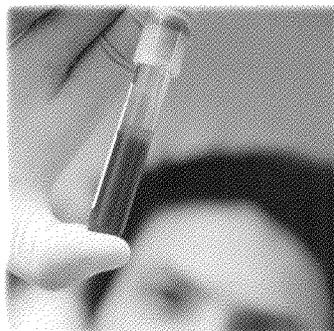
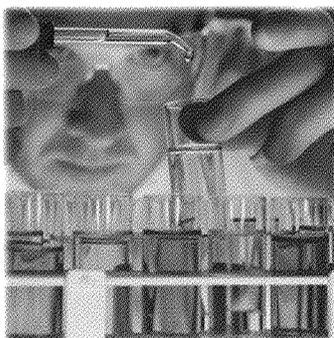




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Inhibitex, Inc.



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Washington, DC 20549

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## Dear Fellow Stockholders:

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Dear Fellow Stockholders:

During 2008 and early 2009, we made notable progress toward our overall strategic objectives that culminated in the achievement of three key goals:

- The successful completion of our Phase I program for FV-100 (varicella zoster virus);
- The selection of promising lead compounds from our series of hepatitis C virus (HCV) nucleoside polymerase inhibitors for further development, and;
- The realignment of our resources and operations to lower our cost structure.

Our strategy is to create shareholder value in the near-term by advancing both FV-100 and a clinical candidate from our series of HCV polymerase inhibitors through clinical proof of concept. Based on our recent progress and encouraging results to date, we believe we are well positioned to achieve this objective.

**FV-100** is our highly potent, orally available, nucleoside analogue that rapidly inhibits the growth of varicella zoster virus (VZV), which causes both chicken pox and shingles. Worldwide, it is estimated that there are greater than 2.5 million cases of shingles each year. When compared to existing antiviral therapies, we believe FV-100 has the potential to further reduce shingles-related symptoms, including the severity and duration of acute pain and the incidence of post herpetic neuralgia. Based on favorable safety and pharmacokinetic results from our Phase I trials, we plan to soon initiate a well controlled Phase II safety and efficacy clinical trial of FV-100 in shingles patients.

Our novel, next generation, "protide" **HCV polymerase** inhibitors represent a significant opportunity to address the unmet needs of the estimated 170 million individuals worldwide infected with chronic hepatitis C, a leading cause of cirrhosis, liver cancer and liver failure. Currently available treatments for these patients are sub-optimal. As compared to other compounds in their class, our proprietary protides have demonstrated superior potency against the most common and hard-to-treat forms of HCV. Based on favorable preclinical data to-date, we have initiated IND-enabling studies with our lead compound. Upon successful completion of these studies, we plan to file an IND (Investigational New Drug Application) and initiate clinical trials in the first half of next year.

Given the prevailing conditions in the global capital markets, in 2008 we realigned our operations, placing the development of two of our programs, Aurexis and HIV integrase inhibitors, on hold. This realignment, plus diligent cost containment, allowed us to close 2008 with over \$33 million in cash. We anticipate that our current financial position will support our strategic and development goals for FV-100 and our HCV program well into the second half of 2010.

At Inhibitex, we are committed to executing our strategic plan and building shareholder value in a timely and highly cost effective manner. We appreciate your continued support and look forward to keeping you apprised of our progress throughout 2009.



Sincerely,

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

Russell H. Plumb  
President and Chief Executive Officer

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

SEC  
Mail Processing  
Section

MAY 07 2009

Washington, DC  
121

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

For the fiscal year ended December 31, 2008

or

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

For the transition period from to

Commission file number: 000-50772

**Inhibitex, Inc.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**74-2708737**

(I.R.S. Employer  
Identification Number)

**9005 Westside Parkway  
Alpharetta, GA**

(Address of Principal Executive Offices)

**30009**

(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 Capital 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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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   
(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

The approximate aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price on June 30, 2008 was \$20,842,031.

Number of shares of Common Stock outstanding as of March 16, 2009: 43,509,860

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the definitive Proxy Statement with respect to the 2009 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission (Part III).

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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-stage product candidates;
- the expected timing of certain milestones and events, and the development plans associated with our product candidates;
- our ability to successfully execute our strategy;
- the expected timing of initiating and/or completing a Phase II trial of FV-100;
- our goal to file an IND for a lead candidate from our HCV polymerase inhibitor program, and the expected timing of this filing;
- our current plans to indefinitely postpone the development of our HIV integrase inhibitor program;
- our intent to establish strategic collaborations in the future to accelerate the development and commercialization of our product candidates;
- our plans to support our existing collaboration with Wyeth;
- the potential for our product candidates to have improved potency, safety profiles, less adverse side effects, to be used in combination therapy to improve efficacy, reduce acute pain and PHN, and superior dosing schedules;
- the size of the potential markets for FV-100;
- our plans, and the length of time it may take, to enter into a co-development, collaboration or other 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;
- the adequacy of our office and laboratory 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: Wyeth not terminating our license and collaborative research agreements; our 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 an appropriate safety and/or efficacy profile of our product candidates; our ability to secure and use third-party clinical and preclinical research and data management organizations and manufacturers not fulfilling their contractual obligations or otherwise performing 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 or not infringe on the intellectual property rights of others; the inherent uncertainties and unreliability of estimates for market size for products; 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; 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>, 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. We are currently targeting our efforts and resources on the development of small molecule antiviral compounds, and in particular, therapies to treat shingles (herpes zoster) and chronic hepatitis C infections ("HCV"). Currently available antiviral therapies have various therapeutic limitations, such as inadequate potency, significant adverse side effects, complex dosing schedules, inconvenient methods of administration and diminishing efficacy due to the emergence of drug-resistant viruses. 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.

We believe there are significant business advantages in focusing on the development of new compounds to treat infectious diseases, and in particular viral infections, which include the following:

- infectious disease research and development programs, and in particular with respect to anti — viral products, generally have shorter development cycle times when compared to various therapeutic areas such as cardiovascular and central nervous system disorders;
- historical data suggest that anti-infective development programs that enter clinical development generally have a higher clinical success rate, on average, as compared to various other development program areas such as oncology, cardiovascular and central nervous system disorders;
- the clinical and regulatory pathway for many anti-infective indications are well established and understood;

- many antiviral targets have been validated in previous preclinical or clinical trials of other antiviral compounds, thus providing the ability to benchmark or otherwise compare the safety and efficacy of new compounds at relatively early stages of development; and
- the emergence of drug resistance creates a continuing need for new drugs to treat certain infectious diseases, thus creating new markets and growing business opportunities.

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. We were incorporated in the state of Delaware in May 1994.

## **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 can affect the entire body, while others are 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 or available therapies can prevent or fight the infection. The market for anti-infective drugs can be divided into three main categories: antiviral, antibacterial and antifungal.

The widespread use of anti-infective drugs has led to a significant reduction in the 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 or toxic 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 fully comply with treatment dosing schedules. As a result, physicians are often required to modify therapy regimens throughout the course of treatment.

Moreover, a patient's failure to comply fully with a treatment dosing schedule can both accelerate and exacerbate drug resistance. 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 recent years, the increasing prevalence of drug resistant strains has created ongoing treatment challenges with respect to many infectious diseases, including HIV/AIDS and staphylococcus aureus ("*S. aureus*") infections.

## **Viruses**

Viruses are microscopic infectious agents consisting of an outer layer of protein surrounding a core of genetic material comprised of DNA or RNA. Viruses generally invade living host cells in order to grow and replicate. 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 fully destroy the responsible 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 viruses can be both acute and chronic. Acute infection is associated with viruses such as influenza or varicella zoster virus ("*VZV*"), and generally lasts for a relatively short period of time and in most cases will ultimately self-resolve. Chronic infection, such as those caused by HCV or HIV, do not typically self-resolve and can cause disease for many months or years if left untreated. Viruses can also be characterized as either latent or active. A latent virus, such as varicella zoster, or *VZV*, can remain in the body for long periods of time generally and only causes disease when the body's immune system weakens, fails or is suppressed. An active virus can cause a persistent infection or disease over an extended period of time, such as infections caused by HCV and HIV.

Vaccines have been used for many years to prevent an active viral infection from occurring. Antiviral drugs designed to treat or suppress, rather than prevent viral diseases are generally small molecule, chemical entities. Antiviral drugs are increasingly being developed to inhibit or stop the replication of a specific virus, some are active against a family of viruses.

Viruses that develop resistance to antiviral drugs are increasingly 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 using drugs that do not quickly and completely inhibit viral replication. Resistance occurs because viruses will 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 that antiviral drug often diminishes, resulting in treatment failure and creates a need for an alternate therapy with different or possibly new drugs or classes of drugs. In general, viruses that cause chronic infections, such as HIV /AIDS, are the viruses are more likely to develop drug resistance due to the long-term and persistent exposure of the virus to the antiviral therapy.

***Bacteria***

Unlike viruses, bacteria do not generally need to invade a living host cell in order to grow and replicate. 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 totally 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” antibacterials.

Antibiotics, which are small molecule compounds, comprise the vast majority of currently marketed antibacterial drugs. Antibiotics have historically proved to be highly successful in controlling the morbidity and mortality that accompany many bacterial infections. However, due to the widespread use of antibiotics over time and the ability of bacteria to quickly 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, and has become a public health issue of significant concern. Accordingly, in recent years, a number of novel approaches to prevent and treat bacterial infections, including new classes of antibiotics, vaccines and the use of antibodies, have emerged in development.

**Our Pipeline**

The following table summarizes key information regarding our anti-infective product candidates:

<u>Drug Candidate</u>	<u>Indication</u>	<u>Stage of Development</u>	<u>Status</u>	<u>Marketing Rights</u>
<b>Antivirals</b>				
FV-100	<i>Treatment of Herpes Zoster (shingles)</i>	Clinical	• Phase I complete; initiation of a expected Phase II trial in Q2 of 2009	Inhibitex
HCV Polymerase Inhibitors	<i>Treatment of Chronic HCV Infection</i>	Preclinical	• Advanced preclinical studies	Inhibitex
HIV Integrase Inhibitors	<i>Treatment of HIV Infection</i>	Preclinical	• Lead optimization; further development indefinitely suspended	Inhibitex
<b>Antibacterials</b>				
Aurexis	<i>Treatment of Serious S. aureus Infections</i>	Clinical	• Completed Phase IIa; seeking to out-license	Inhibitex
Staphylococcal Vaccines	<i>Active Vaccine to Prevent S. aureus infections</i>	Preclinical	• Preclinical studies in progress	Wyeth

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

FV-100 is an orally available nucleoside analogue prodrug we are developing for the treatment of herpes zoster, or shingles, which is caused by the reactivation of VZV. Published preclinical studies demonstrate that FV-100 is significantly more potent against VZV than acyclovir, valacyclovir, and famciclovir, the only FDA-approved drugs for the treatment of shingles. Preclinical studies further demonstrate that FV-100 has a much more rapid onset of antiviral activity and can fully inhibit the replication of VZV more rapidly than these drugs at significantly lower concentration levels. We believe these characteristics 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 lesions, acute pain and post herpetic neuralgia ("PHN"). In addition, pharmacokinetic data from recently completed Phase I clinical trials suggest FV-100 has the potential to be dosed orally once-a-day at significantly lower levels than valacyclovir, acyclovir, and famciclovir.

We recently completed our Phase I clinical trials of FV-100, including a multiple ascending dose study in subjects aged 18 to 55 and a separate trial conducted in subjects 65 years of age or older. We reported that there were no serious adverse events in either trial and that FV-100 appeared to be well tolerated at all dose levels. There were no differences noted in the safety results for subjects aged 18 to 55 and those aged 65 and older. Further, pharmacokinetic data demonstrated that all doses maintained mean plasma levels of the active form of FV-100 that exceeded the EC50 for approximately 24 hours, supporting the potential for once-a-day dosing in future trials.

Subject to FDA review, we plan to initiate a Phase II clinical trial of FV-100 in shingles patients in the second quarter of 2009. We plan to evaluate the efficacy and safety of two doses of FV-100 compared to valacyclovir. Objectives of the Phase II trial will include, among others, the reduction in the severity and duration of shingles-related pain, the prevalence of PHN, and time to lesion healing.

### ***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. Initial infections with VZV, or chicken pox, generally occur during childhood. After the chickenpox infection subsides, VZV remains latent in the individual's dorsal root and cranial nerve ganglia. Individuals who have had chickenpox are at risk for reactivation of the VZV virus, known as herpes zoster, or shingles.

Although shingles can occur in any individual with a prior VZV infection, its incidence varies with age and immune status, which are the key risk factors. In 2007, there were an estimated 1.1 million cases of shingles in the U.S. In Europe and Japan, the estimated number of shingles cases is 1.0 and 0.4 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 of the population in many industrialized countries, as well as 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 20-30% of all persons in the U.S. will suffer from shingles during their lifetime.

The symptoms associated with shingles generally include localized lesions, rash and pain. Shingles generally starts as small lesions, with new lesions continuing to form for a week or more. However, in certain cases the patient may notice localized prodromal pain prior to the appearance of lesions. The lesions generally follow the path of nerves that emanate from the spinal cord around the torso, however the infection is also commonly found on the face and neck. Eventually, the lesions will pustulate and the infected areas will typically crust over and heal. The dermatological symptoms associated with a shingles infection typically will resolve in two to four weeks. In rare instances, lesions 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 an episode of shingles is a result of damage to the nerve fibers caused by the replication of VZV and the subsequent inflammation associated with the infection. Pain symptoms are commonly described as a burning sensation, with bouts of stabbing and shooting pain, often set off by

touching the affected area. The majority of shingles patients experience acute pain in connection with their infection. In some patients, shingles-related pain does not resolve when the rash and lesions heal but, rather, continues for months, or possibly years. Persistent shingles-related pain that lasts more than several months is referred to as PHN and it is the most common complication of shingles. Approximately 20% of all shingles patients experience PHN, although the incidence of PHN increases in patients over 60 years of age. Previous studies have established that additional risk factors for PHN include greater acute pain intensity, severity of the dermatological symptoms, and the presence and greater severity of a painful prodrome preceding the rash.

In 2006, Merck & Co.Inc., received approval to market a vaccine to prevent the incidence of shingles for individuals 60 years of age and older. Clinical data indicated that the vaccine reduced the incidence of shingles by approximately 51% in this population, although the vaccine's effectiveness decreased over time.

Valacyclovir, acyclovir and famciclovir are oral antivirals currently indicated and approved by the FDA and in many other countries to treat shingles. These drugs are referred to as "pan-herpetic" drugs, as they are currently being used to treat infections caused by various viruses in the herpes virus group, including herpes simplex 1 and 2, and herpes zoster. Unlike these drugs, FV-100 only demonstrates antiviral activity against VZV, and not other viruses in the herpes family. The majority of the over \$2.3 billion in annual sales these drugs generate in the United States is for non-shingles use. However, based upon IMS Health, Inc. ("IMS") data, we currently estimate that the size of the market for oral antivirals to treat shingles exceeds \$300 million per year in the United States. However, we believe that the market opportunity for a differentiated antiviral drug that can address the unmet medical needs of shingles patients, as outlined below, could be substantially larger.

#### *Limitations of Current Therapies*

Clinical trial data demonstrate that a seven to ten day administration of valacyclovir, acyclovir, and famciclovir, beginning less than 72 hours after the appearance of a shingles-related rash or lesion, can lessen the duration of the dermatological symptoms associated with shingles. However, these currently approved pan-herpetic antiviral drugs, when used to treat shingles, have a number of limitations, including the following:

- *No Approved Label for the Reduction of Acute Pain and PHN.* Currently, there are no oral antiviral therapies indicated for the reduction or prevention of shingles-related acute pain and PHN. There is also no cure for PHN; rather, treatment of PHN is accomplished through pain management. The most commonly prescribed medications are opioids, antidepressants, anticonvulsants and a topical lidocaine patch. Based upon previously published data, antiviral therapy can reduce acute pain and PHN, and we believe a highly potent, fast acting anti-VZV compound, such as FV-100, may have the potential to more rapidly inhibit the replication of VZV, thus reducing the incidence of shingles-related nerve damage and therefore, acute pain and PHN. We believe an antiviral therapy that can reduce acute pain and PHN may have a significant competitive advantage relative to the currently available oral antiviral shingles therapies.
- *Inconvenient Dosing.* Due to their suboptimal pharmacokinetic properties and potency against VZV, current pan-herpetic oral antiviral therapies require shingles patients to take three to five oral doses each day for seven to ten days. Specifically, current dosing regimens are as follows: valacyclovir — 1,000 mg, three times per day; famciclovir — 500 mg, three times per day; and acyclovir - 800 mg, five times per day. Given the fact that many 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.
- *Doses of Current Antiviral Drugs Must be Adjusted for Patients with Insufficient Renal Function.* Although current pan-herpetic oral antiviral therapies are generally safe and well tolerated in shingles patients, dosing of valacyclovir, famciclovir and acyclovir must be adjusted for certain patients with insufficient renal (kidney) function to avoid potential adverse events. Clinical data from our Phase I trials of FV-100 in healthy volunteers indicated that FV-100 was generally well tolerated and does not appear to be primarily excreted through the kidneys. While its safety profile will be further studied, FV-100 may not need to be adjusted for patients with insufficient renal function. We believe that an oral antiviral therapy that has a

similar safety profile to valacyclovir, famciclovir and acyclovir, but is not required to be adjusted for patients with insufficient renal function, may have a competitive advantage over currently approved shingles therapies.

We believe there is a significant unmet need for a more potent and faster acting, once-a-day oral antiviral agent such as FV-100 that has the potential to reduce the incidence, severity, and duration of shingles-related symptoms, including rash, lesions, acute pain and PHN. Due to its demonstrated potency and ability to rapidly penetrate cells, we also believe that the amount of FV-100 necessary to fully inhibit viral replication of VZV may be significantly lower than that of the current antiviral therapies, resulting in smaller doses and potentially fewer side effects. We also believe that the pharmacokinetic properties of FV-100, as observed to-date in preclinical studies and in our recently completed Phase I trial, may provide for less frequent oral dosing than valacyclovir, acyclovir and famciclovir.

#### *FV-100 Clinical Trials*

*Phase I.* In February 2009, we completed a blinded, placebo controlled multiple ascending dose trial designed to evaluate the safety and pharmacokinetics of five oral doses of FV-100 (100, 200, 400 and 800 mg administered once daily and 400 mg administered twice daily, each for seven days) in healthy subjects aged 18 to 55. Each dose cohort consisted of six subjects that received FV-100 and two that received placebo. The results of the trial demonstrated that there were no serious adverse events and FV-100 appeared to be generally well tolerated at all dose levels evaluated. Further, pharmacokinetic data demonstrated that all doses maintained mean plasma levels of CF-1743, the active form of FV-100, which exceeded its EC50 for at least 24 hours, supporting the evaluation of once a day dosing of FV-100 in future clinical trials. The EC50 represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*.

We also completed a blinded, placebo controlled Phase I trial to evaluate single and multiple doses of FV-100 in healthy subjects 65 years of age and older. One dose cohort consisted of twelve healthy subjects, ten of whom received a single administration of 400 mg of FV-100 and two of whom received placebo, and the second cohort also consisted of twelve healthy subjects, ten of whom received 400 mg of FV-100 administered once daily for seven consecutive days and two of whom received placebo. The results of this trial demonstrated no significant differences between these subjects and those from the multiple ascending dose trial.

In August 2008, we completed a Phase I single ascending dose clinical trial of FV-100. The blinded, placebo-controlled trial evaluated the safety and pharmacokinetics of four doses of FV-100 in six cohorts of healthy volunteers (100, 200, 400, and 800 mg, as well as a two 400 mg food effect groups). Each cohort consisted of six subjects that received FV-100 and two that received placebo. There were no serious adverse events observed and the compound appeared to be generally well tolerated in the trial. In addition, pharmacokinetic data demonstrated that all doses evaluated in the trial maintained plasma levels of CF-1743, the active form of FV-100, which exceeded its EC50 for at least 24 hours.

In December 2007, we completed a blinded, placebo-controlled single ascending dose Phase I clinical trial of FV-100, which was conducted under an exploratory Investigational New Drug Application (“IND”). The trial was designed to evaluate the safety and pharmacokinetics of three oral doses of FV-100 (10, 20 and 40 mg) in healthy volunteers 18 to 55 years of age. Each of the three dose cohorts consisted of six subjects that received FV-100 and two that received placebo. The results of the trial demonstrated that there were no serious adverse events observed and that the compound appeared to be generally well tolerated. In addition, pharmacokinetic data demonstrated that all three doses achieved plasma levels of CF-1743, the active form of FV-100, which exceeded the EC50, with the 40 mg dose maintaining such levels for approximately eight hours.

#### *HCV Nucleoside Polymerase Inhibitors*

Our HCV program currently consists of a series of nucleoside polymerase inhibitors we are developing for the treatment of chronic hepatitis C, which is caused by the HCV virus. More specifically, we are developing a series of phosphoramidate nucleoside analogues, also referred to as pronucleotides or protides, which are prodrugs of nucleosides that target the RNA-dependent RNA polymerase (“NS5b”) of HCV. We believe that

our prolide approach possesses several pharmacological advantages over earlier, first generation approaches that use the parent nucleoside alone. These include a significant increase in antiviral activity, higher concentrations of the anti-virally active triphosphate in liver and potentially less toxicity due to reduced systemic exposure.

We have initiated advanced preclinical studies with a lead candidate. Our decision to proceed into advanced preclinical studies was based on favorable results from *in vitro* and *in vivo* studies we have completed to-date, in which these compounds demonstrated excellent potency in various HCV replicon assays, rapid conversion to the triphosphate in primary human hepatocytes, favorable pharmacokinetic properties in orally dosed primates and rodents, and a favorable profile. *In vitro* studies using a HCV genotype 1a and 1b subgenomic replicon system demonstrate that our protides are among the most potent HCV nucleoside polymerase inhibitors currently in development.

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

HCV is a leading cause of chronic liver disease, including cirrhosis, organ failure and cancer, and the leading cause of death from liver disease in the United States. HCV is often found among hemodialysis patients, hemophiliacs and recipients of blood transfusions before 1992. 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. It is estimated that 3 to 4 million people worldwide are newly infected each year, the majority of whom will develop chronic hepatitis C. The Center for Disease Control ("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 typically appear until its later stages, carriers often do not realize they are infected, and therefore 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 for 48 weeks. 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. Ribavirin is an antiviral drug that does not specifically target HCV RNA, but interferes with the replication of viruses. Unlike HIV, HCV is curable in the sense that current standard of care can result in a sustained viral response, ("SVR") defined as the absence of a detectable amount of the virus in the blood six months after the completion of treatment. There are several subtypes, 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 patients with HCV genotypes 1a and 1b achieve a SVR when treated with current standard of care.

Despite these limitations and a suboptimal side effect profile, current HCV therapies generated worldwide sales of approximately \$2.2 billion in 2005, and sales of these products are forecast to increase to more than \$3.0 billion by 2010 and \$7.0 billion by 2015. Accordingly, there are a number of pharmaceutical and biopharmaceutical companies pursuing the development of various classes of antiviral compounds that directly inhibit the replication of HCV by targeting various proteins and enzymes of the virus. Direct antiviral therapy is now emerging as a potential complement or alternative to the current standard of care. There are several classes of direct antiviral compounds currently being developed, including protease inhibitors, which are the most clinically advanced class, nucleoside and non-nucleoside polymerase inhibitors and other emerging antivirals that inhibit other HCV molecular targets. In order to optimize the potential of direct antiviral therapy, it is believed that these various classes will ultimately be used in combination, akin to what has evolved in the treatment of HIV/AIDS. Further, similar to current HIV/AIDS therapy, where nucleosides have become a cornerstone of combination therapy, we believe NS5b nucleoside polymerase inhibitors will play a similar role in the treatment of chronic hepatitis C infections.

There are currently two approaches to inhibiting the activity of the HCV polymerase. The one we are utilizing 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 and 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 inhibitors 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 ability to replicate. The activity of non-nucleoside compounds 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 tends to be higher with non-nucleoside than with nucleoside analogues.

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 HCV polymerase. The most advanced nucleoside polymerase inhibitors are currently in Phase II clinical trials.

### ***HIV Integrase Inhibitors***

Integrase inhibitors are an emerging class of antiretroviral agents being developed for the treatment of HIV/AIDS. This class of compounds blocks or inhibits the insertion of HIV 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 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 antiretroviral classes, as the only integrase inhibitor approved for sale.

In August 2008, we announced that we had assigned our HCV nucleoside polymerase inhibitor program a higher priority than our HIV program and have realigned our internal resources in order to maximize the potential of accelerating our HCV program. Due to the challenging economic environment and our strategic focus on conserving our capital resources for the development of FV-100 and our HCV polymerase program, at this time we are not allocating any internal resources to our HIV program and have indefinitely suspended our plan to complete such activities.

### ***Aurexis***

Aurexis is a humanized monoclonal antibody being developed as a first-line therapy, in combination with antibiotics, for the treatment of serious, life-threatening *S. aureus* bloodstream infections in hospitalized patients. Aurexis targets clumping factor A, ("ClfA") a protein found on the surface of virtually all strains of *S. aureus*, including methicillin resistant *S. aureus*, ("MRSA"). Therefore, we believe Aurexis may have the potential to be effective in treating infections caused by methicillin sensitive *S. aureus* or MRSA. We have completed an exploratory 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.

Due to our strategic focus on antivirals, and more specifically advancing the development of FV-100 and our HCV polymerase program, we do not intend to allocate any additional resources to advance the clinical development of Aurexis at this time. We continue to seek licensing, co-development collaborations, or other business arrangements that can provide financial resources and other synergistic capabilities to support its further development.

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

*S. aureus* is one of the leading causes of hospital-associated infections worldwide. 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 incrementally 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, over antibiotics alone.

### *Aurexis Clinical Trials*

**Phase II.** In May 2005, we reported the results from a 60 patient Phase II clinical 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, pharmacokinetics, and biological activity of a single dose of Aurexis. In the trial, Aurexis appeared to be generally well tolerated. Further, 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.

### *Staphylococcal Vaccine*

Worldwide, over 112 million people undergo non-emergency surgical operations each year, representing a large target population at risk for acquiring a *S. aureus* infection. This population represents a significant opportunity for a vaccine to prevent such infections, particularly in those countries with a high incidence of MRSA. There are also 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 the elderly, who are at high risk of acquiring a *S. aureus* infection. Further, target groups for *S. aureus* infection prevention strategies include patients with an impaired immune system, HIV or cancer chemotherapy patients, as well as premature and critically ill infants and acute surgery patients. For these high-risk groups, we believe an active vaccine that can enhance immunity against staphylococcal organisms may be a lower cost and preferred mode of therapy. We have entered into a license and collaboration agreement with Wyeth Pharmaceuticals, ("Wyeth") for the development of 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, ("3M") for the development of certain diagnostic products using intellectual property from our MSCRAMM protein technology. In exchange for this license, we received an upfront license payment and the right to receive future milestone payments, financial support of certain research and development activities, and royalty payments on product sales. 3M has discontinued its efforts to commercialize certain antibody-based diagnostics and terminated its license and commercialization agreement with us effective March 2009. As a result, all MSCRAMM-related intellectual property sublicensed to 3M for the development of infectious disease

diagnostics will revert back to us. The conclusion of this agreement will not have a material effect on our financial position or operations.

### **Our Strategy**

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

- *Focus Our Resources on the Development of Our Antiviral Product Candidates that can Achieve Clinical Proof of Concept in the Next 12-24 months.* Over the next one to two years, we plan to focus our resources on further developing our most advanced clinical antiviral compound, FV-100, and our HCV nucleoside polymerase inhibitors. More specifically, we plan to:
  - Complete a Phase II proof of concept clinical trial of FV-100 in shingles patients; and
  - Complete IND-enabling studies for a lead candidate from our HCV nucleoside polymerase program, file an IND for a lead candidate in the first half of 2010.

We currently do not plan to allocate any additional resources to advance the preclinical or clinical development of our HIV compounds and our MSCRAMM protein platform, including Aurexis. We do intend to pursue licensing, co-development, collaborations or other business arrangements that can provide financial and other synergistic capabilities to support the further development and potential of Aurexis. Further, we also plan to continue to support our existing MSCRAMM — based license and collaboration agreement with Wyeth for the development of staphylococcal vaccines.

- *Accelerate Growth Through Collaborations.* We intend to establish strategic collaborations, partnerships and alliances that we believe can accelerate the development and commercialization of our antiviral product candidates beyond clinical proof of concept by utilizing the financial, clinical development, manufacturing and commercialization capabilities of a leading pharmaceutical company.

### **Research and Development**

Our research and development expense in 2008 and 2007 was \$12.5 million and \$42.6 million, respectively. We plan to focus our resources on our most advanced clinical antiviral compound, FV-100, and our HCV nucleoside polymerase inhibitors.

### **Sales and Marketing**

We currently have no commercialization capabilities. At this time, we anticipate partnering or collaborating with other larger pharmaceutical or biopharmaceutical companies to support the development of our antiviral product candidates beyond clinical proof of concept, through late-stage clinical development, and if successful, commercialization. However, other than our agreements with Wyeth, we may decide not to license any development and commercialization rights to our product candidates in the future.

### **Manufacturing**

We do not own or operate any manufacturing facilities. We currently rely on contract manufacturers to produce materials required to conduct certain preclinical studies and clinical trials under current good manufacturing practices, (“cGMP”) with oversight by our management team. We currently rely on a single manufacturer for the preclinical and clinical trial materials of each of our product candidates. However, we believe there are alternate sources of supply and other contract manufacturers that can produce materials 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., (“Davos”) to produce clinical trial material for use in the clinical trials of FV-100. As of December 31, 2008, we have no long-term, non-cancellable 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. Key competitive factors in our industry include, among others, the ability to successfully 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, if ever achieved; government reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; 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, or any product candidate from our current or future 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, hepatitis C, HIV and bacterial infections in the future. Some of the large pharmaceutical 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; Roche and Schering-Plough in the hepatitis C market, and Pfizer, GlaxoSmithKline, Bristol Meyers Squibb, Johnson & Johnson, Abbott, Merck and Gilead in the HIV market. In addition, there are several other companies developing product candidates, particularly in the HCV market, that may compete with our product candidates in the future.

Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. 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 substances and drug products, marketing and sales. Our competitors may be more successful than we are in obtaining FDA or other regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' drugs or product candidates may be more effective, have fewer negative side effects, be more convenient to administer, have a more favorable drug-resistance profile, or be more effectively marketed and sold than any drug we, or our potential collaborators, may commercialize. New drugs, or new classes of drugs from our competitors may render our product candidates obsolete or non-competitive before we are able to successfully develop them 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 new drug targets become available. If our product candidates do not demonstrate any competitive advantages over existing drugs, new drugs or product candidates, we or our future collaborators may terminate the development or commercialization of our product candidates at any time in the future.

A number of our product candidates, particularly FV-100, will compete directly or indirectly with existing generic drugs, or drugs that will be generic by the time our product candidates 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**

Patent and other proprietary rights are crucial in our business and to support 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 in the pharmaceutical and biopharmaceutical industry 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 thereunder may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential drug product candidate, it is possible that our patent rights in any of our product candidates may expire before such products can be approved for sale and commercialized, or that our relevant patent rights remain in force for only a short period following commercialization. Expiration of patents or rights 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 intellectual property rights for the technology, inventions and improvements we consider important to our product candidates;
- defend our patents and proprietary rights;
- preserve the confidentiality of our trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

We have a licensed to an issued patent and pending patent applications with respect to FV-100 in the United States and internationally. The earliest projected expiration date for patents which may issue from those patent applications is approximately 2018, while many of the pending patents will not expire until at least 2027.

We have a license to multiple pending patent applications, including a corresponding PCT application, relating to our HCV nucleoside polymerase inhibitors. The earliest projected expiration date for any patents that may issue is approximately 2027.

We have a license to an issued patent relating to our HIV integrase inhibitors, and the earliest projected expiration date for this patent is 2025. A related U.S. application is also pending, as are national phase international applications. We also have several pending patent applications in the United States and internationally.

We currently own or are licensed under numerous patents and patent applications in the United States and foreign countries related to our MSCRAMM protein technology. We have four issued U.S. patents relating to the ClfA protein found on *S. aureus* and antibodies to the protein. These patents will expire in 2014, 2014, 2016, and 2017 respectively, if not extended. There are no corresponding foreign rights available for the ClfA protein and nucleic acid sequences. Two issued U.S. patents and their international counterparts relate to Aurexis and contain claims to monoclonal antibodies recognizing the ClfA protein. The U.S. patents will expire in 2022 if not extended.

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

Our strategy is to pursue collaborations, partnerships or license agreements in the future with companies that may utilize our intellectual property in their products, or develop, co-develop, market and sell our product candidates. We have entered into two such agreements to date.

### ***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 upon six months notice. Otherwise, this agreement will terminate upon the expiration of all of the licensed patents in 2023. Pursuant to this agreement, we have received \$6.5 million in an upfront license fee and annual research support payments from Wyeth as of December 31, 2008. We are entitled to receive minimum research support payments of \$1.0 million per year until commercial sales reach a targeted threshold of any product developed under this agreement. We are also entitled to receive milestone payments upon the filing of an Investigational New Drug application, (IND) the commencement of both a Phase II and Phase III clinical trials, the filing of a biologics license application, (BLA) and FDA approval of a licensed product. If all such milestones are achieved relative to one licensed product, we would be entitled to receive a minimum of \$10.0 million in milestone payments from Wyeth. The maximum amount of milestone payments we could receive with respect to all licensed products is \$15.5 million. Finally, we are also entitled to royalties on net sales of licensed products manufactured, sold or distributed by Wyeth.

### *3M*

In January 2007, we entered into a license and commercialization agreement with 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 CifA, 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 the right to receive future milestone payments, financial support of further research and development activities and royalty payments on product sales. 3M has notified us that it has discontinued its efforts to commercialize antibody-based diagnostics and will terminate its license and commercialization agreement with us effective March 2009. As a result, all MSCRAMM-related intellectual property sublicensed to 3M for the development of infectious disease diagnostics will revert to us.

### *Other Licensing Agreements*

In September 2007, we completed the acquisition of FermaVir Pharmaceuticals, Inc (“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, (“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 shares of our common stock with the fair market value of \$0.3 million, plus future milestone payments and royalties on future net sales. 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 annual sponsored research payments. In August 2008, we renewed the cooperative research agreement, at a rate of \$0.5 million in annual sponsored research payments, and relinquished non HIV-related intellectual property rights.

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 HCV nucleoside 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 the sale of our products, if approved, 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, (“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 existing or future 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 is subject to extensive regulation by numerous governmental authorities in the United States, principally the United States Food and Drug Administration, (“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 product candidate, 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 steps:

- the completion of satisfactory preclinical studies under the FDA’s Good Laboratory Practices (“GLP”) 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, (“IRB”), 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 (“GCP”) regulations;

- the development and demonstration of manufacturing processes that conform to FDA-mandated current Good Manufacturing Practices, (“cGMPs”); and
- the submission to, and review and approval by, the FDA of a New Drug Application, (“NDA”) or for biologic pharmaceutical products, a Biologics License Application, (“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 generally 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 supportive of an IND generally take a year or more to complete, and there is no guarantee that an IND based on those studies will become effective, allowing human clinical testing to begin.

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*

This 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 finished drug product in accordance with the FDA’s 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 product candidate. 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 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 on a timely basis. 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 granted. 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 product candidate 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 it. 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 or a drug already on the market for the same indication.
- *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 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 serious or life-threatening diseases, such as HIV and HCV, 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 dose 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 sponsor is eligible for a Special Protocol Assessment, ("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 the FDA or approval of any permissible claims about the product.

Throughout the clinical phases of development, samples of the product candidate 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 subject or 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 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 a 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 amended 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 by 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 results of the FDA evaluation of the NDA or BLA and inspection of manufacturing facilities are favorable, the FDA will 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 determines that they cannot approve the application or abbreviated application in its present form a complete response letter will be issued. A complete response letter will describe all of the specific deficiencies that the agency has identified in an application 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. However, even after submitting this additional information, the FDA ultimately may decide

that the application does not satisfy the regulatory criteria for approval. 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.

### *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 regulations, 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, ("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. Aurexis has been granted Fast Track status.

#### *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, 2008, we had 34 full-time employees, 25 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 on official business days during the hours of 10:00 AM to 3:00PM. 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 in the early stages of development and remain subject to numerous clinical trials, preclinical studies and regulatory approval. If we are unable to successfully develop our product candidates, our business will be materially harmed.*

The 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 II clinical trial for FV-100 in the second quarter of 2009. Further, subject to completion of the requisite preclinical studies, we plan to file an IND for a lead HCV nucleoside polymerase clinical candidate in the first half of 2010.

Our product candidates must satisfy rigorous regulatory 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 or unexpected effects;
- meet applicable regulatory standards;

- be capable of being produced in commercial quantities at acceptable costs; or
- be successfully commercialized by us or by collaborators.

Even if we achieve success in preclinical studies and early-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 experienced significant setbacks and failure in all stages of development, including late stage clinical trials, even after achieving promising results in preclinical testing or early stage clinical trials. Accordingly, results from completed preclinical studies and early stage 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 product candidates to be commercialized by 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 development and 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 trials are expensive, complex, may take many years to complete, and have highly uncertain outcomes. Delays, setbacks or failures may occur at any time, or in any phase of preclinical or clinical development, 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 study or trial design, and issues related to the manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or clinical trials 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 characteristics 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 product candidates, including regulators or IRBs not authorizing us to commence a clinical trial or conduct a clinical trial at a prospective trial site; enrollment in our clinical trials delayed or proceeding at a slower pace than we expected or participants dropping out of our clinical trials at a higher rate than we anticipated, resulting in significant delays; our third party contractors whom upon we rely on for conducting r preclinical studies or clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner; having to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health risks; IRBs or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including noncompliance with regulatory requirements; and the supply or quality of material for our product candidates necessary to conduct our preclinical studies or being 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 and 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.***

Product candidates that we receive regulatory FDA approval to advance through clinical development and ultimately sell are subject to extensive and rigorous domestic and foreign government regulation. In the United States 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 or market 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 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 our 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 milestone 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 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 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 process, as described above and may include additional risks.

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

We have 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 small molecule antiviral compounds. In order to successfully develop our antiviral pipeline we must 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 previously did not possess, including but not limited to virology, medicinal chemistry, drug formulation and pharmacology. We cannot assure you that we will be able to attract or retain such qualified employees, consultants or third-party contractors with appropriate small molecule antiviral drug development experience. In the event we cannot attract such capabilities or successfully develop our antiviral pipeline or manage, our business could be materially harmed.

***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, and directors, 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 clinical-stage and preclinical development programs, we need to retain or attract certain personnel, consultants or advisors 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 retaining key personnel in the past, we may not be able to continue to do so 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 trials for our product candidates may be terminated, delayed, or fail.***

We have limited resources dedicated to 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 clinical trials and preclinical studies. We rely on these vendors and individuals to perform many facets of the development process, including preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of positive relations with the clinical sites and to ensure that these sites are conducting our trials in compliance with the trial protocol 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 preclinical 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 CGP practices. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to applicable regulations, we may be forced to delay, repeat or terminate such clinical trials. Any delay, repetition or termination of our clinical trials and preclinical studies 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 clinical and preclinical 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 clinical and preclinical 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 clinical trials or preclinical studies, 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, (“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, (DEA) and corresponding state and foreign agencies to ensure strict compliance with FDA-mandated 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 or clinical trials, and the development of our products candidates 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 clinical trials or preclinical studies. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidates for an extended period of time.

***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 clinical trials and preclinical studies conducted to-date, our product candidates have generally been well tolerated, although these studies and trials have involved a small number of subjects or patients. We may observe adverse or significant adverse events in future clinical trials or preclinical studies of these product candidates. Any side effects associated with our product candidates in development may outweigh their potential benefit and result in the termination of 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 large pharmaceutical 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; Roche and Schering-Plough in the hepatitis C market, and Pfizer, GlaxoSmithKline, Bristol Meyers Squibb, Johnson & Johnson, Abbott, Merck and Gilead in the HIV market. In addition, there are several other competitors developing product candidates, particularly in the HCV market 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) and through December 31, 2008, we have incurred a cumulative deficit of approximately \$227 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 supporting our operations.

We anticipate incurring losses from operations for the foreseeable future, as we continue 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 or our collaborators successfully developed one of our product candidates, 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 the initiation, success or failure of preclinical studies or 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 significant internal drug discovery capabilities, and therefore, we are dependent on in-licensing intellectual property and early stage development programs from third parties for additional product candidates for our pipeline.***

We do not have significant internal discovery capabilities and at this time, we do not intend to build such capabilities in the near future. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely on obtaining discoveries, new technologies and compounds from third-parties through sponsored research or in-licensing arrangements. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources than we have, in obtaining these in-licensing or sponsored research opportunities. Additional in-licensing opportunities may not be available to us, or if available, the terms may not be acceptable. In-licensed compounds that appear promising in discovery or research studies may fail to progress into product candidates, or ever advance into preclinical development or clinical trials at all. 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, as well as a substantial commitment of personnel and financial 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 reporting requirements of being a publicly-traded company increase our overall operating costs and subject us to increased regulatory risk.***

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, we and/or our executive officers may be subject to sanctions by the SEC, and our ability to raise additional funds in the future maybe impaired and ultimately effect our business. We will continue to incur additional expenses as a result of being a publicly traded company.

***If a product-liability claim is brought against us, our ability to assert a federal preemption defense may be limited.***

In the recent case of Wyeth v. Levine, the United States Supreme Court rejected a pharmaceutical company's argument that certain failure to warn-claims alleging deficiencies in its labeling were preempted by federal law because the FDA approved the labels. Although the court's decision was limited to the facts of that case, if any of our products are approved for sale by the FDA and commercialized, this decision may limit our ability to assert a federal preemption defense in any product liability suit which may be brought in the future against such product.

***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 and disposal 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 and have an adverse effect on our business.

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

***We may delay or terminate the development of a product candidate if the perceived market 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, suspend or terminate the future development of a product candidate at any time for strategic, business, or financial liquidity reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not gain meaningful acceptance, not generate a significant return to shareholders, or otherwise provide any competitive advantages in its intended indication or market.

***If the actual or perceived therapeutic benefits of FV-100 are not sufficiently different from existing generic drugs used to treat shingles, we may terminate the development of FV-100 at any time, or our ability to generate significant revenue from the sale of FV-100, if approved, may be limited and our potential profitability could be harmed.***

Valacyclovir, famciclovir and acyclovir are existing drugs used to treat shingles patients. Famciclovir and acyclovir are generic drugs, and valacyclovir, will become a generic drug in 2009. 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 treating the same condition or disease in a meaningful manner, the existence of generic competition in any indication can impose significant pricing pressure on competing drugs. Accordingly, if at any time we believe that FV-100 may not provide meaningful therapeutic benefits, perceived or real, over these existing generic drugs, we may terminate or delay its future development. We cannot provide any assurance that later-stage clinical trials of FV-100 will demonstrate therapeutic benefits over existing generic drugs.

***If we fail to enter into collaborations or other sales, marketing and distribution arrangements with third parties to commercialize our product candidates, or otherwise fail to 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, if our product candidates are approved, our future profitability will depend largely on our ability to access or develop suitable sales and marketing capabilities. We anticipate that we will need to establish relationships with other companies, through license and collaborations agreements to commercialize our product candidates in North America and in other countries around the world. To the extent that we enter into these 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 marketing capabilities or 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 license and collaboration agreements or other business arrangements with third parties to further 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 any other license or collaboration agreements we may enter into in the future related to any of our 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 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, services and pharmaceuticals. 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 any product candidates 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 and government intervention in the United States healthcare system 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 product candidates 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 product candidates.

***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 them in the future, they may not gain market acceptance or utilization among physicians or patients. The degree of market acceptance that any of our product candidates may achieve 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 social activist groups whose goal it is to reduce the cost of drugs, particularly in less developed nations, may also put downward pressure on the prices of drugs, 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, 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 intellectual property. 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 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; and
- 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.

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, both 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.

#### **Risks Related to Owning Our Common Stock**

***Due to current worldwide economic and business conditions, the biotechnology business model may fall out of favor with investors and the industry may undergo a significant transformation. As such, existing or planned operations of many companies may be restructured, rationalized, postponed, terminated or consolidated in order to conserve cash resources or optimize declining asset values. If we are unable to raise capital due to these business conditions, our business may be harmed.***

Traditionally, biotechnology companies whose product candidates are in the development stage do not generate positive cash flow from operations, and have funded their operations for many years through the issuance of equity or through proceeds from license agreements or collaborations with larger pharmaceutical or biotechnology companies. In light of the current economic conditions, many biotechnology companies, particularly those most advanced programs are in the preclinical or early clinical stage of development, have not been able to access capital on reasonable terms, or at all, and believe they may not be able to access such capital in the near future. Accordingly, many have postponed or terminated one or more development programs, or have

restructured or terminated operations altogether in order to conserve or maximize their cash resources. Further, the industry may consolidate into fewer well capitalized companies with greater cash resources and a highly rationalized pipeline. We may not be able to access capital in the future, which may cause us to restructure, postpone or terminate some or all operations, or rationalize our programs and consolidate our operations with those of other companies to support future development.

***In order to develop our product candidates and support our operations beyond the next 18 months, we expect that we will need to raise additional capital. Such capital may not be available to us on acceptable terms, if at all, which could materially harm our business and business prospects, and your investment could suffer a decline in value.***

We anticipate that our existing cash and cash equivalents and short-term investments as of December 31, 2008, together with proceeds we expect to receive from existing license and collaboration agreements will enable us to operate for a period of at least 18 months. We have no other committed sources of additional capital at this time. Given the current conditions in the capital market markets, 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, restructure, sale, merge, or liquidate our operations, or 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 operations or the development of our product candidates.

The timing and extent of our future financing needs 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;
- the time and cost to complete the requisite preclinical studies, clinical trials and receive regulatory approval to advance our product candidates through the additional phases of clinical development;
- the amount of future payments, if any, received or made under existing or future license, collaboration or similar arrangements; and
- the costs associated with protecting or expanding our patent and other intellectual property rights;

***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 product candidates through preclinical and clinical development activities;
- disclosure of any favorable or unfavorable data from our clinical trials or preclinical studies, 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, 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 such 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 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 Exchange Act, 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 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, which could generate sizable losses.

***We currently do not meet the standards for continued listing on The NASDAQ Capital 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 October 22, 2008 and again on December 23, 2008, we received notification from NASDAQ that it had suspended for a three month period, the enforcement of the rules requiring a minimum \$1.00 closing bid price or a minimum market value of publicly held shares. NASDAQ stated that it would not take any action to delist any security for these concerns during the suspension period. NASDAQ has stated that, given the current extraordinary market conditions, this suspension will remain in effect through April 20, 2009. As a result of this suspension, we now have until July 10, 2009 to regain compliance with the minimum bid price rule. As a result of the suspension, if, at any time before July 10, 2009, the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days, NASDAQ will provide written notification that we have achieved compliance with the minimum bid price rule.

If we do not regain compliance with the minimum bid price rule by July 10, 2009, NASDAQ will provide written notification that our securities will be delisted. At that time, we may appeal NASDAQ's determination to delist its securities to a Listing Qualifications Panel. Any delisting from the NASDAQ Capital Market 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 sales by 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 and fund our current strategy and 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, which could impair the value of our common stock.

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

As of December 31, 2008, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 28% 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 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 have entered into sublease agreements for portions of this facility and are seeking additional sublease agreements for other portions of our facility that are currently unused.

**ITEM 3. LEGAL PROCEEDINGS**

Not Applicable

**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 Capital Market under the symbol “INHX.” At March 16, 2009, the Company had 78 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, 2007.

	<u>2008</u>	
	<u>High</u>	<u>Low</u>
First Quarter .....	\$.90	\$.65
Second Quarter .....	.80	.57
Third Quarter .....	.76	.35
Fourth Quarter .....	.40	.18
Year End Close .....		\$.26
	 <u>2007</u>	
	<u>High</u>	<u>Low</u>
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

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

## **ITEM 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. We are currently targeting our efforts and resources on the development of small molecule antiviral compounds, and in particular, therapies to treat shingles (herpes zoster) and infections caused by hepatitis C virus, ("HCV"). Many currently available antiviral therapies have various therapeutic limitations, such as inadequate potency, diminishing efficacy due to the emergence of drug-resistant viruses, toxic or 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.

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 product revenues from any of our existing or future preclinical development programs or product candidates.

We expect that, for the foreseeable future, our operations will result in a net loss on a quarterly and yearly basis. As of December 31, 2008, we had an accumulated deficit of \$227 million. We are incorporated in the state of Delaware since May 1994.

### **Financial Operations Overview**

**Revenue.** We have generated revenues from the licensing of our products, but do not expect substantial product-related revenues until we or our collaborators obtain regulatory approval for and commercialize our product candidates. Our revenues represent the amortization of up-front license fees and periodic research and development support payments we have received in connection with license and collaboration agreements. If our or any of our existing or future collaborators' development efforts result in regulatory approval and the successful commercialization of any of our product candidates, we expect the majority of our future revenues would then result from upfront license fees, milestones, royalties, or other product revenue agreements. In 2009, we expect our revenues will decrease as 3M discontinued its efforts to commercialize antibody-based diagnostics.

**Research and Development Expense.** Research and development expense consists of the costs incurred to license, 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 laboratory facility costs. We charge all research and development expenses to operations as incurred.

***In-Process Research and Development Expense.*** In connection with the acquisition of FermaVir in 2007, 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 for the treatment of shingles, or herpes zoster, which is caused by the varicella zoster virus (“VZV”). The CMV program we obtained in connection with the acquisition did not qualify as a project for IPR&D purposes, and was therefore 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 that the combined company will have no further involvement in the ongoing development and commercialization of the projects at some point in the future. 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 was in the early stages of the development cycle at the time and had no alternative future use, the amount allocated to IPR&D was recorded as an expense immediately upon completion of the acquisition.

The following table summarizes our research and development expenses for the years ended December 31, 2008 and 2007. Direct external costs represent expenses paid to third parties that specifically relate to product candidates in preclinical or clinical development, such as the costs to acquire programs, payments to third parties that perform development services, such as the 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 chemistry, formulation and manufacturing materials for preclinical studies and clinical trials. All remaining research and development expenses, such as salaries and personnel-related expenses, supplies, depreciation, patent services, consulting, general licenses, facility costs and other overhead expense, 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 necessarily indicative of spending in future periods.

	<u>Years Ended</u> <u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
	(In millions)	
Direct external costs:		
FV-100 . . . . .	\$ 3.5	\$33.9
Preclinical programs . . . . .	0.5	1.6
Unallocated costs and overhead . . . . .	<u>8.5</u>	<u>7.1</u>
Total research and development expenses . . . . .	<u>\$12.5</u>	<u>\$42.6</u>

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

We anticipate that our research and development costs will increase in 2009, as compared to our expenses for 2008, due to our development plans for FV-100 and our HCV preclinical program. 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, anticipated market opportunity and the availability of capital to fund our programs.

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.

***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, 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 2009, we expect our general and administrative expense to remain relatively consistent with the level we incurred in 2008.

*Interest and Other Income (Expense), net.* Interest income consists of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest incurred on capital leases and notes payable. Other income and (expense) has historically consisted of the proceeds from the sale of excess raw materials and the gain or loss on the disposal of equipment. In 2009, we expect our net interest and other income to decrease substantially as interest rates have decreased and our balance of cash, cash equivalents and short-term investments is expected to decline.

### **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. Historically our estimates for our critical accounting policies have been not been materially inaccurate.

*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 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 the conduct of our clinical trials, certain research organizations that perform preclinical studies, and fees owed to certain contract manufacturers in conjunction with the formulation or manufacture of materials for our preclinical studies and clinical trials. In order to estimate costs incurred to date, but have not been invoiced, we analyze the progress and related activities, the terms of the underlying contract or agreement, any invoices received and the 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 use the Black-Scholes method to estimate the value of stock options granted to employees and directors. Our forfeiture rate is based on historical

experience as well as anticipated turnover and other qualitative factors, which may change over time. There may be adjustments to future periods if actual forfeitures differ from current estimates. Our awards are issued with graded vesting. The compensation cost for these graded vesting awards is recognized on the straight-line method. Please refer to Note 13 to our Financial Statements for further information on share-based compensation.

**Lease Accounting.** In May 2005, we began a non-cancelable ten year agreement to lease 51,000 square foot research and office facility. In January 2005, we took possession of and controlled the physical use of the property and occupied the facility in May 2005. We have the option to extend the term of the lease for two successive additional periods of five years each by giving prior written notice.

A portion of the leasehold improvements at the research and office facility were capitalized as leasehold improvements paid by the lessor pursuant to the lease agreement. The leasehold improvement assets are being amortized over the economic life 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, 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. Further, we recognize 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.

In 2008, we subleased 6,000 square feet of our office facility under a sublease. The initial term on the sublease shall terminate on December 31, 2013 with an option by the subtenant to extend the term until April 2015. In connection with this sublease agreement, we accrued a loss on rent, reflecting the present value net difference in the rent it expects to receive under the sublease and the estimated cost it would incur on the subleased space over the life of the sublease. We recognize the sublease rental income on a straight-line basis over the life of the sublease.

### **Recent Accounting Pronouncements**

In 2008, we adopted Financial Accounting Standards Board (“FASB”) SFAS No. 157, *Fair Value Measurements* (“SFAS 157”) and SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (“SFAS 159”). SFAS No. 157 provides enhanced guidance for using fair value to measure assets and liabilities and expands disclosure with respect to fair value measurements and 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. In adopting SFAS No. 159, we did not elect to measure any new assets or liabilities at their respective fair values. The adoption of SFAS No. 157 and No. 159, did not have a significant impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (Revised), *Business Combinations* (“SFAS No. 141R”). SFAS No. 141R establishes principles and requirements for how an acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed (including intangibles), and any non-controlling interest in an acquiree. SFAS No. 141R also provides guidance for recognizing and measuring the goodwill acquired in a 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, is not expected to have a significant impact on our consolidated financial statements based on its current operations.

In May 2008, the FASB issued SFAS 162, *The Hierarchy of Generally Accepted Accounting Principles* (“SFAS 162”), which identifies the sources of accounting principles and the framework for selecting the

principles to be used in the preparation of financial statements of non-governmental entities that are presented in conformity with generally accepted accounting principles (“GAAP”) in the United States. The effective date of SFAS 162 is yet to be determined; it will become effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The adoption of SFAS 162 is not expected to have a significant impact on our consolidated financial statements.

## Results of Operations

### *Fiscal Years Ended December 31, 2008 and 2007*

**Summary.** For 2008, we reported a net loss of \$13.2 million, as compared to a net loss of \$41.5 million for the same period in 2007 and basic and diluted net loss per share of \$0.31 as compared to \$1.22 for the same period of 2007. The significant decrease in net loss and net loss per share, as compared to 2007, was principally due to an in-process research and development charge of \$32.6 million that we recorded in the third quarter of 2007 in connection with our acquisition of FermaVir Pharmaceuticals, Inc., a slight increase in revenues, and a decrease in general and administrative expenses, offset in part by an increase in research and development expenses associated with the clinical development of FV-100 and the preclinical development of our HCV nucleoside polymerase and HIV integrase inhibitors programs and a decrease in other income and net interest income in 2008. We expect to incur losses for the foreseeable future as we intend to continue to support the development of FV-100 and our HCV program.

**Revenue.** Revenue increased to \$3.2 million in 2008 from \$2.8 million in 2007. This increase of \$0.4 million or 14%, was due to an increase in the minimum license and support fees earned under an existing collaboration agreement. 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 the related program.

**Research and Development Expense.** Research and development expense decreased to \$12.5 million in 2008 from \$42.6 million in 2007, representing a decrease of \$30.1 million, or 71%. The following table summarizes the components of our research and development expense for 2008 and 2007.

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
	(In millions)	
In-process research and development expenses . . . . .	\$(0.1)	\$32.6
Preclinical, clinical and manufacturing related expenses . . . . .	4.1	1.4
Salaries, benefits and share-based compensation expenses . . . . .	4.0	3.6
License fees, legal and other expenses . . . . .	2.4	2.9
Depreciation and facility related expenses . . . . .	<u>2.1</u>	<u>2.1</u>
Total research and development expense . . . . .	<u>\$12.5</u>	<u>\$42.6</u>

In-process research and development expenses decreased in 2008 due to a \$32.6 million in-process research and development charge in 2007. Preclinical, clinical and manufacturing costs increased by a total of \$2.7 million due to a \$2.6 million increase in clinical trial expenses, preclinical studies and manufacturing-related expenses associated with our FV-100 program and a \$1.6 million increase in preclinical studies and chemistry associated with our HCV and HIV programs, offset in part by a \$1.4 million reduction in expense associated with the settlement of litigation on a production and supply agreement and \$0.1 million reduction in other program expenses. Salaries, benefits and share-based compensation expenses decreased primarily due to a decrease in personnel costs and reduced share-based compensation. License fees, legal and other expenses decreased by \$0.5 million due to a \$1.1 million license fee to obtain our HIV integrase inhibitor program that we recorded in 2007, offset by higher laboratory supply costs and patent-related legal fees and other expenses.

**General and Administrative Expense.** General and administrative expense decreased to \$5.1 million in 2008 from \$6.3 million in 2007, representing a decrease of \$1.2 million, or 19%. The following table summarizes the components of our general and administrative expense for 2008 and 2007.

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
	(In millions)	
Professional and legal fees expenses . . . . .	\$1.1	\$1.0
Salaries, benefits and share-based compensation expenses . . . . .	2.3	3.4
Public company related expenses and other expenses . . . . .	1.1	1.3
Depreciation and facility related expenses . . . . .	<u>0.6</u>	<u>0.6</u>
Total general and administrative expense . . . . .	<u>\$5.1</u>	<u>\$6.3</u>

Professional and legal fees increased by \$0.1 million, due to a favorable mediation settlement of \$0.5 million in 2007 in connection with third party litigation, offset by lower consulting, legal and auditing expenses in 2008. Salaries, benefits and share-based compensation expense decreased by \$1.1 million in 2008 as a result of a charge for severance and termination benefits recorded in 2007 and a decrease in personnel. Other expenses decreased by \$0.2 million due to a decrease in insurance premiums and various other public company related expenses.

**Interest and Other Income, net.** Interest and other income, net, decreased to \$1.3 million for 2008 from \$4.6 million in 2007. The decrease of \$3.3 million was largely the result of a \$1.9 million decrease in other income from the sale of excess raw material in 2007 that did not recur in 2008 and a decrease of \$1.7 million in net interest income due to lower interest rates and lower average cash balances, offset by \$0.3 million decrease in interest expense.

**Liquidity and Capital Resources**

**Sources of Liquidity**

Since our inception in May 1994 through December 31, 2008, 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, 2008, we have also borrowed a total of \$12.8 million under various notes payable, a credit facility with a commercial bank and capital leases, and have received approximately \$15.2 million in license fees, collaborative research payments and grants, of which \$0.7 million and \$0.8 million were recorded as deferred revenue as of December 31, 2008 and December 31, 2007, respectively.

At December 31, 2008, cash, cash equivalents and short-term investments were \$33.1 million and we held no investments with an average 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 treasury securities, United States government agency securities, high-grade corporate bonds, commercial paper, and money market accounts that have an average maturity date of less than 12 months.

**Cash Flows**

For the year ended December 31, 2008, cash, cash equivalents, and short-term investments decreased by \$17.2 million, from \$50.3 million to \$33.1 million. This decrease resulted primarily from cash used for operating activities, an arbitration settlement related to a production and supply agreement, purchase of capital equipment, and the repayment of capital lease obligations and notes payable.

Net cash used in operating activities was \$16.4 million in 2008, which reflects our net \$13.2 million loss for the period plus net cash used from changes in operating accounts of \$4.8 million, offset by non-cash charges of \$1.6 million included in our net loss. Our net loss was largely the result of the cost of funding our clinical

trials, preclinical studies and other research and development activities, and general and administrative expenses, offset in part by the amortization of deferred revenue from our license and collaboration agreements and net interest income.

The \$4.8 million net cash used by the net changes in operating accounts consisted of \$5.0 million in decreased accounts payable and accrued liabilities, which was largely due to the payments of \$3.5 million on an arbitration settlement award related to a production and supply agreement and a \$1.4 million reduction of accrued expense with the settlement of such arbitration as well as decreases in various other accruals, \$0.1 increase in accounts receivable and \$0.1 million increase in deferred revenue, offset in part by \$0.4 million decrease in prepaid expenses and other assets.

We received approximately \$14.5 million of cash from investing activities during 2008, which primarily consisted of net proceeds from short-term investments of \$15.1 million and \$0.1 million in proceeds from sale of equipment, offset in part by \$0.5 million in cash paid for capital expenditures and \$0.2 million in exit costs related to the FermaVir acquisition in 2007.

We used net cash of \$0.8 million from financing activities during 2008, which consisted of \$1.1 million in scheduled payments on our capital leases and promissory notes, \$0.1 million for repurchase of our common stock, offset in part by \$0.4 million in proceeds from a capital lease relating to the financing of equipment.

### ***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;
- our development plans;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the variability, timing and costs associated with conducting preclinical 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 the 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; and
- the cost of filing, prosecuting, and enforcing patent and other intellectual property claims.

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 and short-term investments of \$33.1 million as of December 31, 2008, including proceeds from anticipated existing licensing agreements and collaborations, will enable us to operate for a period of at least 18 months. Our estimate assumes that we advance FV-100 into a Phase II proof of concept trial in 2009 and file an IND for a lead HCV nucleoside polymerase clinical candidate in the first half of 2010. This estimate does not include any costs for the further development of the MSCRAMM platform, including Aurexis, or our HIV integrase inhibitor program or 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 18 months to continue the development of our product candidates, or possibly sooner in the event we enter into other transactions or change our strategy or development plans, we may need to secure additional capital. We would expect to do so primarily through the sale of additional common stock or other equity securities, as well as through proceeds from 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 future 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. If additional capital is not available to us, we may need to obtain funds through license agreements, collaborative or partner arrangements pursuant to which we will likely relinquish rights to certain product candidates that we might otherwise choose to develop or commercialize independently, or be forced to enter into such arrangements earlier than we would prefer, which would likely result in less favorable transaction terms. 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, 2008 and 2007, 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, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inhibitex, Inc. at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Atlanta, Georgia  
March 23, 2009

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

	December 31,	
	2008	2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 11,507,137	\$ 14,178,143
Short-term investments . . . . .	21,634,880	36,088,309
Prepaid expenses and other current assets . . . . .	621,797	1,058,426
Accounts receivable . . . . .	108,558	44,988
Total current assets . . . . .	33,872,372	51,369,866
Property and equipment, net . . . . .	2,328,707	2,564,345
Other assets . . . . .	31,876	—
Total assets . . . . .	\$ 36,232,955	\$ 53,934,211
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 1,276,215	\$ 1,160,351
Accrued expenses . . . . .	1,001,047	6,605,253
Current portion of notes payable . . . . .	312,500	312,500
Current portion of capital lease obligations . . . . .	254,291	698,151
Current portion of deferred revenue . . . . .	441,667	441,667
Other current liabilities . . . . .	224,922	154,824
Total current liabilities . . . . .	3,510,642	9,372,746
Long-term liabilities:		
Notes payable, net of current portion . . . . .	390,625	703,125
Capital lease obligations, net of current portion . . . . .	387,892	68,710
Deferred revenue, net of current portion . . . . .	237,500	387,500
Other liabilities, net of current portion . . . . .	1,279,994	1,202,328
Total long-term liabilities . . . . .	2,296,011	2,361,663
Total liabilities . . . . .	5,806,653	11,734,409
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2008 and 2007, none issued and outstanding at December 31, 2008 and 2007 . . . . .	—	—
Common stock, \$.001 par value; 75,000,000 shares authorized at December 31, 2008 and 2007, 43,380,570 and 42,785,318 shares issued and outstanding at December 31, 2008 and 2007, respectively . . . . .	43,381	42,785
Additional paid-in capital . . . . .	243,825,057	240,634,018
Accumulated other comprehensive income . . . . .	111,450	106,480
Warrants . . . . .	13,742,630	15,551,492
Accumulated deficit . . . . .	(227,296,216)	(214,134,973)
Total stockholders' equity . . . . .	30,426,302	42,199,802
Total liabilities and stockholders' equity . . . . .	\$ 36,232,955	\$ 53,934,211

See accompany notes to the consolidated financial statements

**INHIBITEX, INC.**

**Consolidated Statements of Operations**

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Revenue:</b>		
License fees and milestones . . . . .	\$ 1,650,000	\$ 1,650,000
Collaborative research and development . . . . .	1,500,000	1,125,000
Grants and other revenue . . . . .	—	28,500
<b>Total revenue . . . . .</b>	<b>3,150,000</b>	<b>2,803,500</b>
<b>Operating expense:</b>		
In-process research and development . . . . .	(129,251)	32,569,709
Research and development . . . . .	12,677,681	10,016,279
<b>Total research and development . . . . .</b>	<b>12,548,430</b>	<b>42,585,988</b>
General and administrative . . . . .	5,075,048	6,300,863
<b>Total operating expense . . . . .</b>	<b>17,623,478</b>	<b>48,886,851</b>
<b>Loss from operations . . . . .</b>	<b>(14,473,478)</b>	<b>(46,083,351)</b>
Other income, net . . . . .	87,651	1,969,216
Interest income, net . . . . .	1,224,584	2,654,753
<b>Net loss . . . . .</b>	<b>\$(13,161,243)</b>	<b>\$(41,459,382)</b>
<b>Basic and diluted net loss per share . . . . .</b>	<b>\$ (0.31)</b>	<b>\$ (1.22)</b>
<b>Weighted average shares used to compute basic and diluted net loss per share . . . . .</b>	<b>43,090,432</b>	<b>34,026,250</b>

See accompany notes to the consolidated financial statements

**INHIBITEX, INC.**

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

	Series A Preferred Stock		Common Stock Subscription		Common Stock		Accumulated Other Comprehensive Income (Loss)	Common Stock Warrants	Accumulated Deficit	Total Stockholders' Equity (Deficit)	
	Shares	Par Value	Shares	Par Value	Par Value	Additional Paid-in Capital					
Balance at January 1, 2007 . . . . .	—	\$—	—	\$—	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
Exercise of stock options and issuances of restricted stock and employee stock purchase plan . . . . .	—	—	—	—	789,342	790	14,388	—	—	—	15,178
Expiration of common stock warrants . . . . .	—	—	—	—	—	—	1,815,921	—	(1,815,921)	—	—
Issuance of common stock warrants . . . . .	—	—	—	—	—	—	—	—	7,059	—	7,059
Share-based compensation expense . . . . .	—	—	—	—	—	—	1,491,119	—	—	—	1,491,119
Repurchase of common stock and retirement . . . . .	—	—	—	—	(194,090)	(194)	(130,389)	—	—	—	(130,583)
Net loss . . . . .	—	—	—	—	—	—	—	—	—	(13,161,243)	(13,161,243)
Other comprehensive income . . . . .	—	—	—	—	—	—	—	4,970	—	—	4,970
Comprehensive loss . . . . .	—	—	—	—	—	—	—	—	—	—	(13,156,273)
Balance at December 31, 2008 . . . . .	—	\$—	—	\$—	43,380,570	\$43,381	\$243,825,057	\$111,450	\$13,742,630	\$(227,296,216)	\$ 30,426,302

See accompany notes to the consolidated financial statements

**INHIBITEX, INC.**

**Consolidated Statements of Cash Flows**

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(13,161,243)	\$(41,459,382)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
In-process research and development	(129,251)	32,569,709
Stock issued in connection with in-license agreement	—	300,000
Depreciation and amortization	966,345	1,029,046
Share-based compensation expense	1,491,119	2,034,276
Gain on sale of property and equipment	(74,076)	(25,770)
Amortization of investment premium or discount	(647,417)	(1,352,215)
<b>Changes in operating assets and liabilities, net of acquisition:</b>		
Prepaid expenses and other assets	411,812	(32,607)
Accounts receivable	(63,570)	287,681
Accounts payable and other liabilities	335,098	(346,297)
Accrued expenses	(5,367,203)	(1,280,076)
Deferred revenue	(150,000)	100,000
Net cash used in operating activities	(16,388,386)	(8,175,635)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(468,507)	(73,650)
Purchases of investments	(45,913,947)	(75,192,391)
Proceeds from maturities and sales of investments	61,019,763	82,227,000
Proceeds from sale of property and equipment	81,730	40,425
Cash paid in connection with the acquisition, net of cash acquired	(179,222)	(3,024,663)
Net cash provided by investing activities	14,539,817	3,976,721
<b>Cash flows from financing activities:</b>		
Proceeds from capital leases	368,121	—
Payments on promissory notes and capital leases	(1,075,153)	(1,321,902)
Repurchase of common stock	(130,583)	—
Proceeds from the issuance of common stock, net of issuance costs	15,178	17,098
Net cash used in financing activities	(822,437)	(1,304,804)
Decrease in cash and cash equivalents	(2,671,006)	(5,503,718)
Cash and cash equivalents at beginning of period	14,178,143	19,681,861
Cash and cash equivalents at end of period	\$ 11,507,137	\$ 14,178,143
<b>Supplemental cash flow information:</b>		
Interest paid	\$ 67,972	\$ 143,890
<b>Non-cash investing and financing activities:</b>		
Fixed assets capitalized using capital lease	\$ 269,854	\$ —
<b>Assets and liabilities assumed by acquisition:</b>		
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

See accompany notes to the consolidated financial statements

## 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 to prevent and treat serious infections.

The Company is currently targeting its development efforts on therapies to treat shingles (herpes zoster) and infections caused by hepatitis C virus ("HCV"). Currently available antiviral therapies have various therapeutic limitations, such as inadequate potency, diminishing efficacy due to the emergence of drug-resistant viruses, toxic and adverse side effects, complex dosing schedules and inconvenient routes of administration. The Company believes that its drug candidates may have the potential to address a number of these limitations and unmet needs in their respective, intended indications.

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

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, the successful development of its preclinical programs and product candidates, entering into collaboration or partnership agreements, executing future financings and ultimately, upon the approval of its products for sale and 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 generate significant revenue and become profitable.

### 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. ("FermaVir") and its subsidiary. In September 2007, FermaVir merged with Frost Acquisition Corp, which changed its name to FermaVir Pharmaceuticals, Inc. 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. 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. 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 loss. The cost basis of all securities sold is based on the specific identification method.

**INHIBITEX, INC. — (Continued)**

The Company adopted SFAS 157, *Fair Value Measurements*, (“SFAS 157”) in 2008 related to financial assets and liabilities. This did not have a material impact the Company’s consolidated financial statements. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. In February 2008 the FASB issued FSP No. 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13*, which amends SFAS 157 to remove certain leasing transactions from its scope. In February 2008 the FASB issued FSP No. 157-2, *Effective Date of FASB Statement No. 157*, which delays the effective date of SFAS 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. As permitted by SFAS No. 157-2, the Company elected to defer the adoption of SFAS No. 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis, until January 1, 2009. In October 2008, the FASB issued FSP No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*, which clarifies how management’s internal assumptions should be considered in measuring fair value when (i) observable data are not present, (ii) observable market information from an inactive market should be taken into account, and (iii) the use of broker quotes or pricing services should be considered in assessing the relevance of observable and unobservable data to measure fair value.

Available-for-sale securities as of December 31, 2008 and 2007 consisted primarily of United States treasury bills, commercial paper, United States 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 Principles 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 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.

## INHIBITEX, INC. — (Continued)

**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, payments to preclinical and/or clinical research organizations that the Company has made in advance of the services being performed, and deferred lease assets.

**Share-based Compensation.** Share-based compensation is accounted for in accordance with SFAS No. 123(R), *Share-Based Payment* ("SFAS No. 123(R)"). The Company uses the Black-Scholes method to estimate the value of share-based awards granted to employees and directors. The Company's forfeiture rate is based on historical experience as well as anticipated turnover and other qualitative factors which may change over time. 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.

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 Company's financial instruments consist principally of cash, cash equivalents, short-term investments, accounts payable, accrued expenses, and capital lease and debt obligations. Cash, cash equivalents and short-term investments are reported at fair value pursuant to SFAS 157. The Company believes the recorded values of all of our other financial instruments approximate their current fair values.

The Company also adopted SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which 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. In adopting SFAS 159, the Company did not elect to measure any new assets or liabilities at their respective 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 maintain principal and liquidity through its policies on diversification, investment maturity, and investment grade.

**Limited Suppliers.** The Company may rely on single-source third-party suppliers and contract manufactures to make its product candidates, due to inherent FDA current good manufacturing practices, ("cGMP") requirements for all approved pharmaceuticals. The failure of single-source suppliers or single-source contract manufactures for production of specific candidates to deliver on schedule, or at all, could delay or interrupt the development process and adversely affect the Company's operating results.

**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

## INHIBITEX, INC. — (Continued)

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.

*Research and Development Expense.* Research and development expense consists of the costs incurred to license, develop, test and manufacture 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 clinical trials and monitoring, accumulating and evaluating the related data; salaries and personnel-related expenses for 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 laboratory facility costs. 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 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"). FIN 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*. FIN 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. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted the provisions of FIN 48 effective January 1, 2007. No cumulative adjustment was required or recorded as a result of the adoption of FIN 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.

*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 the economic life 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

**INHIBITEX, INC. — (Continued)**

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.

*Recent Accounting Pronouncements.* In December 2007, the FASB issued SFAS No. 141 (Revised), *Business Combinations* (“SFAS No. 141R”). SFAS No. 141R establishes principles and requirements for how an acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed (including intangibles), and any non-controlling interest in an acquiree. SFAS No. 141R also provides guidance for recognizing and measuring the goodwill acquired in a 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, is not expected to have a significant impact on the Company’s consolidated financial statements based on its current operations.

In May 2008, the FASB issued SFAS 162, *The Hierarchy of Generally Accepted Accounting Principles*, which identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of non-governmental entities that are presented in conformity with generally accepted accounting principles (“GAAP”) in the United States. The effective date of SFAS 162 is yet to be determined; it will become effective 60 days following the SEC’s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. SFAS 162 is not expected to have a significant impact on the Company’s 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 for the period by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss 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 is the same as basic net loss per share since common stock equivalents are excluded from the calculation of diluted net loss per share as their effect is anti-dilutive.

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

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Historical</b>		
Numerator:		
Net loss . . . . .	\$(13,161,243)	\$(41,459,382)
Denominator:		
Weighted average common shares outstanding . . . . .	43,090,432	34,026,250
Basic and diluted net loss per share . . . . .	\$ (0.31)	\$ (1.22)

**INHIBITEX, INC. — (Continued)**

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,	
	2008	2007
Common stock options . . . . .	4,820,459	4,958,131
Restricted common stock . . . . .	140,000	902,959
Common stock warrants . . . . .	8,022,863	8,535,097
<b>Total . . . . .</b>	<b>12,983,322</b>	<b>14,396,187</b>

**4. Acquisition of FermaVir**

On September 19, 2007, the Company completed the acquisition of all of the common stock 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 available bicyclic nucleoside analogue in preclinical development for the treatment of shingles, and a series of preclinical compounds with the potential to prevent or treat infections caused by cytomegalovirus, (“CMV”). The consolidated statements of operations include the results of FermaVir from September 19, 2007, the closing date of the acquisition.

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 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
Transaction and exit costs . . . . .	1,816,728
Cash advance consideration as note receivable . . . . .	1,500,000
<b>Total purchase price . . . . .</b>	<b>\$31,453,040</b>

The acquisition was accounted for as an acquisition of assets in accordance with SFAS, No. 142, *Goodwill and Other Intangible Assets*. The total 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. As FermaVir was a development stage enterprise, the acquisition was not considered to be a business combination, and the excess allocation of the purchase price did not result in goodwill, but rather was reallocated to the acquired assets.

**INHIBITEX, INC. — (Continued)**

The 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 . . . . .	<u>(256,116)</u>
Net fair value of acquired assets and liabilities . . . . .	(987,418)
In-process research and development . . . . .	<u>32,440,458</u>
Total purchase price . . . . .	<u><u>\$31,453,040</u></u>

The acquired IPR&D project is FV-100, a compound in development for the treatment of shingles, or herpes zoster, which is caused by the varicella zoster virus (“VZV”). 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 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.

***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>	
	<b>2008</b>	<b>2007</b>
	<b>(Unaudited)</b>	
Revenues . . . . .	<u>\$ 3,150,000</u>	<u>\$ 2,803,500</u>
Operating expenses . . . . .	<u>\$ 17,623,478</u>	<u>\$ 53,109,371</u>
Net loss . . . . .	<u>\$(13,161,243)</u>	<u>\$(53,592,586)</u>
Basic and diluted net loss attributable to common share . . . . .	<u>\$ (0.31)</u>	<u>\$ (1.27)</u>

The pro forma results for the twelve months ended December 31, 2007 include \$32,440,458 of non-recurring charges for the write-off of the in-process research and development asset.

**INHIBITEX, INC. — (Continued)**

**5. Fair Value Measurements and Investments**

Effective January 1, 2008, the Company adopted SFAS 157. SFAS No. 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- Level 1** Quoted prices in active markets for identical assets or liabilities.
- Level 2** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table sets forth the financial assets and liabilities that were measured at fair value on a recurring basis at December 31, 2008 by level within the fair value hierarchy. The Company did not have any non-financial assets or liabilities that were measured or disclosed at fair value on a recurring basis at December 31, 2008. As required by SFAS No. 157, assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

	<u>Total</u>	<u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>
Cash equivalents . . . . .	\$11,262,261	\$11,262,261	\$ —	\$—
Short-term investments available- for-sale . . . . .	<u>21,634,880</u>	<u>754,762</u>	<u>20,880,118</u>	<u>—</u>
Total . . . . .	<u>\$32,897,141</u>	<u>\$12,017,023</u>	<u>\$20,880,118</u>	<u>\$—</u>

Cash equivalents consist primarily of money market funds and certificates of deposit with original maturity dates of three months or less. 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, United States treasury bills and United States government agency notes.

The Company has had no realized gains or losses from the sale of investments for the years ended December 31, 2008 and 2007. The following table shows the unrealized gains and losses and fair values for those investments as of December 31, 2008 and 2007 aggregated by major security type:

<u>December 31, 2008</u>	<u>At Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized (Losses)</u>	<u>At Fair Value</u>
Certificates of deposit and money market funds . . . . .	\$11,603,992	\$ —	\$ (386)	\$11,603,606
Commercial paper . . . . .	845,999	1,551	—	847,550
Corporate debt notes . . . . .	9,122,672	30,488	(8,117)	9,145,043
Debt securities of U.S. government agencies . . . . .	10,458,387	88,584	(791)	10,546,180
US Treasury securities . . . . .	<u>754,641</u>	<u>157</u>	<u>(36)</u>	<u>754,762</u>
Total . . . . .	<u>\$32,785,691</u>	<u>\$120,780</u>	<u>\$(9,330)</u>	<u>\$32,897,141</u>

**INHIBITEX, INC. — (Continued)**

<u>December 31, 2007</u>	<u>At Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized (Losses)</u>	<u>At Fair Value</u>
Certificates of deposit and money market funds . . . . .	\$ 6,928,400	\$ —	\$ —	\$ 6,928,400
Commercial paper . . . . .	8,422,131	3,379	—	8,425,510
Corporate debt notes . . . . .	25,679,900	95,406	(3,759)	25,771,547
Asset-backed securities . . . . .	9,109,979	11,574	(120)	9,121,433
Total . . . . .	<u>\$50,140,410</u>	<u>\$110,359</u>	<u>\$(3,879)</u>	<u>\$50,246,890</u>

As of December 31, 2008, the Company had investments in an unrealized loss position. The Company has determined that the unrealized losses on these investments at December 31, 2008 are temporary in nature.

All available-for-sale securities held at December 31, 2008 will mature during 2009.

**6. Property and Equipment**

The components of property and equipment are as follows:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Laboratory equipment . . . . .	\$ 3,034,990	\$ 3,379,563
Leasehold improvements . . . . .	2,455,321	2,451,096
Computer software and equipment . . . . .	574,798	577,203
Office furniture and fixtures . . . . .	<u>115,002</u>	<u>115,002</u>
Sub-total . . . . .	6,180,111	6,522,864
Less accumulated depreciation and amortization . . . . .	<u>(3,851,404)</u>	<u>(3,958,519)</u>
Total property and equipment, net . . . . .	<u>\$ 2,328,707</u>	<u>\$ 2,564,345</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 \$966,345 and \$1,029,046 for the years ended December 31, 2008 and 2007, respectively.

In 2008, the Company retired \$632,193 in laboratory equipment, \$16,752 in computer equipment and \$4,385 in software. 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 Company entered into a lease for its office and laboratory 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 \$616,821 and \$802,121 as of December 31, 2008 and 2007.

**INHIBITEX, INC. — (Continued)**

**7. Accrued Expenses**

The components of accrued expenses are as follows:

	December 31,	
	2008	2007
Preclinical, clinical and manufacturing development expense . . . . .	\$ 149,019	\$4,972,179
Severance, payroll and benefits expense . . . . .	306,694	707,992
Professional fee expense . . . . .	309,022	302,307
Other operating expense . . . . .	236,312	622,775
Total . . . . .	\$1,001,047	\$6,605,253

**8. Commitments**

*Lease Commitments.* In May 2005, the Company began a non-cancelable 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. The Company has the option to extend the term of the lease for two successive additional periods of five years each by giving prior written notice.

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 and 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).

In 2008, the Company subleased 6,000 square feet of its office facility under a sublease. The initial term on the sublease shall terminate on December 31, 2013 with an option by the subtenant to extend the term until April 2015. In connection with this sublease agreement, the Company accrued a loss on rent, reflecting the present value net difference in the rent it expects to receive under the sublease and the estimated cost it would incur on the subleased space over the life of the sublease. The balance of this sublease loss liability as of December 31, 2008 is \$231,224 and is classified in the balance sheet as other liabilities (See 10-Other Liabilities). The Company recognizes the sublease rental income on a straight-line basis over the life of the sublease. The future minimum sublease rental receipts are disclosed in the table below.

The Company also leases office equipment under 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, 2008 and 2007, gross rent expense totaled approximately \$920,000 and \$1,071,000, respectively; these amounts were offset against sublease rental income of \$104,000 and \$16,000,

**INHIBITEX, INC. — (Continued)**

respectively. Future minimum payments and receipts under these operating leases at December 31, 2008 are as follows:

<u>Year Ending December 31,</u>	<u>Payments</u>	<u>Receipts</u>
2009 .....	\$ 910,460	\$ (93,000)
2010 .....	926,555	(97,500)
2011 .....	948,710	(102,000)
2012 .....	967,940	(106,500)
2013 and after .....	<u>2,350,834</u>	<u>(111,000)</u>
Total minimum lease payments and receipts under operating leases .....	<u>\$6,104,499</u>	<u>\$(510,000)</u>

*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 expression of recombinant monoclonal antibodies to bacterial surface proteins for use in the manufacture of Aurexis (See Note 16-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 future minimum purchase commitment of approximately 75,000 pounds sterling in cumulative annual license fees as of December 31, 2008. 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, (“UGARF”), for intellectual property covering a series of HIV integrase inhibitors 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 16-Research and License Agreements). Pursuant to this license agreement, the Company entered into a series of cooperative research agreements with UGARF for which the Company has a future minimum purchase commitment of approximately \$225,000 in cooperative research agreement funding as of December 31, 2008. The cooperative research agreement is set to expire August 31, 2009.

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 a series of cooperative research agreements with Cardiff University and Katholieke Universiteit for which the Company has a future minimum purchase commitment of approximately 108,000 pounds sterling in annual cooperative research agreement funding as of December 31, 2008. 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 capital lease obligations related to the acquisition of certain laboratory and other equipment. The amortization of assets acquired under these capital leases has been recorded as depreciation expense. These capital leases bear interest at rates ranging from 6.55% to 14.00%, and expire at various dates from February 2009 to December 2011. In connection with a capital lease entered into in 2008, the Company granted the lessor a warrant to purchase 24,342 common shares at an exercise price of \$0.38 per share. This warrant was recorded at the estimated fair value of \$0.29 per share, using the Black-Scholes method. This amount will be amortized as interest expense over the life of the lease.

**INHIBITEX, INC. — (Continued)**

Future payments under capital lease agreements as of December 31, 2008 are as follows:

<u>Year Ending December 31,</u>	
2009 . . . . .	\$ 308,249
2010 . . . . .	238,658
2011 . . . . .	<u>188,914</u>
Total future minimum lease payments . . . . .	735,821
Less amount representing interest . . . . .	<u>(93,638)</u>
Present value of future minimum lease payments . . . . .	642,183
Less current portion of capital lease obligations . . . . .	<u>(254,291)</u>
Long-term portion of capital lease obligations . . . . .	<u>\$ 387,892</u>

*Notes Payable.* 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, 2008 and December 31, 2007, \$703,125 and \$1,015,625 were outstanding under this note payable, respectively.

Future minimum payments due under notes payable as of December 31, 2008 are as follows:

<u>Year Ending December 31,</u>	
2009 . . . . .	\$312,500
2010 . . . . .	312,500
2011 . . . . .	<u>78,125</u>
Total future payments . . . . .	<u>\$703,125</u>

**10. Other Liabilities**

The components of other liabilities are as follows:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Deferred amortization of leasehold improvements and deferred rent. . . . .	\$1,240,764	\$1,352,727
Other. . . . .	264,152	4,425
Less current portion of other liabilities . . . . .	<u>(224,922)</u>	<u>(154,824)</u>
Long term portion of other liabilities . . . . .	<u>\$1,279,994</u>	<u>\$1,202,328</u>

The Company entered into a lease for its office and laboratory 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-

**INHIBITEX, INC. — (Continued)**

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, 2008, the Company had available federal net operating loss (“NOL”) carry forwards of approximately \$178,235,195 and state NOL carry forwards of \$169,043,691 which will begin to expire in the year 2010. 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 \$3,605,767 of research and development (“R&D”) tax credit carry forwards as of December 31, 2008 which begin to expire in the year 2017. Included in the current year total are \$9,191,505 of federal NOL carry forwards and \$119,009 R&D tax credit carry forwards from the FermaVir acquisition. The Company’s NOL carry forwards and R&D tax 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 NOL 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 NOL and R&D tax 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 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, 2008, 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, 2008. 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, 2008 and 2007. The primary factors causing income tax expense to be different than the federal statutory rates are as follows:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Income tax benefit at statutory rate . . . . .	\$(4,474,823)	\$(14,096,190)
State income tax benefit, net of federal tax benefit . . . . .	(548,995)	(348,197)
IPR&D expense. . . . .	(43,945)	11,073,701
General business credit . . . . .	(425,273)	(141,633)
Other . . . . .	(194,829)	193,695
Valuation allowance. . . . .	<u>5,687,865</u>	<u>3,318,624</u>
Income tax expense . . . . .	<u>\$ —</u>	<u>\$ —</u>

**INHIBITEX, INC. — (Continued)**

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:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Deferred tax assets:		
Net operating loss carry forwards . . . . .	\$ 67,294,096	\$ 57,039,860
Research and development tax credit carry forwards . . . . .	3,605,767	3,061,485
Depreciation and amortization . . . . .	1,809,081	1,943,687
Accruals and reserves . . . . .	138,765	1,879,329
Compensation accruals . . . . .	1,133,880	1,245,003
Deferred revenue . . . . .	257,812	314,752
Other, net . . . . .	<u>192,520</u>	<u>15,819</u>
Total deferred tax assets . . . . .	74,431,921	65,499,935
Less valuation allowance . . . . .	<u>(74,431,921)</u>	<u>(65,499,935)</u>
Net deferred tax assets . . . . .	<u>\$ —</u>	<u>\$ —</u>

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 \$8,931,986 and \$3,318,624 in 2008 and 2007 as follows:

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Deferred tax valuation allowance at beginning of year . . . . .	\$65,499,935	\$62,181,311
Change in cumulative tax due to FermaVir acquisition . . . . .	3,244,121	—
Change in cumulative tax differences . . . . .	<u>5,687,865</u>	<u>3,318,624</u>
Deferred tax valuation allowance at end of year . . . . .	<u>\$74,431,921</u>	<u>\$65,499,935</u>

**12. Stockholders' Equity**

*Common Stock.* As of December 31, 2008 and 2007, 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, 2008. Employees who are 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

**INHIBITEX, INC. — (Continued)**

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, 2008, the Company had 11,667 shares committed to be released to employees and had granted 48,878 shares out of the plan. The Company recorded \$1,619 of share-based compensation expense on all discounts to the fair market value during the purchase period of 2008.

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

	December 31, 2008	December 31, 2007
Common stock options . . . . .	4,820,459	4,958,131
Restricted common stock . . . . .	140,000	902,959
Common stock warrants . . . . .	8,022,863	8,535,097
Total . . . . .	12,983,322	14,396,187

*Common Stock Warrants.* In 2008, a total of 536,576 warrants expired with a weighted average exercise price of \$14.04. The total Black-Scholes value of those warrants was \$1,815,921 and such amount was reclassified from warrants to additional paid-in capital. Additionally in 2008, the Company issued a total of 24,342 warrants with an exercise price of \$0.38 in connection with a new capital lease. The total Black-Scholes value of these warrants was \$7,059 and this amount will be amortized as interest expense over the life of the lease.

As of December 31, 2008 and 2007, there were 8,022,863 and 8,535,097 warrants outstanding, respectively. As of December 31, 2008, all of the warrants are exercisable and expire from January 15, 2009 to September 26, 2018. The weighted average strike price as of December 31, 2008 and 2007 was \$2.87 and \$3.58, 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, 2008 and 2007, the Company recorded share-based compensation expense related to grants from these plans of \$1,491,119 and \$2,034,276, or \$0.03 and \$0.06 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, 2008 and 2007.

*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

**INHIBITEX, INC. — (Continued)**

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.

*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 four years, respectively, from the grant date. As of December 2008, 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, 2008, there were 4,688,703 outstanding option awards to purchase the Company’s common stock and 140,000 restricted stock awards, with 1,597,061 shares available for grant under the 2004 Plan. As of December 31, 2008, there were 55,900 outstanding awards to purchase the Company’s common stock and no options available for grant under the Director Plan.

As of December 31, 2008, the Company has \$1,333,781 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 for 2007 and 2008.

***Stock Options***

The fair value of each stock award was estimated at the date of grant using the Black-Scholes method in 2008 and 2007 with the following assumptions:

	December 31,	
	2008	2007
Risk-free interest rate . . . . .	2.72%	4.13%
Expected life . . . . .	4 years	4 years
Weighted average fair value of options granted . . . . .	\$ .43	\$ .79
Volatility . . . . .	.68	.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

**INHIBITEX, INC. — (Continued)**

and future employee terminations to determine expected life and forfeitures. Expected volatility is based on historical volatilities from the Company's publicly traded stock.

	<u>Number of Options</u>	<u>Weighted-Average Exercise Price per Option</u>	<u>Weighted-Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u> (\$000)
Balance at December 31, 2007 . . . .	4,958,131	\$2.35		
Granted . . . . .	121,500	\$0.81		
Exercised . . . . .	(6,303)	\$0.68		
Forfeited or expired . . . . .	<u>(252,869)</u>	<u>\$2.01</u>	—	—
Balance at December 31, 2008 . . . .	<u>4,820,459</u>	<u>\$2.33</u>	<u>6.02</u>	—
Vested or expect to vest at				
December 31, 2008 . . . . .	<u>4,424,276</u>	<u>\$2.42</u>	<u>5.78</u>	—
Exercisable at December 31, 2008 . .	<u>2,918,158</u>	<u>\$2.77</u>	<u>4.60</u>	—

Stock options granted during the twelve month period ended December 31, 2008 were 121,500. The weighted-average grant date fair value of all stock options granted during the twelve month period ended December 31, 2008 was \$0.43. As of December 31, 2008, there was \$1,333,120 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 2.4 years.

The total intrinsic value of stock options exercised during the twelve month period ended December 31, 2008 was \$4,948 from which the Company received cash proceeds of \$4,286 for the twelve month period ended December 31, 2008. 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, 2008:

<u>Exercise Prices</u>	<u>December 31, 2008</u>				
	<u>Outstanding</u>			<u>Exercisable</u>	
	<u>Number of Shares</u>	<u>Weighted Average Remaining Contractual Life</u> (In Years)	<u>Weighted Average Exercise Price</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
\$0.29 — \$1.36 . . . . .	955,756	5.87	\$1.11	740,506	\$1.19
\$1.45 . . . . .	1,964,200	8.72	1.45	491,050	1.45
\$1.62 — \$2.00 . . . . .	889,248	3.68	1.92	751,748	1.91
\$2.05 — \$9.07 . . . . .	920,214	3.14	5.20	843,988	4.97
\$9.38 . . . . .	90,341	1.28	9.38	90,341	9.38
\$9.69 . . . . .	<u>700</u>	<u>2.83</u>	<u>9.69</u>	<u>525</u>	<u>9.69</u>
	<u>4,820,459</u>	<u>6.02</u>	<u>\$2.33</u>	<u>2,918,158</u>	<u>\$2.77</u>

**INHIBITEX, INC. — (Continued)**

A summary of the Company's non-vested restricted stock as of December 31, 2008 is presented below:

<u>Restricted Stock</u>	<u>Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
Outstanding at December 31, 2007 .....	902,959	\$1.83
Granted .....	—	—
Released .....	(762,959)	\$1.84
Forfeited .....	—	—
Outstanding at December 31, 2008 .....	<u>140,000</u>	<u>\$1.76</u>

As of December 31, 2008, there was \$661 of total unrecognized share-based compensation expense related to unvested restricted stock granted, not discounted for future forfeitures. This balance is expected to be recognized during the first quarter of 2009.

**14. 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.

**15. Comprehensive Loss**

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

	<u>Twelve Months Ended December 31</u>	
	<u>2008</u>	<u>2007</u>
Net loss .....	\$(13,161,243)	\$(41,459,382)
Change in net unrealized gains on investments .....	<u>4,970</u>	<u>94,480</u>
Comprehensive loss .....	<u>\$(13,156,273)</u>	<u>\$(41,364,902)</u>

**16. Research and License Agreements**

**In-licensing Agreements**

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

*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 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 paid \$25,000 to Cardiff as of December 31, 2008.

*University of Georgia Research Foundation.* In addition in September 2007, the Company obtained an exclusive royalty bearing worldwide license from 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 \$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, 2008. Pursuant to this license agreement, the Company also entered into a series of cooperative research agreement with UGARF for annual sponsored

## INHIBITEX, INC. — (Continued)

research payments that currently expires in August 31, 2009. Pursuant to this agreement, the Company has paid \$602,000 to UGARF as of December 31, 2008.

*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 the agreement, the Company entered into a series of cooperative research agreement with Cardiff University in annual sponsored research payments. Pursuant to this agreement, the Company has paid \$531,000 to Cardiff University as of December 31, 2008.

*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 payment of \$25,000 annually until the license agreement expires or is terminated.

### Out-licensing Agreements

*Wyeth.* In August 2001, the Company entered into an exclusive worldwide license and development collaboration agreement with Wyeth Pharmaceuticals, Inc., ("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 \$6,500,000 in an upfront license fee and annual research support payments from Wyeth as of December 31, 2008. The Company is entitled to receive minimum research support payments of \$1,000,000 per year until the reaching a target sales threshold of any product developed under this agreement. The Company is also entitled to receive milestones upon the filing of an investigational new drug application ("IND"), the commencement of both a 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 licensed product, 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

**INHIBITEX, INC. — (Continued)**

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 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. In December 2008, 3M notified the Company of its termination of the agreement. In March 2009, all MSCRAMM related intellectual property sublicensed to 3M for the development of infectious disease diagnostics will revert to back to the Company. Pursuant to this agreement, the Company has received \$4,000,000 in an upfront license fee and annual research support payments from 3M as of December 31, 2008.

**17. 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 \$124,000 and \$114,000 in 2008 and 2007, 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 no measurable event has occurred as described under SFAS No. 112, *Accounting for Post-employment Benefits*, as of December 31, 2008.

**18. 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, 2008</b>				
First Quarter . . . . .	\$787,500	\$ (3,960,115)	\$ (3,447,799)	\$(0.08)
Second Quarter . . . . .	787,500	(2,542,941)	(2,208,875)	(0.05)
Third Quarter . . . . .	787,500	(4,199,889)	(3,955,532)	(0.09)
Fourth Quarter . . . . .	787,500	(3,770,533)	(3,549,037)	(0.08)
<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)

**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 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, 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, 2008. 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, 2008, 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.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report.

March 23, 2009

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fourth quarter of 2008 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

#### (a) Financial Statements and Schedules

The financial statements are set forth under Item 8 of this Annual report on Form 10-K. Financial statement schedules have been omitted since they are not required, not applicable or the information is otherwise included.

#### (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).
10.10	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).
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).

<u>Exhibit No.</u>	<u>Description</u>
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).
10.35	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).
10.48	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).
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 (incorporated by reference to Exhibit 10.52 of the Annual Report on Form 10-K filed the Securities and Exchange Commission on November on March 14, 2008).
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 of the Annual Report on Form 10-K filed the Securities and Exchange Commission on November on March 14, 2008).
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.

## 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 23rd day of March, 2009.

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 23, 2009
/s/ Michael A. Henos Michael A. Henos	Chairman of the Board of Directors	March 23, 2009
/s/ M. James Barrett, Ph.D. M. James Barrett, Ph.D.	Director	March 23, 2009
/s/ Chris McGuigan, M.Sc., Ph.D. Chris McGuigan	Director	March 23, 2009
/s/ A. Keith Willard. A. Keith Willard.	Director	March 23, 2009
/s/ Russell M. Medford, M.D., Ph.D. Russell M. Medford, M.D., Ph.D.	Director	March 23, 2009
/s/ Robert A. Hamm Robert A. Hamm	Director	March 23, 2009
/s/ Marc L. Preminger Marc L. Preminger	Director	March 23, 2009
/s/ Gabriele M. Cerrone Gabriele M. Cerrone	Director	March 23, 2009

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statements and related prospectuses of Inhibitex, Inc. listed below of our report dated March 23, 2009, with respect to the consolidated financial statements of Inhibitex, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2008:

Registration Statement No. 333-128070 on Form S-3

Registration Statement No. 333-129126 on Form S-3

Registration Statement No. 333-149843 on Form S-3

Registration Statement No. 333-116446 on Form S-8

Registration Statement No. 333-129122 on Form S-8

Registration Statement No. 333-147335 on Form S-8

/s/ Ernst & Young LLP

Atlanta, Georgia  
March 23, 2009

**Certification of 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**

I, Russell H. Plumb, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2008 of Inhibitex, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Russell H. Plumb

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President, Chief Executive Officer, Chief Financial  
Officer, Secretary and Treasurer

Date: March 23, 2009

**Certification Pursuant To Section 906 of the  
Sarbanes-Oxley Act 2002**

In connection with the Annual Report on Form 10-K of Inhibitex, Inc. (the "Company") for the year ended December 31, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

1. The report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Russell H. Plumb

President, Chief Executive Officer, Chief Financial  
Officer, Secretary and Treasurer

March 23, 2009

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## Inhibitex Leadership

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### SENIOR MANAGEMENT TEAM

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**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

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**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.

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

Professor – Cardiff University

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

Chairman and President – Salutria Pharmaceuticals, 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

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**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 9, 2009, at 8:30 am EST at the company's headquarters in Alpharetta, Georgia.

**Investor Information Requests**

Copies of the Inhibitex, Inc. 2008 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 Capital 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)