are delisted from this exchange, the value of your investment may substantially decrease.***

On January 9, 2008, we were notified by the Nasdaq Global Market that we failed to meet the minimum listing requirements due to the fact that our common stock had not traded above \$1 per share for 30 days. To maintain our listing on The NASDAQ Global Market, our common stock must have a closing bid price of \$1.00 for ten consecutive days before July 8, 2008, in addition to meeting other continued listing requirements of NASDAQ Marketplace Rule 4450(a)(5). If we are unable to meet the closing bid price requirement before July 8, 2008, we may apply to transfer our listing to the NASDAQ Capital Market if our common stock satisfies all of the criteria under Marketplace Rule 4310(c) for initial inclusion on such market, other than compliance with the minimum bid price rule. If our application is approved, the NASDAQ Marketplace Rules provide that we will be afforded an additional 180 calendar days to comply with the minimum bid price rule while listed on the NASDAQ Capital Market. If we fail to maintain our listing on the NASDAQ Capital Market, our shares will likely trade on the NASDAQ OTC Market. We may consider a reverse stock split of our common stock to increase the bid price above \$1.00. Any future delisting or change in market class from NASDAQ may adversely affect the trading price of our common stock, significantly limit the liquidity of our common stock and impair our ability to raise additional funds.

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

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

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

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

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

As of December 31, 2007, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 33% of the outstanding shares of our common stock. As a result, these stockholders, acting together, may have the ability to delay or prevent a change in control that may be favored by other stockholders and otherwise exercise significant influence over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including:

- the appointment of directors;
- the appointment, change or termination of management;
- any amendment of our certificate of incorporation or bylaws;
- the approval of some acquisitions or 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 with the ability to designate the terms of and issue new series of preferred stock without stockholder approval.

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

## **ITEM 2. PROPERTIES**

We lease our 51,000 square foot office and laboratory facility, which is located in Alpharetta, Georgia, a northern suburb of Atlanta. We entered into this lease in December 2003 and occupied this facility during the second quarter of 2005. Our minimum lease obligations for this facility will approximate \$0.9 to \$1.0 million per annum for the lease term of ten years. We believe that our facility is adequate for our current business as a conducted, as well as our expected business for the foreseeable future. We are seeking to sub-lease portions of our facility that are currently unused.

## **ITEM 3. LEGAL PROCEEDINGS**

On April 28, 2006, we announced that we did not anticipate performing any additional clinical trials in very low birth weight infants with a donor-selected immune globulin form of Veronate and therefore would halt the manufacture of the clinical trial material used in the clinical development of Veronate. As a result, we terminated our contract manufacturing relationship with Nabi Biopharmaceuticals, Inc., or Nabi, and suspended future purchases of all raw materials used to manufacture the donor-selected immune globulin form of Veronate. Subsequent to the termination date, Nabi invoiced us for approximately \$4.5 million in cancellation penalties and other amounts it contends are due as a result of our termination of the manufacturing agreement, which we disputed. On July 18, 2006, Nabi commenced an arbitration action against us seeking to recover a total of approximately \$4.7 million in connection with the termination of the manufacturing agreement. On February 7, 2007, an arbitrator ruled we were liable to Nabi Biopharmaceuticals, Inc. for restitution and cancellation payments in the aggregate amount of approximately \$4.5 million, including \$1.2 million with respect to restitution for prior production under the agreement and \$3.3 million relating to cancellation fees, as a result of our termination of a contract manufacturing agreement with Nabi during 2006. We recorded a charge of \$4.5 million in 2006 as a result of the arbitrator's ruling. The ruling provided for interest at a rate of 9% per annum commencing 30 days after the date of the award. In March 2007, Nabi filed a petition with the Supreme Court of the State of New York (the "Court") to confirm the arbitrator's award, and we cross-petitioned to have the award set aside.

On October 18, 2007, we learned that the Court had vacated approximately \$3.3 million out of a total of approximately \$4.5 million that an arbitrator had awarded Nabi in February 2007. The Court confirmed the

\$1.2 million award of restitution and vacated the \$3.3 million award of cancellation fees. On January 28, 2008, we paid the \$1.2 million award with accrued interest. On January 30, 2008, Nabi filed a Notice of Appeal of the Court's decision to the extent it vacated the portion of the arbitration award relating to the \$3.3 million of cancellation fees.

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

Not Applicable

**PART II**

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

The Company's common stock trades on the NASDAQ Global Market under the symbol "INHX." At March 11, 2008, the Company had 94 common stockholders of record. This figure does not represent the actual number of beneficial owners of common stock because shares are generally held in "street name" by securities dealers and others for the benefit of individual owners who may vote the shares.

The following table shows the range of high and low prices and year-end closing prices for our common stock for each completed fiscal quarter since January 1, 2006.

	2007	
	High	Low
First Quarter . . . . .	\$1.84	\$1.53
Second Quarter . . . . .	1.74	1.19
Third Quarter . . . . .	1.52	1.08
Fourth Quarter . . . . .	1.34	.74
Year End Close . . . . .		\$ .78
	2006	
	High	Low
First Quarter . . . . .	\$9.35	\$7.00
Second Quarter . . . . .	3.05	1.75
Third Quarter . . . . .	1.87	1.42
Fourth Quarter . . . . .	2.37	1.49
Year End Close . . . . .		\$1.65

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.

**Unregistered Sales of Equity Securities**

On December 31, 2007, the Company issued 225,870 shares of its common stock with a fair market value of \$1.33 per share, in consideration for an exclusive royalty-bearing worldwide license agreement from the University of Georgia Research Foundation for intellectual property for a series of HIV integrase inhibitors and other antiviral compounds. The shares were issued in the Private Placement to several accredited investors without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws.

## **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 focused on the development of differentiated anti-infective products to prevent and treat serious infections. In 2006 we adopted a strategy to pursue pre-clinical or clinical-stage antiviral development programs via in-licensing, or acquisition, and postponed the initiation of any additional clinical trials of Aurexis pending the finalization of these strategic activities. In connection with this strategy, we entered into the following transactions as described below.

On April 9, 2007, we entered into a definitive Agreement and Plan of Merger and Reorganization with FermaVir Pharmaceuticals, Inc. or FermaVir. On September 19, 2007, we consummated the acquisition of FermaVir. FermaVir's development-stage antiviral pipeline included FV-100, a nucleoside analogue for the treatment of herpes zoster infections (shingles), and a series of preclinical nucleoside analogue compounds for the treatment of human cytomegalovirus, or CMV disease.

On September 11, 2007, we entered into an exclusive worldwide license agreement with the University of Georgia Research Foundation, or UGARF, for intellectual property covering a series of human immunodeficiency virus, or HIV, integrase inhibitors and other antiviral compounds in exchange for an upfront license fee, future milestone payments and royalties on future net sales. The license agreement also includes intellectual property related to hepatitis C polymerase, or HCV, inhibitors. In connection with this license agreement, we also entered into a sponsored research agreement with UGARF to provide up to three years of financial support for specified research and development activities related to the licensed compounds and intellectual property.

On November 19, 2007, we entered into an exclusive worldwide license agreement with Cardiff University in Wales, United Kingdom and Katholieke Universiteit in Leuven, Belgium for intellectual property covering a series of hepatitis C virus (HCV) polymerase inhibitors in exchange for an upfront license fee, future milestone payments and royalties on future net sales.

As a result of these transactions, we have changed our strategic focus with respect to the anti-infective market and are primarily concentrating our efforts on the development of antiviral small molecules. We intend to target our antiviral development efforts on treatments for shingles, HIV infection, chronic hepatitis C, and cytomegalovirus, or CMV. Due to this strategic transformation, we have exited the development stage for financial statement presentation and all periods prior to October 1, 2007 were presented as a development stage company.

From our inception in 1994 to until mid 2006, we devoted substantially all of our resources and efforts towards the discovery and development of novel antibody-based products for the prevention and treatment of serious bacterial and fungal infections, all of which were based upon our proprietary MSCRAMM protein platform. In November 2005, we completed enrollment of a pivotal Phase III clinical trial of Veronate, our lead product candidate at that time, which we had been developing for the prevention of hospital-associated *Staphylococcal aureus* infections in premature, very low birth weight infants. On April 3, 2006, we announced that this pivotal Phase III trial did not achieve its primary endpoint, or any of its secondary endpoints.

In light of these Phase III trial results, we discontinued the development of Veronate, reduced our workforce and realigned our operations consistent with the status of other MSCRAMM-based development programs. We do not plan to allocate any additional resources to advance the clinical development of programs based upon our MSCRAMM protein platform, but rather further leverage our capabilities and intellectual property associated with our MSCRAMM protein platform by pursuing licenses, co-development, collaborations or other business arrangements that can provide financial and other synergistic capabilities to support the further development and potential of these programs, including Aurexis.

We have neither received regulatory approval for any of our product candidates, nor do we have any commercialization capabilities; therefore, it is possible that we may never successfully derive significant collaboration revenues or any commercial revenues from any of our existing or future product candidates or preclinical development programs.

We expect that our future operations will result in a net loss on a quarterly and yearly basis for the foreseeable future. As of December 31, 2007, we had an accumulated deficit of \$214 million.

### Financial Operations Overview

**Revenue.** We have begun to generate revenues from the licensing of our products, but would not expect substantial product-related revenues until we or our collaborators obtain regulatory approval for and commercialize our product candidates. Our revenues represented the amortization of an up-front license fee and periodic research and development support payments we have received in connection with a license and collaboration agreements with Wyeth and 3M, and from time to time, grant revenue and proceeds from research activities we performed under a materials transfer agreement not covered by a license or collaboration agreement. We may generate future revenues from up-front license fees or milestone payments in connection with existing or future collaborators, or other strategic relationships and royalties resulting from the licensing of our intellectual property. If our or any of our collaborators' future development efforts result in regulatory approval and the successful commercialization of any of our product candidates or collaborated product candidates, we expect the majority of our future revenues would then result from milestones, royalties, or other product revenue agreements.

**Research and Development Expense.** Research and development expense consists of the costs incurred to discover, develop, test and manufacture our product candidates. These costs consist primarily of research activities and preclinical studies and supplies associated with development activities by internal staff; 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 for our internal staff, including share-based compensation; the cost of product candidates, including contract manufacturing services; legal fees associated with patents and intellectual property, consulting, depreciation, 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, 2007 and 2006. Direct external costs represent expenses paid to third parties that specifically relate to product candidates in pre-clinical or clinical development, such as payments to third parties that perform development services, such as toxicological tests, 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 including raw materials. All remaining research and development expenses, such as salaries and personnel-related expenses, supplies, depreciation, legal patent services, consulting, general licenses and sponsored research, facility costs and other overhead costs, are not tracked to a specific product development program and are included in unallocated costs and overhead. Research and development spending for past periods is not indicative of spending in future periods.

	<u>Years Ended</u> <u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
	(In millions)	
Direct external costs:		
Veronate . . . . .	\$ —	\$ 9.6
Aurexis . . . . .	—	0.1
FV-100 . . . . .	33.9	—
Preclinical Programs . . . . .	1.6	.6
Unallocated costs and overhead . . . . .	<u>7.1</u>	<u>13.1</u>
Total research and development expenses . . . . .	<u>\$42.6</u>	<u>\$23.4</u>

For the year ended December 31, 2007, FV-100 includes \$32.6 million of in-process research and development expense incurred in connection with the FermaVir acquisition.

We anticipate that our research and development costs will increase in 2008, as compared to our annualized expense for fourth quarter of 2007 due to our development plans for FV-100 and our other preclinical other programs. Due to the uncertainty regarding the timing and regulatory approval of clinical trials and preclinical studies, our future expenditures are likely to be highly volatile in future periods depending on the outcomes. From time to time, we will make determinations as to how much funding to direct to these programs in response to their scientific, clinical and regulatory success, and anticipated market opportunity.

A discussion of the risks and uncertainties associated with completing the development of our existing or future product candidates, if at all, and some of the possible consequences of failing to do so, is set forth in the "Risk Factors" section of this Form 10-K.

*In-Process Research and Development Expense.* In connection with the acquisition of FermaVir, we recorded an in-process research and development ("IPR&D") charge of \$32.6 million during the third quarter of 2007. The acquired IPR&D project is FV-100, a compound in development as a potential treatment of varicella zoster virus ("VZV"), the causative agent for shingles and chickenpox. The CMV program acquired did not qualify as a project for IPR&D purposes and was excluded from the purchase price allocation. The fair value of the IPR&D project was determined utilizing the income approach, assuming that the rights to the IPR&D project will be sublicensed in the future to third parties in exchange for certain upfront, milestone and royalty payments, and the combined company will have no further involvement in the ongoing development and commercialization of the projects. Under the income approach, the expected future net cash flows from sublicensing the IPR&D project are estimated, risk-adjusted to reflect the risks inherent in the development process and discounted to their net present value. Because the acquired IPR&D project is in the early stages of the development cycle and has no alternative future use, the amount allocated to IPR&D was recorded as an expense immediately upon completion of the acquisition.

*General and Administrative Expense.* General and administrative expense consists primarily of salaries and personnel-related expenses, including share-based compensation for personnel in executive, finance, accounting, information technology, sales and marketing, business development and human resources functions. Other significant costs include professional fees for legal, auditing, market research and other consulting services, as well as premiums for insurance, other expenses a result of being publicly-traded, and depreciation and facility expenses. In 2008, we expect our general and administrative expenses to remain relatively consistent as those we incurred in 2007.

*Interest and Other Income (Expense), net.* Interest income consists of interest earned on our cash, cash equivalents short-term investments and long-term investments. Interest expense consists of interest incurred on capital leases and notes payable. Other income and (expense) has historically consisted of the proceeds from the sale of excess raw materials, the gain or loss on the disposal of equipment, and the reversal of a liability for which the obligation to provide further services or settlement is not required.

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

This discussion and analysis of our current financial condition and historical results of operations are based on our audited financial statements, which have been prepared in accordance with generally accepted accounting principles 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 believe the following critical accounting policies are important in understanding our financial statements and operating results.

*Use of Estimates.* The preparation of our financial statements in conformance with generally accepted accounting principles in the United States requires us to make estimates and judgments with respect to the selection and application of accounting policies that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosures of contingent assets and liabilities. We base our estimates on historical experience, current economic and industry conditions, and on various other factors that are believed to be reasonable at the time, the results of which form the basis for making judgments about the carrying values of

certain assets and liabilities. Actual future results may differ from these estimates under different assumptions or conditions.

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

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

*Share-Based Compensation.* We adopted Statement of Financial Accounting Standards ("SFAS") No. 123(R), *Share-Based Payment*, ("SFAS No. 123(R)") on January 1, 2006. We adopted the fair value recognition provisions of SFAS No. 123(R), using the modified-prospective transition method. Under this transition method, share-based compensation cost recognized in 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, ("SFAS No. 123") and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated. We use the Black-Scholes method to estimate the value of stock options granted to employees and apply it not only to new awards, but to previously granted awards that were not fully vested on the effective date of January 1, 2006. Awards granted prior to our initial public offering that were unvested as of January 1, 2006 are valued using the minimum value method.

Upon the adoption of SFAS No. 123(R), we recorded a cumulative effect of change in accounting principle of approximately \$58,000 related to expected forfeitures for previously expensed share-based compensation. We recorded share-based compensation expense of \$2.0 million, or \$0.06 per share for the twelve months ended December 31, 2007, of which \$0.6 million was recorded as a research and development expense and \$1.4 million was recorded as a general and administrative expense. As of December 31, 2007, we have \$3.1 million, of unvested awards not yet recognized as an expense, not discounting for future forfeitures. This amount less assumed forfeitures will be expensed over the respective vesting period of the granted awards, which for stock options is generally four years and for restricted stock, is one to two years. In 2006, upon the adoption of SFAS No. 123(R), we commenced issuing awards of restricted stock, but in 2007 grants we only issued stock options. We may continue to issue a mix of stock options and restricted stock in the future. Please refer to Note 13 to our Financial Statements for further information on share-based compensation.

*Income Taxes.* We adopted the provisions of Interpretation No. 48 effective January 1, 2007. No cumulative adjustment was required or recorded as a result of the implementation of Interpretation No. 48. As of December 31, 2007, the Company had no unrecognized tax benefits. The Company will recognize accrued

interest and penalties related to unrecognized tax benefits in income tax expense when and if incurred. The Company had no interest or penalties related to unrecognized tax benefits accrued as of December 31, 2007. The Company does not anticipate that the amount of the unrecognized benefit will significantly increase or decrease within the next 12 months.

*Lease Accounting.* We have entered into a lease for our facility pursuant to which leasehold improvements paid by the lessor pursuant to the lease agreement were capitalized. The leasehold improvement assets are being amortized over seven years and the liability is being amortized over life of the lease, which is ten years for the liability. The amortization is recorded as a discount to rent expense for the liability and the amortization expense to leasehold improvements for the asset. The balances of the capitalized lessor-paid leasehold improvements are classified in the balance sheet as leasehold improvements for the asset and other liabilities for the liability, respectively. In addition, we took possession, or control of, the physical use of the facility in January 2005, at which time the work was initiated on the leasehold improvements. The leasehold improvements were completed in May 2005. This four month gap constituted a rent holiday. As such, we accrued rent for that time period. This accrued rent is being amortized as a discount to rent over the remaining 10 year life of the lease. The balance of this rent accrual is classified in the balance sheet as other liabilities.

### **Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. We do not expect the adoption of SFAS No. 157 to have a material impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 permits companies to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS No. 159 to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, and SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 141(R) requires an acquirer to measure the identifiable assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at their fair values on the acquisition date, with goodwill being the excess value over the net identifiable assets acquired. SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary should be reported as equity in the consolidated financial statements. The calculation of earnings per share will continue to be based on income amounts attributable to the parent. SFAS No. 141(R) and SFAS No. 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We have not yet determined the effect on our consolidated financial statements, if any, upon adoption of SFAS No. 141(R) or SFAS No. 160.

### **Results of Operations**

#### ***Fiscal Years Ended December 31, 2007 and 2006***

*Summary.* For 2007, we reported a net loss of \$41.5 million, as compared to a net loss of \$31.1 million for the same period in 2006 and basic and diluted net loss per share of \$1.22 as compared to \$1.03 for the same period of 2006. The significant increase in net loss and net loss per share for 2007, as compared to 2006, was principally due to the \$32.6 million in-process research and development charge related to the acquisition of FermaVir in 2007, offset in part by 2006 non-recurring restructuring charges of \$9.1 million and the discontinuation of the Veronate program in 2006 and lower ongoing research and development and general and administrative expenses in 2007.

*Revenue.* Revenue increased to \$2.8 million in 2007 from \$0.8 million in 2006. This increase of \$2.0 million or 250% was the result of license and collaboration research and development fees from a new license and development agreement entered into in early 2007. Revenue consists of quarterly collaborative research and development support fees and license fees from our collaborators. The collaborative research and development support fees are based on the number of full-time employee equivalents that collaborate on a program.

*Research and Development Expense.* Research and development expense increased to \$42.6 million in 2007 from \$23.4 million in 2006. The increase of \$19.2 million, or 82%, was the result of a \$32.6 million in-process research and development expense in 2007 in connection with the acquisition of FermaVir and an increase of \$0.5 million in license fees, legal and other expenses, offset in part an \$8.9 million decrease in clinical, preclinical and manufacturing expense of product candidates, a \$2.9 million decrease in salaries, benefits, and share-based compensation expense and a \$2.1 million decrease in depreciation and facility related expenses. In-process research and development expense increased as result of the acquisition of FermaVir Pharmaceuticals in 2007. License fees, legal and other expenses increased due to the in-licensing of our HIV integrase inhibitor program and hepatitis C virus polymerase inhibitor program, offset in part by a decreases in patent-related legal expenses, and fewer supplies used in our research activities. Clinical trial expenses decreased by \$3.9 million due to the completion of the Veronate Phase III clinical trial in April 2006, and a decrease of \$0.1 million in clinical trial expenses for the Aurexis program, offset in part by a \$0.3 million increase for trial expenses for the FV-100 program in 2007 related to the recently completed exploratory Phase I trial. Preclinical development costs increased by \$0.6 million in 2007 due to preclinical studies related to our FV-100 program, offset by a slight decrease in sponsored research activities. Manufacturing expenses decreased by \$5.8 million in 2007 due to the non-recurring costs being recorded in 2006 related to the termination of a contract manufacturing agreement in 2006 and the completion of trial material for the Veronate program in 2006. Salaries, benefits, and share-based compensation expenses decreased in 2007 due to reductions in personnel levels and lower severance and termination obligations of \$2.4 million that were recorded in 2006, as well as a reduction in share-based compensation expense of \$0.5 million. Depreciation and facility-related expenses decreased in 2007 due to a lower amount of depreciable assets and lower facility operating expenses as compared to 2006.

The following table summarizes the components of our research and development expense for 2007 and 2006.

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
	(In millions)	
Clinical, preclinical and manufacturing related expenses . . . . .	\$ 1.4	\$10.3
Salaries, benefits and share-based compensation expenses . . . . .	3.6	6.5
License fees, legal and other expenses . . . . .	2.9	2.4
Depreciation and facility related expenses . . . . .	2.1	4.2
In-process research and development expenses . . . . .	<u>32.6</u>	<u>—</u>
Total research and development expense . . . . .	<u>\$42.6</u>	<u>\$23.4</u>

*General and Administrative Expense.* General and administrative expense decreased to \$6.3 million in 2007 from \$12.8 million in 2006. The decrease of \$6.5 million, or 51%, was primarily due to a decrease of \$2.4 million in professional and legal fees and market research expenses, a \$1.9 million decrease in salaries, benefits, and share-based compensation expense, a \$1.5 million decrease in depreciation and facility-related expenses and a \$0.7 million decrease in public company related expenses and other expenses. Professional and legal fees and market research expenses decreased in 2007 largely due to a \$1.0 million of transaction costs we incurred in connection with merger and acquisition activities in 2006 and a \$1.5 million decrease in marketing research, advisory services related to commercialization, general corporate matters, accounting services, and investor relations activities. Salaries, benefits, and share-based compensation expense decreased in 2007 primarily due to reductions in personnel levels and lower severance and termination obligations of \$1.8 million, and lower share-based compensation expense of \$0.1 million. Depreciation and facility-related expenses decreased in 2007 due to a lower amount of depreciable assets related to a change in estimated life and accelerated depreciation in 2006 on leasehold improvements and general office assets related to our

facility, and lower facility operating expenses as compared to 2006. Public company related expenses and other expenses decreased in 2007 due to lower insurance premiums, board compensation expenses and general office expenses as compared to 2006.

The following table summarizes the components of our general and administrative expense for 2007 and 2006.

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
	(In millions)	
Professional and legal fees and market research expenses .....	\$1.0	\$ 3.4
Salaries, benefits and share-based compensation expenses .....	3.4	5.3
Public company related expenses and other expenses .....	1.3	2.0
Depreciation and facility related expenses .....	<u>0.6</u>	<u>2.1</u>
Total general and administrative expense .....	<u>\$6.3</u>	<u>\$12.8</u>

*Interest and Other Income, net.* Interest and other income, net, increased to \$4.6 million for 2007 from \$4.2 million in 2006. The increase of \$0.4 million was the result of a \$0.9 million increase in other income from the sale of excess raw material that was originally purchased for the manufacture of Veronate, offset in part by a decrease of \$0.5 million decrease in net interest income due to lower average cash balances on investments and higher interest expenses.

## Liquidity and Capital Resources

### *Sources of Liquidity*

Since our inception in May 1994 through December 31, 2007, we have funded our operations primarily with \$214.4 million in gross proceeds raised from a series of five private equity financings, our IPO in June 2004, and two PIPE financings, or private placement of public equity financings.

From inception through December 31, 2007, we have also borrowed a total of \$12.2 million under various notes payable, a credit facility with a commercial bank and capital leases, and have received approximately \$12.2 million in license fees, collaborative research payments and grants, of which \$0.8 million and \$0.7 million were recorded as deferred revenue as of December 31, 2007 and December 31, 2006, respectively.

At December 31, 2007, cash, cash equivalents and short-term investments were \$50.3 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, asset-backed securities, commercial paper, certificates of deposit, and money market accounts that have an average maturity date of less than 12 months.

### *Cash Flows*

For the year ended December 31, 2007, cash, cash equivalents, and short-term investments decreased by \$11.1 million, from \$61.4 million to \$50.3 million. This decrease resulted primarily from cash used for operating activities as well as from acquisition and in-licensing activities, the payment of accrued restructuring charges, the repayment of capital lease obligations and notes payable and capital expenditures.

Net cash used in operating activities was \$8.2 million in 2007, which reflects our net loss for the period of \$41.5 million plus net cash used from changes in operating accounts of \$1.3 million, excluding those operating accounts acquired in the FermaVir acquisition, offset by non-cash charges of \$34.6 million included in our net loss. Our net loss was largely the result of the acquisition of FermaVir, cost of funding our preclinical studies and clinical trials associated with FV-100, other research and development activities, general and administrative expenses and expenses associated with the in-licensing of our new product candidates, offset by the sale of excess raw materials, the amortization of deferred revenue from license and collaboration agreements, and net interest income.

The \$1.3 million net cash used by the net changes in operating accounts, excluding those operating accounts acquired in the FermaVir acquisition, consisted of \$1.6 million in decrease accounts payable and accrued liabilities associated largely with the payment of severance and termination obligations, and professional and legal fees associated with merger and acquisition activities, offset by \$0.2 million decrease in receivables and a \$0.1 million increase in deferred revenue due to revenue earned.

We received approximately \$4.0 million of cash from investing activities during 2007, which primarily consisted of net sales of short-term investments of \$7.0 million, offset by \$3.0 million of cash paid in connection with the acquisition of FermaVir.

We used net cash of \$1.3 million from financing activities during 2007, which consisted of largely of payments on our capital leases and promissory notes.

### ***Funding Requirements***

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

- any changes in our strategy in the future;
- the development plans and timing of our pipeline;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the variability, timing and costs associated with conducting pre-clinical studies;
- the cost of manufacturing preclinical study and clinical trial materials for our product candidates;
- the variability, timing and costs associated with conducting clinical trials, the rate of enrollment in such clinical trials and the results of these clinical trials;
- the cost to obtain and timing of regulatory approvals required to advance the development of our programs or product candidates;
- the number of product candidates we may advance into clinical development;
- future payments we may receive or make under existing or future license or collaboration agreements if any;
- whether we obtain additional preclinical or clinical-stage product candidates or programs through future in-licensing or acquisition;
- the cost to maintain a corporate infrastructure to support being a publicly-traded company;
- the cost of filing, prosecuting, and enforcing patent and other intellectual property claims; and
- the future need to acquire additional licenses or acquire product candidates or programs.

Based on our current strategy and operating plan, and considering the potential costs associated with advancing the development of our existing pipeline on our planned timelines, we believe that our existing cash, cash equivalents, short-term and long-term investments of \$50.3 million as of December 31, 2007, including proceeds from anticipated existing licensing agreements and collaborations will enable us to operate for a period of at least 24 months from the date of this filing, even if the lower court's decision in our favor is overturn on appeal or the dispute is otherwise resolved. Our estimate assumes that we advance FV-100, and one or two of our other antiviral programs into clinical development. This estimate does not include the potential costs for the further development of the MSCRAMM platform, including Aurexis, and any other significant transaction or change in our strategy or development plans.

We currently do not have any commitments for future funding, nor do we anticipate that we will generate significant revenue from the sale of any products in the foreseeable future. Therefore, in order to meet our anticipated liquidity needs beyond 24 months, or possibly sooner in the event we enter into other transactions or change our strategy or development plans, we may need to raise additional capital. We would expect to do so primarily through the sale of additional common stock or other equity securities or licensing agreements, strategic collaborations, forms of debt financing, or any other financing vehicle. Funds from these sources 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 preclinical studies and clinical trials, or obtain funds through license agreements, collaborative or partner arrangements pursuant to which we will likely have 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.

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

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of Inhibitex, Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inhibitex, Inc. at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Atlanta, Georgia  
March 13, 2008

**INHIBITEX, INC.**  
**Consolidated Balance Sheets**

	December 31,	
	2007	2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 14,178,143	\$ 19,681,861
Short-term investments .....	36,088,309	41,676,223
Prepaid expenses and other current assets .....	1,058,426	1,002,810
Accounts receivable .....	44,988	332,669
Total current assets .....	51,369,866	62,693,563
Property and equipment, net .....	2,564,345	3,530,796
Total assets .....	<u>\$ 53,934,211</u>	<u>\$ 66,224,359</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 1,160,351	\$ 629,249
Accrued expenses .....	6,605,253	7,392,210
Current portion of notes payable .....	312,500	833,333
Current portion of capital lease obligations .....	698,151	816,184
Current portion of deferred revenue .....	441,667	191,667
Other current liabilities .....	154,824	152,728
Total current liabilities .....	9,372,746	10,015,371
Long-term liabilities:		
Notes payable, net of current portion .....	703,125	625,000
Capital lease obligations, net of current portion .....	68,710	829,871
Deferred revenue, net of current portion .....	387,500	537,500
Other liabilities, net of current portion .....	1,202,328	1,139,599
Total long-term liabilities .....	2,361,663	3,131,970
Total liabilities .....	11,734,409	13,147,341
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2007 and 2006, none issued and outstanding at December 31, 2007 and 2006 .....	—	—
Common stock, \$.001 par value; 75,000,000 shares authorized at December 31, 2007 and 2006, 42,785,318 and 30,278,135 shares issued and outstanding at December 31, 2007 and 2006, respectively ..	42,785	30,278
Additional paid-in capital .....	240,634,018	214,192,588
Accumulated other comprehensive income .....	106,480	12,000
Warrants .....	15,551,492	11,517,743
Accumulated deficit .....	(214,134,973)	(172,675,591)
Total stockholders' equity .....	42,199,802	53,077,018
Total liabilities and stockholders' equity .....	<u>\$ 53,934,211</u>	<u>\$ 66,224,359</u>

**INHIBITEX, INC.**  
**Consolidated Statements of Operations**

	<u>Year Ended December 31,</u>	
	<u>2007</u>	<u>2006</u>
Revenue:		
License fees and milestones .....	\$ 1,650,000	\$ 150,000
Collaborative research and development .....	1,125,000	500,000
Grants and other revenue .....	28,500	195,577
Total revenue .....	<u>2,803,500</u>	<u>845,577</u>
Operating expense:		
In-process research and development .....	32,569,709	—
Research and development .....	10,016,279	23,417,091
Total research and development .....	42,585,988	23,417,091
General and administrative .....	6,300,863	12,758,063
Total operating expense .....	<u>48,886,851</u>	<u>36,175,154</u>
Loss from operations .....	(46,083,351)	(35,329,577)
Other income, net .....	1,969,216	1,059,993
Interest income, net .....	2,654,753	3,124,524
Net loss .....	<u>\$(41,459,382)</u>	<u>\$(31,145,060)</u>
Basic and diluted net loss per share .....	<u>\$ (1.22)</u>	<u>\$ (1.03)</u>
Weighted average shares used to compute basic and diluted net loss per share .....	<u>34,026,250</u>	<u>30,259,979</u>

**INHIBITEX, INC.**

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

	Series A Preferred Stock		Common Stock Subscription		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Common Stock Warrants	Deferred Stock Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Par Value	Shares	Par Value	Shares	Par Value						
Balance at January 1, 2006	—	\$—	—	\$	30,219,715	\$30,220	\$212,290,902	\$(79,971)	\$11,514,793	\$(772,347)	\$(141,530,531)	\$ 81,453,066
Exercise of stock options and issuances of employee stock purchase plan	—	—	—	—	58,420	58	83,087	—	—	—	—	83,145
Reversal of deferred stock compensation	—	—	—	—	—	—	(772,347)	—	—	772,347	—	—
Issuance of common stock warrants	—	—	—	—	—	—	—	—	2,950	—	—	2,950
Share-based compensation expense	—	—	—	—	—	—	2,649,406	—	—	—	—	2,649,406
Cumulative effect for change in accounting principle	—	—	—	—	—	—	(58,460)	—	—	—	—	(58,460)
Net loss	—	—	—	—	—	—	—	—	—	—	(31,145,060)	(31,145,060)
Other comprehensive income	—	—	—	—	—	—	—	91,971	—	—	—	91,971
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(31,053,089)
Balance at December 31, 2006	—	—	—	—	30,278,135	30,278	214,192,588	12,000	11,517,743	—	(172,675,591)	53,077,018
Exercise of stock options and issuances of restricted stock and employee stock purchase plan	—	—	—	—	812,053	812	16,286	—	—	—	—	17,098
Expiration of common stock warrants	—	—	—	—	—	—	4,140,065	—	(4,140,065)	—	—	—
Share-based compensation expense	—	—	—	—	—	—	2,034,276	—	—	—	—	2,034,276
Issuance of common stock	—	—	—	—	225,870	226	299,774	—	—	—	—	300,000
Issuance of common stock, options, and warrants for the acquisition of FermaVir Pharmaceuticals, Inc.	—	—	—	—	11,469,260	11,469	19,951,029	—	8,173,814	—	—	28,136,312
Net loss	—	—	—	—	—	—	—	—	—	—	(41,459,382)	(41,459,382)
Other comprehensive income	—	—	—	—	—	—	—	94,480	—	—	—	94,480
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(41,364,902)
Balance at December 31, 2007	—	\$—	—	\$—	42,785,318	\$42,785	\$240,634,018	\$106,480	\$15,551,492	\$—	\$(214,134,973)	\$ 42,199,802

**INHIBITEX, INC.**

**Consolidated Statements of Cash Flows**

	Year Ended December 31,	
	2007	2006
Cash flows from operating activities:		
Net loss .....	\$(41,459,382)	\$(31,145,060)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development .....	32,569,709	—
Stock issued in connection with in-license agreement .....	300,000	—
Depreciation and amortization .....	1,029,046	4,876,124
Share-based compensation expense .....	2,034,276	2,649,406
Loss (gain) on sale of property and equipment .....	(25,770)	1,017
Amortization of investment premium or discount .....	(1,352,215)	(225,642)
Cumulative effect of change in accounting principle .....	—	(58,460)
Changes in operating assets and liabilities, net of acquisition:		
Prepaid expenses and other assets .....	(32,607)	914,626
Accounts receivable .....	287,681	(287,746)
Accounts payable and other liabilities .....	(346,297)	(2,404,527)
Accrued expenses .....	(1,280,076)	2,075,304
Deferred revenue .....	100,000	(150,000)
Net cash used in operating activities .....	(8,175,635)	(23,754,958)
Cash flows from investing activities:		
Purchases of property and equipment .....	(73,650)	(232,863)
Purchases of investments .....	(75,192,391)	(62,875,565)
Proceeds from maturities of investments .....	82,227,000	74,713,000
Proceeds from sale of property and equipment .....	40,425	—
Cash paid in connection with the acquisition, net of cash acquired .....	(3,024,663)	—
Net cash provided by investing activities .....	3,976,721	11,604,572
Cash flows from financing activities:		
Payments on promissory notes and capital leases .....	(1,321,902)	(2,188,756)
Proceeds from the issuance of common stock, net of issuance costs .....	17,098	178,066
Net cash used in financing activities .....	(1,304,804)	(2,010,690)
Decrease in cash and cash equivalents .....	(5,503,718)	(14,161,076)
Cash and cash equivalents at beginning of period .....	19,681,861	33,842,937
Cash and cash equivalents at end of period .....	\$ 14,178,143	\$ 19,681,861
Supplemental cash flow information:		
Interest paid .....	\$ 143,890	\$ 297,585
Non-cash investing activities:		
Assets and liabilities assumed by acquisition:		
Prepaid expenses and other current assets .....	\$ 23,009	\$ —
Property and equipment, net .....	3,600	—
Other assets .....	43,890	—
Accounts payable .....	870,754	—
Accrued expenses .....	271,743	—

## INHIBITEX, INC.

### 1. Operations

Inhibitex, Inc. ("Inhibitex" or the "Company") was incorporated in the state of Delaware in May 1994. Inhibitex is a biopharmaceutical company focused on the development of differentiated anti-infective products that can diagnose, prevent and treat serious infections. In 2006, the Company adopted a strategy to pursue pre-clinical or clinical-stage antiviral development programs via in-licensing, or acquisition, and postponed the initiation of any additional clinical trials of Aurexis pending the finalization of these strategic activities. In connection with this strategy, the Company entered into the following transactions as described below.

On April 9, 2007, the Company entered into a definitive Agreement and Plan of Merger and Reorganization with FermaVir Pharmaceuticals, Inc. or FermaVir. On September 19, 2007, the Company consummated the acquisition of FermaVir. FermaVir's development-stage antiviral pipeline included FV-100, a nucleoside analogue for the treatment of herpes zoster infections (shingles), and a series of preclinical nucleoside analogue compounds for the treatment of human cytomegalovirus, or CMV disease.

On September 11, 2007, the Company entered into an exclusive worldwide license agreement with the University of Georgia Research Foundation, or UGARF, for intellectual property covering a series of human immunodeficiency virus, or HIV, integrase inhibitors and other antiviral compounds in exchange for an upfront license fee, future milestone payments and royalties on future net sales. The license agreement also includes intellectual property related to hepatitis C polymerase, or HCV, inhibitors

On November 19, 2007, the Company entered into an exclusive worldwide license agreement with Cardiff University in Wales, United Kingdom and Katholieke Universiteit in Leuven, Belgium for intellectual property covering a series of hepatitis C virus (HCV) polymerase inhibitors in exchange for an upfront license fee, future milestone payments and royalties on future net sales.

As a result of the above transactions, the Company has changed its strategic focus with respect to the anti-infective market and is primarily concentrating its efforts on the development of antiviral small molecules. The Company intends to target its antiviral development efforts on the treatments of shingles, HIV infection, chronic hepatitis C, and cytomegalovirus, or CMV. Due to this strategic transformation, the Company in the fourth quarter of 2007 exited the development stage and accordingly the financial statements for all periods are not presented as a development stage company. The Company previously issued financial statements for periods prior to October 1, 2007, as a development stage company, as prescribed by Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises."

The Company has incurred operating losses in each year since its inception and expects such annual losses to continue. These losses have largely been the result of research and development expenses incurred in connection with the discovery and development of novel antibody-based products for the prevention and treatment of serious bacterial and fungal infections, all of which were based upon the Company's proprietary MSCRAMM protein platform. In 2006, the Company's previous lead product candidate, Veronate®, failed to meet its primary endpoint in a pivotal Phase III clinical trial and its development was discontinued. Aurexis, the Company's second product candidate from its MSCRAMM protein platform, has completed one Phase II clinical trial to evaluate it in combination with antibiotics, in the treatment of serious life-threatening *Staphylococcus aureus* (*S. aureus*) bloodstream infections. The Company has also licensed the rights to use certain targets and intellectual property from its MSCRAMM protein platform to Wyeth for use in the development of staphylococcal vaccines and to 3M Company for use in developing diagnostic applications.

The Company plans to continue to finance its operations with its existing cash, cash equivalents, short-term investments, or through future equity and/or debt financings, or proceeds from potential future collaborations or partnerships or other financing vehicles. The Company's ability to continue its operations is dependent, in the near term, upon managing its cash resources, successful development of its product candidates, entering into additional in-licensing, collaboration or partnership agreements, executing future financings or transactions and ultimately, upon achieving positive cash flow from operations. There can be no assurance that additional funds will be available on terms acceptable to the Company or that the Company will ever become profitable.

## INHIBITEX, INC. — (Continued)

### 2. Summary of Significant Accounting Policies

*Principles of Consolidation.* In April 2007, the Company formed Frost Acquisition Corp., a Delaware corporation, as a wholly-owned subsidiary. Frost Acquisition Corp. does not engage in any operations and was formed solely to facilitate the acquisition of FermaVir Pharmaceuticals, Inc. or (“FermaVir”). In September 2007, FermaVir was merged with Frost Acquisition Corp and included the subsidiary of FermaVir Research Corp. The accompanying consolidated financial statements include all accounts of the Company and its subsidiaries. All inter-company balances have been eliminated.

*Use of Estimates.* The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or U.S. GAAP, 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 or less days when purchased. Cash equivalents are carried at cost, which approximates their fair market value. Investments with original maturities between 90 and 365 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 No. 115”).

The Company has classified its entire investment portfolio as available-for-sale with no concentration of credit risk higher than 10% of the total portfolio. These securities are recorded as either cash equivalents or short-term investments. Short-term investments are carried at the fair value based upon quoted market prices. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Amortization and accretion are included in interest income, net, and realized gains and losses are also included in interest income, net. All unrealized gains and losses are reported in other comprehensive income (See Note 16). The cost basis of all securities sold is based on the specific identification method.

Available-for-sale securities as of December 31, 2007 and 2006 consisted of commercial paper, government 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:

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

In accordance with AICPA Statement of Position 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*, the Company also includes in property and equipment capitalized costs related to computer software developed for internal use. When property and equipment are retired or sold, the assets and accumulated depreciation are removed from the respective accounts and any gain or loss is recognized in other income, net. Expenditures for repairs and maintenance are charged to expense as incurred. The Company performs annual and quarterly reviews of asset lives and related impairment testing in accordance with guidance set forth in SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Asset* and Accounting Principals Board Opinion No. 20, *Accounting Changes*.

*Revenue Recognition.* To date, the Company has not generated any revenue from the sale of products. Revenue relates to fees recovered or received for licensed technology, collaborative research and development agreements, materials transfer agreements and grants awarded to the Company. The Company follows the revenue recognition criteria outlined in SEC Staff Accounting Bulletin (“SAB”) No. 101, *Revenue Recognition*

## INHIBITEX, INC. — (Continued)

*in Financial Statements* (“SAB No. 101”) as amended by SAB No. 104, *Revenue Recognition* and Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables*. 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 as one unit of accounting. Revenue received for ongoing research and development activities under collaborative arrangements and materials transfer agreements are recognized as these activities are performed pursuant to the terms of the related agreements. Any amounts received in advance of the performance of the related activities are recorded as deferred revenue until earned.

*Reclassifications.* Certain amounts in the 2006 audited financial statements have been reclassified to conform to the 2007 presentation.

*Accrued Expenses.* As part of the process of preparing the Company’s 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 and cost of services performed by third parties 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 preclinical and/or clinical research and data management organizations, clinical investigators, contract manufacturers in conjunction with the manufacture of preclinical and clinical trial materials, other professional fees, and accrued benefits for employees. Estimates of these expenses and the related accruals are derived based upon 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 in arrears for services performed. Management makes its estimates based upon the facts and circumstances known to it at the time.

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

*Share-based Compensation.* On January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment* (“SFAS No. 123(R)”). Prior to January 1, 2006, the Company accounted for share-based awards it granted pursuant to the 2004 Stock Incentive Plan and the 2002 Non-Employee Directors Stock Option Plan under the recognition and measurement provisions of Accounting Principles Board (“APB”) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations, as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation* (“SFAS No. 123”). The Company adopted the fair value recognition provisions of SFAS No. 123(R), using the modified-prospective transition method. Under that transition method, compensation cost recognized in 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (b) compensation expense for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated. The Company uses the Black-Scholes method to estimate the value of share-based awards granted to employees and directors and applied it not only to new awards, but to previously granted awards that were not fully vested on the effective date of January 1, 2006.

Upon the adoption of SFAS No. 123(R), the Company recorded a cumulative effect of a change in accounting principle totaling \$58,460 related to expected forfeitures for previously expensed share-based compensation. The Company’s forfeiture rate is based on historical experience as well as anticipated turnover and other qualitative factors. There may be adjustments to future periods if actual forfeitures differ from current estimates.

The Company’s awards are issued with graded vesting. The compensation cost for these graded vesting awards is recognized on the straight-line method.

## INHIBITEX, INC. — (Continued)

SFAS No. 123(R) requires the cash flows resulting from the tax benefits on tax deductions in excess of the compensation cost recognized for those awards (excess tax benefits) to be classified as financing cash flows. The Company currently records a full valuation allowance for all tax benefits due to uncertainties with respect to the Company's ability to generate sufficient taxable income in the future.

*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.* 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.

*In-Process Research and Development Expense.* In-process research and development expense consists of the costs incurred in connection with the acquisition of FermaVir in September 2007. The acquisition was accounted for as an acquisition of assets in accordance with SFAS, No 142, *Goodwill and Other Intangible Assets*. The allocation of purchase price requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective values. Please see Note 4-Acquisition of FermaVir.

*Research and Development Expense.* Research and development expense primarily consists of costs incurred in the discovery, development, testing and manufacturing of the Company's product candidates. These expenses consist primarily of (i) fees paid to third-party service providers to perform, monitor and accumulate data related to the Company's preclinical studies and clinical trials, (ii) costs related to obtaining patents and licenses and sponsored research agreements, (iii) the costs to procure and manufacture materials used in clinical studies and clinical trials, (iv) laboratory supplies and facility-related expenses to conduct development, and (v) salaries, benefits, and share-based compensation for personnel. These costs are charged to expense as incurred.

*General and Administrative Expense.* General and administrative expense reflects the costs incurred to manage the Company and support the Company's research and development activities. These costs primarily consist of salaries, benefits and share-based compensation for personnel in executive, finance, accounting, information technology, business development, sales and marketing and human resource functions. Other significant costs include expenses related to being publicly-traded, professional fees for legal and auditing services, investor relations and other related expenses, market research and other consulting services, facility expenses, as well as insurance premiums, including those for directors' and officers' liability.

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

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). Interpretation No. 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with Statement of Financial Accounting Standards ("SFAS") No. 109, "Accounting for Income Taxes." Interpretation No. 48 prescribes a recognition threshold and measurement attributes for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Interpretation No. 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods,

## INHIBITEX, INC. — (Continued)

disclosure and transition. The Company adopted the provisions of Interpretation No. 48 effective January 1, 2007. No cumulative adjustment was required or recorded as a result of the adoption of Interpretation No. 48. Please see Note 11-Income Taxes.

*Comprehensive Loss.* The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income* (“SFAS No. 130”). SFAS No. 130 establishes standards for the reporting and display of comprehensive loss and its components for general purpose financial statements. For the periods presented, comprehensive loss did not differ materially from reported net loss. Please see Note 16-Comprehensive Income.

*Lease Accounting.* The Company entered into a lease for its facility (See Note 8-Commitments) where leasehold improvements paid by the lessor pursuant to the lease agreement were capitalized. The leasehold improvement assets are being amortized over seven years and the liability is being amortized over life of the lease, which is ten years. The amortization is recorded as a discount to rent expense for the liability and the amortization expense to leasehold improvements for the asset. The balances of the capitalized lessor-paid leasehold improvements are classified in the balance sheet as leasehold improvements for the asset and other liabilities for the liability (See Note 10-Other Liabilities), respectively. In addition, the Company took possession, or control of, the physical use of the facility in January 2005, at which time the work was initiated on the leasehold improvements. The leasehold improvements were completed in May 2005. This four month gap constituted a rent holiday. As such, the Company accrued rent for that time period. This accrued rent is being amortized as a discount to rent over the remaining 10 year life of the lease. Further, the Company recognizes rent expense on a straight-line basis over the life of the lease. The difference between cash rent payments and rent expense is recorded as deferred rent. The balance of this rent liability is classified in the balance sheet as other liabilities (See Note 10-Other Liabilities).

*Recent Accounting Pronouncements.* In September 2006, the FASB issued Statement of Financial Accounting Standards (“SFAS”) No. 157, *Fair Value Measurement*. (“SFAS No. 157”). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The new standard is not expected to have any significant effect on the Company’s financial position or results of operations. SFAS No. 157 will become effective for the Company as of the first quarter of 2008.

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities” (“SFAS No. 159”). SFAS No. 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The new standard is not expected to have any significant effect on the Company’s financial position or results of operations.

In December 2007, the FASB issued SFAS No. 141 (Revised), *Business Combinations* (“SFAS No. 141R”). SFAS No. 141R establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed (including intangibles), and any noncontrolling interest in the acquiree. SFAS No. 141R also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141R is effective for fiscal years beginning after December 15, 2008. The adoption of SFAS No. 141R on January 1, 2009 will require the company to expense all direct transaction costs for business combinations which may be significant to the Company depending on its acquisition activity.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51* (“SFAS No. 160”). SFAS No. 160 establishes accounting and reporting standards for a parent company’s noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. The adoption of

## INHIBITEX, INC. — (Continued)

SFAS No. 160 on January 1, 2009 will require the Company to record gains or losses upon changes in control, which is not expected to have a significant impact on the consolidated financial statements.

### 3. Net Loss Per Share

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

The following table sets forth the computation of historical basic and diluted net loss per share:

	Year Ended December 31,	
	2007	2006
<b>Historical</b>		
Numerator:		
Net loss .....	\$(41,459,382)	\$(31,145,060)
Denominator:		
Weighted average common shares outstanding .....	34,026,250	30,259,979
Basic and diluted net loss per share .....	\$ (1.22)	\$ (1.03)

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,	
	2007	2006
Common stock options .....	4,958,131	2,081,054
Restricted common stock .....	902,959	1,659,157
Common stock warrants .....	8,535,097	3,807,706
Total .....	14,396,187	7,547,917

### 4. Acquisition of FermaVir

On September 19, 2007, the Company consummated the acquisition of all of the common shares of FermaVir pursuant to an Agreement and Plan of Merger and Reorganization dated as of April 9, 2007, the (“Merger Agreement”). Pursuant to the merger agreement, FermaVir merged with and into Frost Acquisition Corp., a wholly-owned subsidiary of the Company, which is referred to as the merger sub, with the merger sub continuing as a wholly-owned subsidiary of the Company under the name FermaVir Pharmaceuticals, Inc. The assets of FermaVir included FV-100, an orally bioavailable bicyclic nucleoside analogue for the treatment of shingles and a series of preclinical compounds for the treatment of human cytomegalovirus, or CMV, disease to the Company’s pipeline. The consolidated statements of operations include the results of FermaVir from September 19, 2007, the closing date of the acquisition.

**INHIBITEX, INC. — (Continued)**

The fair value of the issuance of 11,469,260 of Inhibitex common stock in exchange for all outstanding FermaVir common shares was \$18,924,279 or \$1.65 per share, based on the average of the closing prices for a range of trading days (April 7, 2007 through April 11, 2007, inclusive) around and including the announcement date of the merger transaction. The fair value of FermaVir's stock options and stock warrants assumed by Inhibitex for all employees and non-employees was determined using the Black-Scholes option pricing model with the following weighted average assumptions: stock price of \$1.65, which is the value ascribed to the Inhibitex's common stock in determining the purchase price; volatility of 71%; dividend rate of 0%; risk-free interest rate of 4.6%; and a weighted average expected life of 8.3 years.

The estimated purchase price was calculated as follows:

Fair value of Inhibitex common stock issued . . . . .	\$18,924,279
Estimated fair value of FermaVir stock options and stock warrants assumed . . . . .	9,212,033
Estimated transaction and exit costs . . . . .	1,930,352
Cash advance consideration as note receivable . . . . .	<u>1,500,000</u>
Total purchase price . . . . .	<u>\$31,566,664</u>

The acquisition was accounted for as an acquisition of assets in accordance with SFAS, No. 142, *Goodwill and Other Intangible Assets*. The total estimated purchase price was allocated to the tangible and intangible assets acquired and liabilities assumed in connection with the transaction, based on their estimated fair values. The purchase price allocation is preliminary and additional adjustments may occur. As FermaVir was a development stage enterprise, the acquisition was not considered to be a business combination, and the excess allocation of the preliminary purchase price did not result in goodwill, but rather was reallocated to the acquired assets.

The preliminary allocation of the total purchase price, as shown above, to the acquired tangible and intangible assets and assumed liabilities of FermaVir based on their fair values as of the acquisition date are as follows:

Cash and cash equivalents . . . . .	\$ 68,953
Prepaid expenses and other current assets . . . . .	23,009
Property and equipment, net. . . . .	3,600
Other assets . . . . .	43,890
Accounts payable . . . . .	(870,754)
Accrued expenses . . . . .	(271,743)
Net fair value of acquired assets and liabilities . . . . .	(1,003,045)
In-process research and development . . . . .	<u>32,569,709</u>
Total purchase price . . . . .	<u>\$31,566,664</u>

The acquired in-process research and development ("IPR&D") project is FV-100, a compound in development as a potential treatment of varicella zoster virus ("VZV") the causative agent for shingles and chickenpox. The CMV program acquired did not qualify as a project for IPR&D purposes and is excluded from the purchase price allocation. The accounting fair value of IPR&D for FV-100 was \$21,200,000. Due to the application of Emerging Issues Task Force ("EITF") 98-3, the remaining purchase price was reallocated to FV-100 rather than to goodwill.

The fair value of the IPR&D project was determined utilizing the income approach, assuming that the rights to the IPR&D project will be sublicensed in the future to third parties in exchange for certain upfront, milestone and royalty payments, and the combined company will have no further involvement in the ongoing development and commercialization of the projects. Under the income approach, the expected future net cash flows from sublicensing the IPR&D project are estimated, risk-adjusted to reflect the risks inherent in the development process and discounted to their net present value. Because the acquired IPR&D project is in the

**INHIBITEX, INC. — (Continued)**

early stages of the development cycle and has no alternative future use, the amount allocated to IPR&D was recorded as an expense immediately upon completion of the acquisition.

The Company has accrued exit costs in connection with the acquisition of FermaVir. The liability outstanding as of December 31, 2007 is \$221,376 of exit costs in connection with lease terminations and relocation costs.

***Pro Forma Results of Operations***

The results of operations of FermaVir are included in Inhibitex's consolidated financial statements from September 19, 2007, the closing date of the acquisition. The following table presents pro forma results of operations and gives effect to the acquisition transaction as if the acquisition was consummated at the beginning of the period presented. The unaudited pro forma results of operations are not necessarily indicative of what would have occurred had the acquisition of assets been completed at the beginning of the period or of the results that may occur in the future.

	<b>Twelve Months Ended December 31,</b>	
	<u>2007</u>	<u>2006</u>
	<i>(Unaudited)</i>	
Revenues .....	<u>\$ 2,803,500</u>	<u>\$ 845,577</u>
Operating expenses .....	<u>\$ 53,109,371</u>	<u>\$ 39,218,922</u>
Net loss .....	<u>\$(53,592,586)</u>	<u>\$(34,573,696)</u>
Basic and diluted net loss attributable to common share .....	<u>\$ (1.27)</u>	<u>\$ (0.83)</u>

The pro forma results for the twelve months ended December 31, 2007 include \$32,569,709 of non-recurring charges for the write-off of the in-process research and development asset.

**5. Short-Term Investments**

Short-term investments consist of debt securities classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition. The Company has invested in corporate notes, commercial paper, asset-backed securities, and government agency notes. Short-term investments are carried at estimated fair value based upon quoted market prices. The Company has had no realized gains or losses from the sale of investments for the years ended December 31, 2007 and 2006. The following table summarizes the estimated fair value of the Company's short-term investments, not including cash equivalents as of December 31, 2007 and 2006.

	<u>December 31, 2007</u>	<u>December 31, 2007</u>
	<u>At Cost</u>	<u>Estimated Fair Market Value</u>
Corporate debt notes .....	\$25,679,900	\$25,771,547
Commercial paper .....	5,331,663	5,334,007
Asset-backed securities .....	<u>4,978,645</u>	<u>4,982,755</u>
Total .....	<u>\$35,990,208</u>	<u>\$36,088,309</u>

**INHIBITEX, INC. — (Continued)**

	<u>December 31, 2006</u>	<u>December 31, 2006</u>
	At Cost	Estimated Fair Market Value
U.S. agency notes . . . . .	\$ 4,357,885	\$ 4,358,552
Corporate debt notes . . . . .	31,083,997	31,093,936
Commercial paper . . . . .	2,777,343	2,777,415
Certificate of deposit . . . . .	700,000	700,000
Asset-backed securities . . . . .	<u>2,746,080</u>	<u>2,746,320</u>
Total . . . . .	<u>\$41,665,305</u>	<u>\$41,676,223</u>

All available-for-sale securities held at December 31, 2007 will mature during 2008.

**6. Property and Equipment**

The components of property and equipment are as follows:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Laboratory equipment . . . . .	\$ 3,379,563	\$ 3,388,670
Leasehold improvements . . . . .	2,451,096	2,447,143
Computer software and equipment . . . . .	577,203	1,048,272
Office furniture and fixtures . . . . .	<u>115,002</u>	<u>131,967</u>
Sub-total . . . . .	6,522,864	7,016,052
Less accumulated depreciation and amortization . . . . .	<u>(3,958,519)</u>	<u>(3,485,256)</u>
Total property and equipment, net . . . . .	<u>\$ 2,564,345</u>	<u>\$ 3,530,796</u>

Included in property and equipment are assets recorded under capital leases. Amortization of the assets recorded under capital leases is included in depreciation expense. Depreciation expense was \$1,029,046 and \$4,876,124 for the years ended December 31, 2007 and 2006, respectively.

In December 2006, the Company's operating plans for 2007 changed, and the Company determined that it will not utilize a significant portion of its office and laboratory facility in the foreseeable future. Based on these changes, the Company abandoned certain assets and revised its depreciation estimates. In accordance with the change the Company performed an impairment test under guidance set forth in Accounting Principals Board Opinion No. 20, *Accounting Changes*, and SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. As such, the Company accelerated depreciation as an impairment charge on certain assets of \$2,816,098 in December 2006. The assets abandoned were \$871,657 of laboratory equipment, \$2,627,614 of leasehold improvements, \$330,880 of computer software and equipment, and \$527,868 of office furniture and fixtures. In 2007, the Company retired \$26,921 of laboratory equipment, \$469,749 of software, \$7,680 in leasehold improvements, and \$16,965 of office furniture and fixtures. The retirement of software was related to the sale of excess raw materials in 2007 (See note 15-Other Income).

The Company entered into a lease for its facility (See Note 8-Commitments) where leasehold improvements paid by the lessor pursuant to the lease agreement were capitalized. The leasehold improvement assets are being amortized over seven years and the liability is being amortized over the life of lease, which is ten years. The amortization is recorded as a discount to rent expense for the liability and the amortization expense to leasehold improvements for the asset. The balances of the capitalized lessor-paid leasehold improvements are classified in the balance sheet as leasehold improvements for the asset and other liabilities for the liability (See Note 10-Other Liabilities), respectively. Net capitalized leasehold improvements paid by the lessor were \$802,121 and \$987,421 as of December 31, 2007 and 2006.

**INHIBITEX, INC. — (Continued)**

**7. Accrued Expenses**

The components of accrued expenses are as follows:

	December 31,	
	2007	2006
Preclinical, clinical and manufacturing development expense.....	\$4,972,179	\$4,637,849
Severance, payroll and benefits expense .....	707,992	1,878,472
Professional fee expense .....	302,307	725,313
Other operating expense.....	622,775	150,576
Total .....	\$6,605,253	\$7,392,210

See Note 14-Contingency for a discussion on preclinical, clinical, and manufacturing development expense.

**8. Commitments**

*Lease Commitments.* In May 2005, the Company began a ten year agreement to lease 51,000 square foot research and office facility. In January 2005, the Company took possession of and controlled the physical use of the property and occupied the facility in May 2005. The Company's minimum rent payments associated with this facility will, on average, approximate \$900,000 to \$1,000,000 per year under this lease.

A portion of the leasehold improvements at the research and office facility was capitalized as leasehold improvements paid by the lessor pursuant to the lease agreement. The leasehold improvement assets are being amortized over seven years and the liability is being amortized over life of lease, which is ten years. The amortization is recorded as a discount to rent expense for the liability as the amortization expense for leasehold improvements for the asset. The balances of the capitalized lessor-paid leasehold improvements are classified in the balance sheet as leasehold improvements for the asset and other liabilities for the liability (See Note 10-Other Liabilities), respectively. In addition, the Company took possession, or control of, the physical use of the facility in January 2005, at which time the work was initiated on the leasehold improvements. The leasehold improvements were completed in May 2005. This four month gap constituted a rent holiday. As such, the Company accrued rent for that time period. This accrued rent is being amortized as a discount to rent over the remaining 10 year life of the lease. Further, the Company recognizes rent expense on a straight-line basis over the life of the lease since the minimum rent payments escalate over the lease term. The difference between cash rent payments and rent expense is recorded as deferred rent. The balance of these rent liabilities are classified in the balance sheet as other liabilities (See Note 10-Other Liabilities).

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 lease as discussed above. During the years ended December 31, 2007 and 2006, rent expense totaled approximately \$1,071,000, and \$868,000 respectively. Future minimum payments under these operating leases at December 31, 2007 are as follows:

<u>Year Ending December 31,</u>	
2008 .....	\$ 888,925
2009 .....	905,434
2010 .....	921,298
2011 .....	944,329
2012 and after .....	3,318,775
Total minimum lease payments .....	\$6,978,761

*Commitments.* In November 2001, the Company entered into a research evaluation and worldwide non-exclusive license agreement with Lonza Biologics for intellectual property and materials relating to the

## INHIBITEX, INC. — (Continued)

expression of recombinant monoclonal antibodies to bacterial surface proteins for use in the manufacture of Aurexis (See Note 17-Research and License Agreements). Under the terms of the agreement, the Company agreed to pay an annual fee and a royalty on the net sales of any products that it may sell that utilize this technology. Pursuant to this agreement, the Company has a minimum purchase commitment of approximately 75,000 pounds sterling in cumulative annual license fees as of December 31, 2007. However, the Company may terminate the agreement upon 60 days notice. The agreement terminates upon the expiration of the last valid patent or 15 years, whichever is longer. Currently, the latest to expire of the issued patents under the license agreement expires in 2016.

In September 2007, the Company obtained an exclusive, worldwide royalty-bearing license from the University of Georgia Research Foundation, or UGARF for intellectual property covering a series of HIV integrase inhibitors and other antiviral compounds in exchange for an upfront license fee and the fair market value of shares of the Company's common stock, future milestone payments, royalties on future net sales, and reimbursement for related patent expenses (See Note 17-Research and License Agreements). The license agreement also includes intellectual property related to non-nucleoside HCV polymerase inhibitors. Pursuant to this license agreement, the Company entered into cooperative research agreements with UGARF for which the Company has a minimum purchase commitment of approximately \$377,000 in annual cooperative research agreement funding as of December 31, 2007. The Company may terminate the collaboration agreement without cause effective only on either September 30, 2008 or September 30, 2009 with at least ninety days written notice prior to the effective date of termination and UGARF may terminate in the event of an uncured material breach by the Company.

In November 2007, the Company entered into an exclusive royalty-bearing worldwide license agreement with Cardiff University in Wales, United Kingdom and Katholieke Universiteit in Leuven, Belgium for intellectual property covering a series of HCV nucleoside polymerase inhibitors in exchange for an upfront license fee, future milestone payments, royalties on future net sales and reimbursement for related patent expenses. The agreement calls for the Company to make certain milestone payments and pay a royalty on the sale of any products that utilize the underlying technology. Pursuant to this license agreement, the Company entered into cooperative research agreements with Cardiff University and Katholieke Universiteit for which the Company has a minimum purchase commitment of approximately \$69,000 pounds sterling in annual cooperative research agreement funding as of December 31, 2007. However, the Company may terminate the collaboration agreement on three months written notice and Cardiff and Leuven may terminate in the event of an uncured material breach by the Company.

### 9. Capital Leases and Notes Payable

*Capital Lease Obligations.* The Company has existing capital lease obligations related to the acquisition of certain laboratory and other equipment purchased in 2005. The amortization of assets acquired under these capital leases has been recorded as depreciation expense. These capital leases bear interest at rates ranging from 9.62% to 10.38%, and expire at various dates from May 2008 to February 2009.

Future payments under capital lease agreements as of December 31, 2007 are as follows:

<u>Year Ending December 31,</u>	
2008 . . . . .	\$ 741,398
2009 . . . . .	<u>69,588</u>
Total future minimum lease payments . . . . .	810,986
Less amount representing interest . . . . .	<u>(44,125)</u>
Present value of future minimum lease payments . . . . .	766,861
Less current portion of capital lease obligations . . . . .	<u>(698,151)</u>
Long-term portion of capital lease obligations . . . . .	<u>\$ 68,710</u>

**INHIBITEX, INC. — (Continued)**

In December 2004, the Company entered into an interest-free, \$2,500,000 note payable with a local development authority for laboratory-related leasehold improvements at the Company's research and headquarters facility. Beginning in October 2005, the Company made the first of 16 equal quarterly installments of principal of \$208,333. On March 15, 2007, the note payable was amended such that the remaining balance of \$1,250,000 will be paid in 16 equal quarterly installments of \$78,125 over a four year period beginning April 1, 2007. As of December 31, 2007 and December 31, 2006, \$1,015,625 and \$1,458,333 were outstanding under this note payable, respectively.

Future minimum payments due under notes payable as of December 31, 2007 are as follows:

<u>Year Ending December 31,</u>	
2008 .....	\$ 312,500
2009 .....	312,500
2010 .....	312,500
2011 .....	<u>78,125</u>
Total future payments .....	<u>\$1,015,625</u>

**10. Other Liabilities**

The components of other liabilities are as follows:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Deferred amortization of leasehold improvements and deferred rent. . . .	\$1,352,727	\$1,292,327
Other. . . . .	4,425	—
Less current portion of other liabilities .....	<u>(154,824)</u>	<u>(152,728)</u>
Long term portion of other liabilities .....	<u>\$1,202,328</u>	<u>\$1,139,599</u>

The Company entered into a lease for its facility (See Note 8-Commitments) pursuant to which leasehold improvements paid by the lessor pursuant to the lease agreement were capitalized. The leasehold improvement assets are being amortized over seven years and the liability is being amortized over life of lease, which is ten years. The amortization is recorded as a discount to rent expense for the liability and the amortization expense to leasehold improvements for the asset. The balances of the capitalized lessor-paid leasehold improvements are classified in the balance sheet as leasehold improvements for the asset and other liabilities for the liability, respectively. In addition, the Company took possession, or control of, the physical use of the facility in January 2005, at which time the work was initiated on the leasehold improvements. The leasehold improvements were completed in May 2005. This four month gap constituted a rent holiday. As such, the Company accrued rent for that time period. This accrued rent is being amortized as a discount to rent over the remaining 10 year life of the lease. Further, the Company recognizes rent expense on a straight-line basis over the life of the lease. The difference between cash rent payments and rent expense is recorded as deferred rent. The balance of these rent liabilities are classified in the balance sheet as other liabilities.

**11. Income Taxes**

At December 31, 2007, the Company had available net operating loss ("NOL") carry forwards of approximately \$150,263,086 which will begin to expire in the year 2010. The Company has excluded the NOLs carry forwards and R&D tax credit carry forwards from the recently acquired FermaVir acquisition and anticipates finalizing these amounts in 2008. A portion of the Company's existing NOL carry forwards relates to exercises of non-qualified stock options. The tax benefit of which, when utilized, will be recorded as an increase to shareholder equity. The Company also has approximately \$3,061,485 of research and development ("R&D") tax credit carry forwards as of December 31, 2007. The Company's net operating loss carry forwards and

**INHIBITEX, INC. — (Continued)**

research and development credit carry forwards are subject to certain IRC Section 382 and Section 383 limitations on annual utilization due to past changes in ownership. These limitations could significantly reduce the amount of the net operating loss carry forwards available in the future. The utilization of the carry forwards is dependent upon the timing and extent of the Company's future profitability. The annual limitations combined with the expiration dates of the carry forwards may prevent the utilization of all of the net operating loss and research and development credit carry forwards if the Company does not attain sufficient profitability by the expiration dates of the carry forwards.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an Interpretation of FASB Statement No. 109* ("FIN 48"), which provides criteria for the recognition, measurement, presentation and disclosure of uncertain tax positions. The Company adopted the provisions of FIN 48 on January 1, 2007. The Company has no uncertain tax positions and no cumulative adjustment was required or recorded as a result of the implementation of FIN 48. As of January 1, 2007 and December 31, 2007, the Company has no unrecognized tax benefits. The Company will recognize accrued interest and penalties related to unrecognized tax benefits in income tax expense if and when incurred. The Company has no interest or penalties related to unrecognized tax benefits accrued as of December 31, 2007. The Company does not anticipate that unrecognized benefits will be incurred within the next 12 months. Since the Company has tax net operating losses since its inception, all tax years remain open under federal and state statute of limitations.

Inhibitex's income tax expense was \$0 for years ended December 31, 2007 and 2006. The primary factors causing income tax expense to be different than the federal statutory rates are as follows:

	December 31,	
	2007	2006
Income tax benefit at statutory rate . . . . .	\$(14,096,190)	\$(10,589,320)
State income tax benefit, net of federal tax benefit . . . . .	(348,197)	(1,276,232)
IPR&D expense . . . . .	11,073,701	—
Other . . . . .	193,695	(368,222)
General business credit . . . . .	(141,633)	(1,857,395)
Valuation allowance . . . . .	3,318,624	14,091,169
Income tax expense . . . . .	\$ —	\$ —

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

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carry forwards . . . . .	\$ 57,039,860	\$ 54,669,853
Research and development tax credit carry forwards . . . . .	3,061,485	2,919,852
Depreciation and amortization . . . . .	1,943,687	2,407,596
Accruals and reserves . . . . .	1,879,329	1,730,029
Compensation accruals . . . . .	1,245,003	302,111
Deferred revenue . . . . .	314,752	276,792
Other, net . . . . .	15,819	(124,922)
Total deferred tax assets . . . . .	65,499,935	62,181,311
Less valuation allowance . . . . .	(65,499,935)	(62,181,311)
Net deferred tax assets . . . . .	\$ —	\$ —

**INHIBITEX, INC. — (Continued)**

For financial reporting purposes, SFAS No. 109 requires that a valuation allowance be recorded to reduce the balance of deferred income tax assets if it is more likely than not that some portion or all of the deferred income tax assets will not be realized in the future. The Company has established a full valuation allowance equal to the amount of its deferred tax asset due to uncertainties with respect to the Company's ability to generate sufficient taxable income in the future. The valuation allowance increased by \$3,318,624 and \$14,091,169 in 2007 and 2006 as follows:

	December 31,	
	2007	2006
Deferred tax valuation allowance at beginning of year . . . . .	\$62,181,311	\$48,090,142
Change in cumulative tax differences . . . . .	3,318,624	14,091,169
Deferred tax valuation allowance at end of year . . . . .	\$65,499,935	\$62,181,311

**12. Stockholders' Equity**

*Common Stock.* As of December 31, 2007 and 2006, the Company was authorized to issue 75,000,000 shares of common stock. Each holder of common stock is entitled to one vote for each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

*Employee Stock Purchase Plan.* The Company's Board of Directors adopted, and its stockholders approved as of February 20, 2004, its 2004 Employee Stock Purchase Plan, or the Purchase Plan. The purpose of the Purchase Plan is to provide an opportunity for the Company's employees to purchase a proprietary interest in the Company. The Purchase Plan is administered by the Company's Compensation Committee. A total of 210,084 shares of common stock are authorized for issuance under the Purchase Plan as of December 31, 2007. Employees who are customarily employed for more than 20 hours per week and for more than five months in any calendar year and have been so employed for a six-month period are eligible to participate in the Purchase Plan. Employees who would own 5% or more of the total combined voting power or value of all classes of the Company's stock immediately after the grant may not participate in the Purchase Plan. The Purchase Plan is intended to qualify under Section 423 of the Internal Revenue Code and provides for quarterly purchase periods. The Purchase Plan permits participants to purchase common stock through payroll deductions of up to 25% of their eligible base salary. For any calendar year, a participant may not be granted rights to purchase shares to the extent the fair market value of such shares exceeds \$25,000. Amounts deducted and accumulated by the participant are used to purchase shares of common stock at the end of each quarterly purchase period. The purchase price per share is 85% of the lower of the fair market value of the Company's common stock at the beginning of a purchase period or at the end of a purchase period. An employee's participation ends automatically upon termination of employment with the Company. A participant may not transfer rights to purchase the Company's common stock under the Purchase Plan other than by will or the laws of descent and distribution. In the event of a change of control, no further shares shall be available under the Purchase Plan, but all payroll deductions scheduled for collection in that purchase period will be immediately applied to purchase whole shares of common stock. The Board of Directors has the authority to amend or terminate the Purchase Plan, except that, subject to certain exceptions described in the Purchase Plan, no such action may adversely affect any outstanding rights to purchase stock under the Purchase Plan and the Board of Directors may not increase the number of shares available under the Purchase Plan, or amend the requirements as to the eligible class of employees, without stockholder approval. As of December 31, 2007, the Company had 6,461 shares committed to be released to employees and had granted 28,799 shares out of the plan. The Company recorded \$2,755 of share-based compensation expense on all discounts to the fair market value during the purchase period of 2007. (See Note 2 — Summary of Significant Accounting Policies for more discussion on share-based compensation).

**INHIBITEX, INC. — (Continued)**

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

	December 31, 2007	December 31, 2006
Common stock options .....	4,958,131	2,081,054
Restricted common stock .....	902,959	1,659,157
Common stock warrants .....	8,535,097	3,807,706
Total .....	14,396,187	7,547,917

*Common Stock Warrants.* In February 2007, a total of 1,199,671 warrants expired with an exercise price of \$14.07. The total Black-Scholes value of those warrants was \$4,140,065, and such amount was reclassified from warrants to additional paid-in capital. In September 2007, the Company assumed warrants pursuant to the FermaVir acquisition with a fair market value of \$8,173,814. Please see Note 4-Acquisition of FermaVir. As of December 31, 2007 and 2006, there were 8,535,097 and 3,807,706 warrants outstanding, respectively. As of December 31, 2007, all of the warrants are exercisable and expire from August 20, 2008 to January 26, 2017. The weighted average strike price as of December 31, 2007 and 2006 was \$3.58 and \$11.19, respectively.

**13. Share-Based Award Plans**

The Company has two active share-based award plans as described below. For the twelve months ended December 31, 2007 and 2006, the Company recorded share-based compensation expense related to grants from these plans of \$2,034,276 and \$2,649,406, or \$0.06 and \$0.09 per share, respectively. No income tax benefit was recognized in the income statement and no share-based compensation expense was capitalized as part of any assets for the twelve months ended December 31, 2007 and 2006.

During the fourth quarter of 2006, the Company terminated two senior executives in accordance with their employment agreements. As such, the Company accelerated the recognition of expense related to share-based compensation. In addition on September 5, 2006, the Compensation Committee approved a modification provision to allow for a future amendment to certain previously granted stock option agreements in the event that certain executives are terminated from employment with Inhibitex in connection with a change of control. The provision allows for the period of time in which the executive could exercise certain outstanding stock options (if and only if they are terminated in connection with a change of control) be extended to up to three years from the current 90 day window provided for in the existing stock option agreements and 2004 Stock Incentive Plan. Upon meeting the provision criteria, an amendment would then occur, allowing for the three year window to exercise, and for tax purposes, the option would be modified to a non-qualified option from an incentive stock option. One senior executive was terminated under this provision and previously granted stock option grants were modified to allow up to three years for exercise. As such, the Company recorded additional share-based compensation for these modifications to previously issued stock option grants in the fourth quarter of 2006.

*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 ten years from the grant date, and options generally vest ratably over a period of four years from the grant date. As discussed below, upon the adoption of the 2002 Stock Incentive Plan ("2002 Plan"), no additional grants of stock option grants or equity awards were authorized under the 1998 Equity Ownership Plan. All options outstanding under the Plan 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.

**INHIBITEX, INC. — (Continued)**

*2002 Non-Employee Directors Stock Option Plan and 2004 Stock Incentive 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, restricted stock, and other share-based 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 share-based 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 grants to non-employee directors and 1,420,180 share-based awards 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. In May 2005, pursuant to a stockholder vote, the 2004 Plan was further modified by adding 1,500,000 shares of share-based awards of common stock to the number of reserved awards available for grant. On April 9, 2007, the Board of Directors approved the Amended and Restated 2004 Plan which provided for an increase of 2,800,000 in the number of shares of common stock available for awards to be granted under the Incentive 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 awards granted, and the vesting schedule. Under the 2004 Plan and Director Plan, the maximum term for an award is ten and six years from the grant date, respectively. Awards granted under the 2004 Plan and Director Plan generally vest ratably over a period of one to four years, respectively, from the grant date. As of December 2007, an aggregate of 8,163,223 shares of common stock were reserved for issuance under the 2004 Plan and the Director Plan. As of December 31, 2007, there were 4,814,594 outstanding option awards to purchase the Company's common stock and 902,959 restricted stock awards, with 1,477,473 shares available for grant under the 2004 Plan. As of December 31, 2007, there were 64,304 outstanding awards to purchase the Company's common stock and no options available for grant under the Director Plan.

As of December 31, 2007, the Company has \$3,147,290 of unvested share-based compensation to recognize as an expense in future periods, not discounting for future forfeitures. The following is a summary of all share-based activity and related information about the Company's share-based award plans from 2006 through 2007.

**Stock Options**

The fair value of each stock award, excluding those assumed in the FermaVir acquisition (See Note 4-FermaVir Acquisition), was estimated at the date of grant using the Black-Scholes method in 2007 and 2006 with the following assumptions:

	December 31,	
	2007	2006
Risk-free interest rate .....	4.13%	3.62%
Expected life .....	4 years	4 years
Weighted average fair value of options granted .....	\$ .79	\$ 2.05
Volatility .....	.70	.70

The risk-free interest rate is based on the contractual life of the option and the corresponding U.S. Treasury bond, which in most cases is the U.S. five year Treasury bond. The expected term of stock options granted is derived from actual and forecasted option exercise patterns and represents the period of time that options granted are expected to be outstanding. The Company uses historical data to estimate option exercise patterns and future employee terminations to determine expected life and forfeitures. Expected volatility is based on historical volatilities from the Company's publicly traded stock.

**INHIBITEX, INC. — (Continued)**

	<u>Number of Options</u>	<u>Weighted-Average Exercise Price per Option</u>	<u>Weighted-Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value (\$000)</u>
Balance at December 31, 2006 . . . .	2,081,054	\$5.35		
Granted . . . . .	3,521,634	\$1.58		
Exercised . . . . .	(11,977)	\$0.48		
Forfeited or expired . . . . .	<u>(632,580)</u>	<u>\$7.95</u>		
Balance at December 31, 2007 . . . .	<u>4,958,131</u>	<u>\$2.35</u>	<u>6.68</u>	<u>\$41</u>
Vested or expect to vest at December 31, 2007 . . . . .	<u>4,134,779</u>	<u>\$2.43</u>	<u>6.22</u>	<u>\$41</u>
Exercisable at December 31, 2007 . .	<u>2,226,762</u>	<u>\$2.85</u>	<u>4.04</u>	<u>\$41</u>

Stock options granted during the twelve month period ended December 31, 2007 includes 1,303,134 assumed in connection with the FermaVir acquisition (See Note 4-FermaVir Acquisition). The weighted-average grant date fair value of all stock options granted during the twelve month period ended December 31, 2007 was \$0.84. As of December 31, 2007, there was \$2,580,907 of total unrecognized share-based compensation expense related to unvested stock option awards, not discounted for future forfeitures. This unrecognized expense is expected to be recognized over a weighted-average period of 3.07 years.

The total intrinsic value of stock options exercised during the twelve month period ended December 31, 2007 was \$20,018 from which the Company received cash proceeds of \$5,768 for the twelve month period ended December 31, 2007. No actual tax benefits were realized as the Company currently records a full valuation allowance for all tax benefits due to uncertainties with respect to the Company's ability to generate sufficient taxable income in the future.

The following tables summarize information relating to outstanding and exercisable options as of December 31, 2007:

<u>Exercise Prices</u>	<u>December 31, 2007</u>				
	<u>Outstanding</u>			<u>Exercisable</u>	
	<u>Number of Shares</u>	<u>Weighted Average Remaining Contractual Life (In years)</u>	<u>Weighted Average Exercise Price</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
\$0.24 — \$1.36 . . . . .	852,340	6.59	\$1.14	727,340	\$1.19
\$1.45 . . . . .	2,015,500	9.72	1.45	—	—
\$1.62 — \$2.00 . . . . .	1,063,315	3.60	1.92	746,565	1.92
\$2.05 — \$9.07 . . . . .	934,464	4.14	5.21	679,847	4.97
\$9.38 . . . . .	91,812	2.28	9.38	72,660	9.38
\$9.69 . . . . .	700	3.83	9.69	350	9.69
	<u>4,958,131</u>	<u>6.68</u>	<u>\$2.35</u>	<u>2,226,762</u>	<u>\$2.85</u>

## INHIBITEX, INC. — (Continued)

A summary of the Company's non-vested restricted stock as of December 31, 2007 is presented below:

<u>Restricted Stock</u>	<u>Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
Outstanding at December 31, 2006 .....	1,659,157	\$1.87
Granted .....	35,377	1.59
Released .....	(788,225)	1.90
Forfeited .....	<u>(3,350)</u>	<u>2.05</u>
Outstanding at December 31, 2007 .....	<u>902,959</u>	<u>\$1.83</u>

As of December 31, 2007, there was \$566,383 of total unrecognized share-based compensation expense related to unvested restricted stock granted, not discounted for future forfeitures. The unrecognized expense is expected to be recognized over a weighted-average period of 0.6 years.

### 14. Contingency

On April 28, 2006, the Company announced that it would halt the manufacture of the clinical trial material used in the development of Veronate. As a result, the Company terminated its contract manufacturing relationship with Nabi Biopharmaceuticals, Inc., or Nabi, and suspended future purchases of all raw materials used to manufacture the donor-selected immune globulin form of Veronate. Subsequent to the termination date, Nabi invoiced the Company for approximately \$4,500,000 in cancellation penalties and other amounts it contends are due as a result of the Company's termination of the manufacturing agreement, which the Company disputes. On July 18, 2006, Nabi commenced an arbitration action against the Company seeking to recover a total of approximately \$4,700,000 in connection with the termination of the manufacturing agreement. On February 7, 2007, an arbitrator ruled the Company was liable to Nabi for restitution and cancellation payments in the aggregate amount of approximately \$4,500,000, including \$1,200,000 with respect to restitution for prior production under the agreement and \$3,300,000 relating to cancellation fees, as a result of the termination of Company's contract manufacturing agreement with Nabi during 2006. The Company incurred a charge of \$4,500,000 in 2006 as a result of the arbitrator's ruling. The ruling provided for interest at a rate of 9% per annum commencing 30 days after the date of the award. In March 2007, Nabi filed a petition with the Supreme Court of the State of New York to confirm the arbitrator's award, and the Company cross-petitioned to have the award set aside.

On October 18, 2007, the Company learned that the Supreme Court of New York (the "Court") had vacated approximately \$3,300,000 out of a total of approximately \$4,500,000 that the arbitrator had awarded Nabi in February 2007 and the Court confirmed the \$1,200,000 award of restitution and vacated the \$3,300,000 award of cancellation fees. On January 28, 2008, we paid the \$1,200,000 award with accrued interest. On January 30, 2008, Nabi filed a Notice of Appeal of the Court's decision to the extent it vacated the portion of the arbitration award with respect to the \$3,300,000 award relating to the \$3,300,000 of cancellation fees.

### 15. Other Income

During the twelve months ended December 31, 2007, the Company recognized other income in the amount of \$1,944,775 as a result of the sale of excess raw material related to the manufacture of Veronate.

During the twelve months ended December 31, 2006, the Company recognized other income in the amount of \$1,000,000 for amounts received in 1999 pursuant to a collaboration agreement. The Company has determined that this amount no longer represents a liability for which the obligation to provide further services or settlement is required.

**INHIBITEX, INC. — (Continued)**

**16. Comprehensive Income**

The components of comprehensive income for the twelve months ended December 31, 2007 and 2006 are as follows:

	Twelve Months Ended December 31	
	2007	2006
Net loss . . . . .	\$(41,459,382)	\$(31,145,060)
Change in net unrealized gains on investments . . . . .	94,480	91,971
Comprehensive loss . . . . .	\$(41,364,902)	\$(31,053,089)

**17. Research and License Agreements**

**In-licensing Agreements**

The following agreements are associated with intellectual property the Company has in-licensed.

*MSCRAMM Agreements.* As of December 31, 2007, the Company has entered into a number of license and collaborative agreements with various institutions to obtain intellectual property rights and patents relating to MSCRAMM proteins and its product candidates. The Company has also entered into an exclusive worldwide license and collaboration agreement with Wyeth and 3M with respect to its use of the MSCRAMM proteins to develop staphylococcal vaccines. The significant arrangements are described further below.

*Texas A&M University Health Science Center.* The Company has licensed, on an exclusive basis, from the Texas A&M University System a number of issued United States patents, related United States divisional applications and foreign counterpart applications directed to one of the MSCRAMM proteins that the Company's product candidates target. 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. The Company has an obligation to pay a minimum royalty of \$25,000 annually.

In connection with these license agreements, in 1995 the Company entered into the first of several collaboration research agreements with Texas A&M. Pursuant to these agreements, the Company has the exclusive worldwide right to any discoveries resulting from this collaboration, subject to research rights retained by Texas A&M and certain rights of the United States government. The Company also has a right of first refusal to acquire the rights to and file patents on discoveries made by Texas A&M in the field of MSCRAMM proteins that are made outside of the scope of the collaboration. Texas A&M is entitled to a royalty on revenues that the Company receives for products that incorporate technology developed through the collaboration. The Company may terminate this collaboration upon 90 days written notice. Pursuant to these agreements, the Company has paid Texas A&M \$1,904,000 through termination of the agreement. In April 2006, the Company provided notification of its termination of the collaboration research agreement.

*Cardiff University.* In September 2007, the Company completed the acquisition of FermaVir. As part of the acquisition, the Company acquired the rights to a worldwide royalty bearing license from Cardiff University in Wales, United Kingdom, which includes FV-100, a nucleoside analogue for the treatment of VZV infections and a series of preclinical nucleoside analogue compounds for the treatment of cytomegalovirus, or CMV. The agreement calls for the Company to make certain contingent milestone payments and a royalty on the sale of any products that utilize the underlying technology. Pursuant to this agreement, the Company has paid \$25,000 to Cardiff as of December 31, 2007.

*University of Georgia Research Foundation.* In addition in September 2007, the Company obtained an exclusive royalty bearing worldwide license from the University of Georgia Research Foundation, or UGARF

## INHIBITEX, INC. — (Continued)

for intellectual property covering a series of HIV integrase inhibitors and other antiviral compounds in exchange for an upfront license fee and the fair market value of \$300,000 of the Company's common stock, future milestone payments and royalties on future net sales. The license agreement also includes intellectual property related to non-nucleoside HCV polymerase inhibitors. Pursuant to this agreement, the Company has paid \$750,000 to UGARF and issued 225,870 shares of unregistered common stock of the Company as of December 31, 2007. Pursuant to this license agreement, the Company also entered into a cooperative research agreement with UGARF in annual sponsored research payments for up to three years. Pursuant to this agreement, the Company has paid \$377,000 to UGARF as of December 31, 2007.

*Cardiff University and Katholieke Universiteit.* In November 2007, the Company entered into an exclusive royalty-bearing worldwide license agreement with Cardiff University in Wales, United Kingdom and Katholieke Universiteit in Leuven, Belgium for intellectual property covering a series of highly potent HCV nucleoside polymerase inhibitors in exchange for an upfront license fee, future milestone payments and royalties on future net sales. The agreement calls for the Company to make certain milestone payments and pay a royalty on the sale of any products that utilize the underlying technology. Pursuant to this agreement, the Company has accrued \$250,000 to Cardiff and Katholieke Universiteit as of December 31, 2007. Pursuant to the agreement, the Company entered into cooperative research agreement with Cardiff University in annual sponsored research payments. Pursuant to this agreement, the Company has accrued approximately \$135,000 to Cardiff University as of December 31, 2007.

### Out-licensing Agreements

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

Pursuant to this agreement, the Company has received \$5,300,000 in an upfront license fee and annual research support payments from Wyeth as of December 31, 2007. The Company is entitled to receive minimum research support payments of \$500,000 per year until the first commercial sale of any product developed under this agreement. The minimum research payment escalates to \$1,000,000 in the event that Wyeth does not initiate a Phase I by July 31, 2007, which became effective October 1, 2007. The Company is also entitled to receive milestones upon the filing of an investigational new drug application ("IND"), the commencement of both Phase II and Phase III clinical trials, the filing of a BLA, and FDA approval of a licensed product. If all such milestones are achieved relative to one or more licensed products, the Company would be entitled to receive a minimum of \$10,000,000 in additional milestone payments from Wyeth. The maximum milestone payments the Company could receive with respect to all licensed products are \$15,500,000. Finally, the Company is also entitled to royalties on net sales of licensed products manufactured, sold or distributed by Wyeth.

*3M Company.* In January 2007, the Company entered into an exclusive worldwide license and commercialization agreement with 3M Company ("3M") for the development of various diagnostic products using its MSCRAMM protein platform. Under the terms of the agreement, the Company granted 3M exclusive global licenses to use MSCRAMM protein intellectual property in the development of diagnostic products in exchange for license fees, future milestone payments, financial support of future research and development activities and royalty payments on net product sales. The development, manufacture and sale of any products resulting from the collaboration are the responsibility of 3M. The Company may terminate this agreement if

## INHIBITEX, INC. — (Continued)

3M fails to use certain reasonable commercial efforts to bring related products to the market. 3M may terminate the agreement without cause upon three months written notice, upon payment of all license fees, development support for the calendar year, reimbursement of certain patent expenses, and any other amounts potentially due upon the termination of the agreement. Either party may terminate the agreement for cause upon providing two months written notice. Otherwise, the agreement will terminate upon the expiration of all licensed patents. Under the agreement, the Company is entitled to receive the following: (i) non-refundable license fees of \$3,000,000, of which \$1,750,000 was paid in April 2007 and the balance of which is due in the first quarter of 2008, (ii) \$1,000,000 million in development support payments over 2007 and 2008, (iii) milestone payments on the first commercial sale of each (a) diagnostic product that target organisms in the MSCRAMM protein platform, (iv) a tiered royalty based on net sales of diagnostic products, and (v) reimbursement of certain patent expenses related to licensed MSCRAMM proteins. The Company is obligated to provide support to 3M pursuant to a mutually agreed-upon development and collaboration plan for a period of at least two years. The Company will amortize on a straight-line basis the non-refundable license fees of \$3,000,000 over the length of the obligation to provide service, which is two years of collaborative support. Collaborative support fees will be amortized on a straight-line basis over the period the services are provided.

### 18. Employee Benefit Plans

The Company sponsors a 401(k) plan for the benefit of its employees that is a defined contribution plan intended to qualify under Section 401(a) of the Internal Revenue Code of 1986, as amended. Eligible employees may make pre-tax contributions to the 401(k) plan of up to 20% of their eligible earnings, subject to the statutorily prescribed annual limit. The 401(k) plan permits the Company to make discretionary matching and profit sharing contributions. The Company's contributions to the plan were approximately \$114,000 and \$209,000 in 2007 and 2006, 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.

The Company has employment agreements with its current executive officers that allow for certain termination post-employment benefits upon termination. These benefits cannot be reasonably estimated and the event has not occurred as described under SFAS No. 112, *Accounting for Post-employment Benefits*, as of December 31, 2007.

### 19. Quarterly Financial Data (Unaudited)

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

	<u>Revenue</u>	<u>Loss from Operations</u>	<u>Net Income/(Loss)</u>	<u>Net Income (Loss) Attributable to Common Stockholders per Share- Basic and Diluted</u>
<b>Year Ended December 31, 2007</b>				
First Quarter . . . . .	\$668,500	\$ (2,204,232)	\$ 462,199	\$ 0.01
Second Quarter . . . . .	685,000	(2,955,369)	(2,324,316)	(0.08)
Third Quarter . . . . .	662,500	(36,717,815)	(36,072,761)	(1.12)
Fourth Quarter . . . . .	787,500	(4,205,935)	(3,524,504)	(0.08)
<b>Year Ended December 31, 2006</b>				
First Quarter . . . . .	327,887	(9,865,118)	(8,981,775)	(0.30)
Second Quarter . . . . .	184,565	(8,471,546)	(7,672,701)	(0.25)
Third Quarter . . . . .	168,627	(4,295,827)	(2,588,581)	(0.09)
Fourth Quarter . . . . .	164,498	(12,697,086)	(11,902,003)	(0.39)

**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 9AT. 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 of 1934, as amended, or the 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.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework. Management has concluded that, as of December 31, 2007, its internal control over financial reporting is effective based on these criteria.

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

March 14, 2008

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fourth quarter of 2007 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, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

The information required by this item is incorporated by reference from our definitive proxy statement or a subsequent amendment to this Report to be filed with the Securities and Exchange Commission.

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

The information required by this item is incorporated by reference from our definitive proxy statement or a subsequent amendment to this Report to be filed with the Securities and Exchange Commission.

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

The information required by this item is incorporated by reference from our definitive proxy statement or a subsequent amendment to this Report to be filed with the Securities and Exchange Commission.

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

The information required by this item is incorporated by reference from our definitive proxy statement or a subsequent amendment to this Report to be filed with the Securities and Exchange Commission.

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

The information required by this item is incorporated by reference from our definitive proxy statement or a subsequent amendment to this Report to be filed with the Securities and Exchange Commission.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (b) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
3.1	Eighth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.4 of the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 3, 2004 (the "March 2004 S-1")).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 99.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2007).
4.1	Specimen certificate evidencing the common stock (incorporated by reference to Exhibit 4.1 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 2004 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 of the Registration Statement filed on Form S-8 filed with the Securities and Exchange Commission on November 13, 2007).
10.2.2	Non-Employee Directors Stock Option Agreement (incorporated by reference to Exhibit 99.2 of the February 2006 8-K).
10.2.3	Employee Stock Option Agreement (incorporated by reference to Exhibit 10.51 of the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2007).
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).
10.8	Form of Warrant to purchase shares of Series E Preferred Stock (incorporated by reference to Exhibit 10.8 of the March 2004 S-1).
10.9	Form of Amendment to Warrant to purchase shares of Series E Preferred Stock (incorporated by reference to Exhibit 10.9 of the March 2004 S-1).
10.9.1	Form of Second Amendment to Warrant to purchase shares of Series E Preferred Stock, dated May 4, 2004 (incorporated by reference to Exhibit 10.9.1 of Amendment No. 2).
10.10	Amended and Restated Master Rights Agreement, dated December 19, 2003, by and among the registrant and holders of the registrant's capital stock (incorporated by reference to Exhibit 10.10 of the March 2004 S-1).
10.11	Amendment No. 1 to Amended and Restated Master Rights Agreement dated February 20, 2004 (incorporated by reference to Exhibit 10.11 of the March 2004 S-1).
10.11.1	Amendment No. 2 to Amended and Restated Master Rights Agreement dated May 27, 2004 (incorporated by reference to Exhibit 10.1 of the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 16, 2004).
10.12	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.12 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).

<u>Exhibit No.</u>	<u>Description</u>
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).
10.30†	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).
10.35	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).
10.37†	Agreement, dated March 14, 2002, between the registrant and Avid Bioservices, Inc. (incorporated by reference to Exhibit 10.31 of Amendment No. 2).
10.38	Form of Stock and Warrant Purchase Agreements, dated November 4, 2004, between the registrant and each of the investors signatory thereto (including Form of Warrant to Purchase Common Stock issued in connection therewith) (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 10, 2004).
10.39†	Agreement, dated November 5, 2004, between the registrant and Lonza Biologics PLC (incorporated by reference to Exhibit 10.39 of Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on January 19, 2005).
10.40	Loan agreement, dated December 28, 2004 between the registrant and Development Authority of Fulton County (incorporated by reference to Exhibit 10.40 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2005).
10.41	Form of Securities Purchase Agreement dated August 17, 2005 between the registrant and each of the investors signatory thereto (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 17, 2005).
10.42†	License and Development Collaboration Agreement, dated January 3, 2007, by and between the registrant and 3M Company and 3M, Innovative Products Company (incorporated by reference to Exhibit 10.42 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2007).
10.43	Retention Agreement, dated April 24, 2006, by and between the registrant and Russell H. Plumb (incorporated by reference to Exhibit 10.43 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2007).
10.44	Retention Agreement, dated April 24, 2006, by and between the registrant and Joe M. Patti (incorporated by reference to Exhibit 10.48 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2007).
10.48	Employment Agreement, dated December 29, 2006, by and between the registrant and Russell H. Plumb (incorporated by reference to Exhibit 10.48 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2007).
10.49†	License Agreement, dated September 11, 2007, by and between registrant and University of Georgia Research Foundation, Inc. (incorporated by reference to Exhibit 10.49 of the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2007).
10.50	Employment Agreement, dated September 20, 2007, by and between registrant and Geoff Henson (incorporated by reference to Exhibit 10.50 of the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2007).

<u>Exhibit No.</u>	<u>Description</u>
10.51	Employment Agreement, dated February 26, 2007, by and between registrant and Joseph M. Patti (incorporated by reference to Exhibit 10.49 of the Current Report on Form 8-K/A filed with the Securities and Exchange Commission on March 30, 2007).
10.52*	License Agreement, dated November 9, 2007, by and between registrant and University College Cardiff Consultants Limited and Katholieke Universiteit Leuven.
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934.
32.1	Certifications of the Chief Executive Officer and the Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934.

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

\* Confidential treatment has been requested with respect to the omitted portions of this exhibit and such information has been filed separately with the Securities and Exchange Commission

## SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Alpharetta, Georgia on this 14th day of March, 2008.

Inhibitex, Inc.

By: /s/ Russell H. Plumb

Russell H. Plumb  
*President, Chief Executive Officer,  
Chief Financial Officer, Secretary and Treasurer*

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Russell H. Plumb Russell H. Plumb	President, Chief Executive Officer, Chief Financial Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 14, 2008
/s/ Michael A. Henos Michael A. Henos	Chairman of the Board of Directors	March 14, 2008
/s/ M. James Barrett, Ph.D. M. James Barrett, Ph.D.	Director	March 14, 2008
/s/ Chris McGuigan, M.Sc., Ph.D. Chris McGuigan	Director	March 14, 2008
/s/ A. Keith Willard. A. Keith Willard.	Director	March 14, 2008
/s/ Russell M. Medford, M.D., Ph.D. Russell M. Medford, M.D., Ph.D.	Director	March 14, 2008
/s/ Robert A. Hamm Robert A. Hamm	Director	March 14, 2008
/s/ Marc L. Preminger Marc L. Preminger	Director	March 14, 2008
/s/ Gabriele M. Cerrone. Gabriele M. Cerrone	Director	March 14, 2008

# Inhibitex Leadership

## SENIOR MANAGEMENT TEAM

**Russell H. Plumb**

President, Chief Executive Officer and Chief Financial Officer

**Joseph M. Patti, Ph.D.**

Chief Scientific Officer and Senior Vice President of Research and Development

**Geoffrey W. Henson, Ph.D.**

Senior Vice President of Drug Development

## BOARD OF DIRECTORS

**Michael A. Henos, (Chairman)**

Managing General Partner – Alliance Technology Ventures

**M. James Barrett, Ph.D.**

General Partner – New Enterprise Associates

**Gabriele M. Cerrone**

Managing Partner – Panetta Partners, Ltd.

**Robert A. Hamm**

Executive Vice President, Pharmaceutical Operations and Technology – Biogen Idec, Inc.

**Chris McGuigan, BSc, Ph.D.**

Professor – Cardiff University

**Russell M. Medford, M.D., Ph.D.**

President and Chief Executive Officer – AtheroGenics Inc.

**Russell H. Plumb**

President and Chief Executive Officer – Inhibitex, Inc.

**Marc L. Preminger**

Senior Vice President and Chief Financial Officer (retired) – CIGNA Healthcare

**A. Keith Willard**

Chairman and Chief Executive Officer (retired), – Zeneca, Inc.

## STOCKHOLDER INFORMATION

**Headquarters**

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

**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 of stockholders will take place on June 4, 2008, at 9:00 am EST at the company's headquarters in Alpharetta, Georgia.

**Investor Information Requests**

Copies of the Inhibitex, Inc. 2007 Annual Report and Form 10-K and additional information may be obtained through the corporate website, by email or by letter.

**Website**

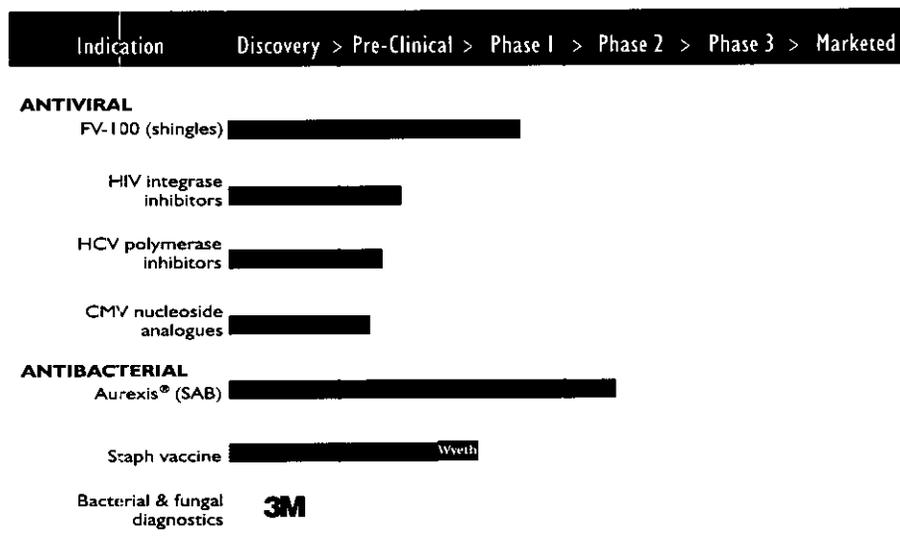
[www.inhibitex.com](http://www.inhibitex.com)

**Email**

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

**Ticker Symbol**

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





9005 Westside Parkway • Alpharetta, Georgia 30004

P: 678.746.1100 • F: 678.746.1299

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

**END**