Inhibitex, Inc.

2009 Annual Report

inhibitex

Fellow Stockholders:

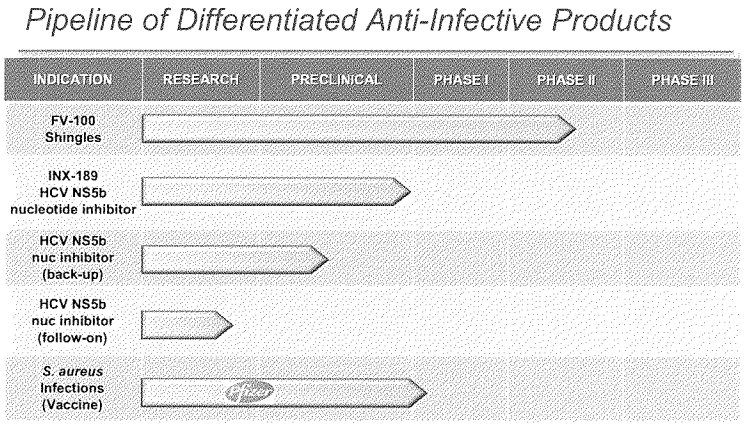
Our operating plan for 2009 was to target our resources to advance our two lead antiviral development programs, FV-100 and INX-189, towards clinical proof of concept. FV-100 is a highly potent and rapid-acting compound that we are developing for the treatment of shingles, and INX-189 is our lead "protide" polymerase inhibitor in development for the treatment of hepatitis C infection.

I am very pleased to report that during the year we achieved our development goals and accomplished several other equally important corporate milestones. The key milestones we achieved in 2009 included:

- Successfully completing an extensive Phase I clinical program for FV-100;
- Initiating a robust, well controlled, randomized 350-patient Phase II trial comparing once-daily doses of 200 mg and 400 mg of FV-100 to 1,000 mg of valacyclovir taken three times per day;
- Successfully completing the requisite preclinical and IND-enabling GLP studies of INX-189;
- Pfizer initiating a large Phase I clinical trial with a multi-component vaccine against Staphylococcus aureus that contains an antigen licensed from our proprietary MSCRAMM protein platform, and;
- Strengthening our balance sheet by successfully raising $23 million from new and existing life science institutional investors.

Based upon our success in 2009, we believe Inhibitex is poised to make great strides over the next year. We are well past the halfway mark in the enrollment of our Phase II trial of FV-100, designed to evaluate its potential as an oral once-a-day therapy to reduce both the acute and chronic pain experienced by shingles patients. A recent interim analysis of safety and efficacy data from the first half of the patients enrolled in the trial resulted in an independent data safety monitoring board recommending that we complete the trial as planned. Our goal is to have complete top-line safety and efficacy data available from this important trial in the fourth quarter of this year.

Over the next several months, we also foresee advancing INX-189 into its initial clinical trial to assess both its safety and its potential to treat chronic hepatitis C infections. In preclinical studies, this promising compound has exhibited best-in-class potency and favorable kinetics, suggesting its potential as a low dose, once-a-day oral therapy. Assuming the successful completion of this initial trial in its planned time frame, our goal is to initiate a second clinical trial of INX-189 in patients infected with chronic hepatitis C later this year, where we will evaluate its ability to reduce the amount of HCV in these patients. In addition to INX-189, we are also evaluating a number of other HCV protide polymerase inhibitors in preclinical studies, with the intention of nominating one or more of these for advanced preclinical development by the end of the year.



As we look forward over the next 12 months, our focus is to create near-term value for our shareholders by successfully completing the clinical "proof of concept" studies for both FV-100 and INX-189. Favorable data from these trials could represent very significant value creation points for each of these programs, and for our company as a whole. We are confident we have the requisite capital and corporate resources needed to achieve these development goals and support our planned operations into 2012.

On behalf of our Board of Directors, I wish to thank you for your trust in our plan and confidence in our team. We have made significant progress over the past several years and remain highly committed to advancing the development of our novel antiviral therapies, which we believe will one day markedly improve the outcomes of the millions of patients who suffer from chronic and acute viral infections each year.

Sincerely,

Russell H. Plumb
President and Chief Executive Officer

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2009

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	**74-2708737**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
9005 Westside Parkway Alpharetta, GA	**30009**
(Address of Principal Executive Offices)	*(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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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, 2009 was $13,038,120.

Number of shares of Common Stock outstanding as of March 10, 2010: 61,562,606.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive Proxy Statement with respect to the 2010 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 completing our Phase II trial of FV-100, a product candidate we are developing to treat shingles, and having top-line data available;
- the expected timing of filing our investigational new drug application ("IND") and initiation of Phase I clinical trial for INX-189, a product candidate we are developing to treat infections caused by hepatitis C virus ("HCV");
- our goal to complete a Phase Ib trial of INX-189 in HCV infected patients;
- our plans to support our existing collaboration with Pfizer and other MSCRAMM intellectual property;
- the potential for our product candidates to address a number of current therapeutic limitations, such as inadequate potency, diminishing efficacy due to the emergence of drug-resistant viruses, toxic or adverse side effects, complex dosing schedules, inconvenient routes of administration, combination therapy, acute pan and post herpetic neuralgia ("PHN"), and other unmet needs in their intended indications.
- the size of the potential markets for FV-100, INX-189 and a staphylococcal vaccine;
- our intent to establish strategic licenses, collaborations or partnerships in the future to accelerate the development and commercialization of our product candidates;
- our plans not to allocate any additional resources to advance Aurexis and length of time it may take to enter into a co-development, collaboration or similar 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: either we, the United States Food and Drug Adminstration, or an investigational review board suspending or terminating the clinical development of FV-100 for lack of safety, manufacturing issues or other clinical reasons; FV-100 not demonstrating sufficient efficacy in reducing the incidence and severity of shingles-related symptoms, including acute pain and PHN, to be clinically relevant or commercially viable; not obtaining regulatory approval on a timely basis, or at all, to advance the development of a INX-189 into clinical trials; the results of ongoing or future preclinical studies of INX-189 not supporting its further development; Pfizer 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 through the regulatory process either in collaboration with a partner or independently; 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; these third-party organizations 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 market our product candidates; our ability to protect and maintain our proprietary intellectual property rights from unauthorized use by others or not infringing on the intellectual property rights of others; our collaborators failing to fulfill their obligations under our agreements with them in the future; our ability to attract suitable organizations to collaborate on the development and commercialization of our product candidates; the inherent uncertainties of estimates of market size for 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®, MSCRAMM®, and Aurexis® are registered trademarks of Inhibitex, Inc.

Overview

We are a biopharmaceutical company focused on the development of differentiated anti-infective products to prevent or treat serious infections. Our research and development efforts are currently focused on small molecule antiviral compounds, and in particular, orally-available therapies to treat herpes zoster, also referred to as shingles, and chronic infections caused by HCV. Currently available antiviral therapies have a number of therapeutic limitations that include 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 antiviral drug candidates have the potential to address a number of these limitations as well as unmet clinical needs in their respective intended indications. In addition to our antiviral programs, we have also licensed the rights to certain intellectual property from our MSCRAMM protein platform to Pfizer for the development of active vaccines to prevent staphylococcal infections.

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 those focusing on antivirals, generally have shorter development cycle times when compared to other 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 studies or clinical trials of other 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 resistant strains creates a continuing need for new drugs to treat certain infectious diseases, thus creating new markets and growing business opportunities.

We have not 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 and bacteria, 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 location, 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 general 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 to avoid treatment failures. 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 must invade living host cells in order to replicate and spread. 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 acute or chronic. Acute infection associated with viruses such as influenza or varicella zoster virus ("VZV"), generally lasts for a relatively short period of time, and in most cases will ultimately self-resolve in most immunocompetent individuals. Chronic infections, such as those caused by HCV, don't typically self-resolve and can cause disease for months or years if left untreated. Viruses can also be characterized as either latent or active. A latent virus, such as VZV, can remain in the body for long periods of time after the initial infection and generally will only cause 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.

Vaccines have been used for many years to prevent active viral infections from occurring. Antiviral drugs designed to treat or suppress rather than prevent viral diseases are generally small molecule, chemical compounds. Antiviral drugs are increasingly being developed to inhibit the replication of specific viruses, while 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 low in number, 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 the need for an alternate therapy with different or possibly new drugs, or classes of drugs. In general, viruses that cause chronic infections, such as HCV, 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 proved to be highly successful in controlling the morbidity and mortality that accompany many bacterial infections. However, due to the widespread use and overuse of antibiotics over time, and the ability of bacteria to quickly develop drug resistance, many antibiotics now have diminished or limited efficacy. The inability to effectively treat serious infections caused by drug-resistant bacteria with antibiotics 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.

Vaccines

Vaccines represent a approach in broadening the available clinical tools against the global health problem of hospital-acquired, or nosocomial bacterial infections. *S. aureus* is the most frequent pathogen to cause nosocomial infections and affects a wide range of different patient groups. Infections are associated with a longer hospital stay, worse clinical outcome and high treatment costs. Mainly due to antibiotic overuse, many resistant strains of *S. aureus* have emerged. The most concerning of those is methicillin-resistant *S. aureus* ("MRSA"), the incidence of which has increased rapidly in both the hospital and more recently, the community setting. The high incidence of *S. aureus* infections and the increasing occurrence of drug-resistant strains are the key drivers for vaccine development. The increasing incidence and the decreasing efficacy of available antibiotics against *S. aureus* suggest that a vaccine to prevent such infections would be highly useful. Particularly in the hospital setting, vaccination of patients could potentially prevent a large number of *S. aureus* infections; but the emergence of certain MRSA strains such as USA300 in the community setting indicates that vaccination would also be particularly useful for high-risk community groups including athletes or prison inmates. Due to the increasing selective pressure on *S. aureus*, new resistance mutations can be

expected to emerge against available drugs. To be able to control *S. aureus* infections, it will therefore be crucial to develop new therapeutic approaches, and an effective vaccine could prove highly useful in both hospital and community settings to limit further spread of the pathogen and to reduce costs to healthcare systems.

Our Pipeline

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

Drug Candidate	Indication	Stage of Development	Status	Marketing Rights
Antivirals				
FV-100	*Treatment of Herpes Zoster (shingles)*	Clinical	• Phase II trial in progress	Inhibitex
INX-189 HCV Nucleotide Polymerase Inhibitor	*Treatment of Chronic Hepatitis C Infection*	Preclinical	• Expect IND filing and initiation of a Phase I trial in first half of 2010	Inhibitex
Antibacterials				
Staphylococcal Vaccines	*Active Vaccine to Prevent S. aureus infections*	Clinical	• Phase I trial in progress	Pfizer
Aurexis	*Treatment of S. aureus Bloodstream Infections*	Clinical	• Completed Phase IIa; seeking to out-license	Inhibitex

FV-100 for Shingles

FV-100 is an orally available nucleoside analogue prodrug of CF-1743 that we are developing for the treatment of herpes zoster, or shingles, which is an infection 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 FDA-approved drugs used 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 to reduce the incidence, severity, and duration of shingles-related symptoms, including acute pain, PHN and lesions. In addition, pharmacokinetic data from our Phase I clinical trial suggests that FV-100 has the potential to be dosed orally once-a-day at significantly lower levels than valacyclovir, acyclovir, and famciclovir.

We initiated a Phase II clinical trial for FV-100 in 2009. The Phase II trial is a well-controlled, double-blind study comparing two arms of FV-100 to an active control (valacyclovir). The trial protocol calls for the enrollment and randomization of approximately 350 patients, aged 50 years and older to one of three treatment arms: 200 mg FV-100 administered once daily; 400 mg FV-100 administered once daily; and 1,000 mg valacyclovir administered three times per day. In addition to further evaluating its safety, the main objectives of the trial are to evaluate the potential therapeutic benefit of FV-100 in reducing the severity and duration of shingles-related pain, the incidence of PHN, and the time to lesion healing. We anticipate having top-line data available from this trial in the fourth quarter of 2010.

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. Chickenpox, the initial infection caused by VZV in an individual, generally occurs during childhood. After the chickenpox infection subsides, VZV remains latent in the individual's dorsal root and cranial nerve ganglia, but can re-emerge later in life. Therefore, individuals who have had chickenpox are at risk for shingles.

Although shingles can occur in any individual with a prior VZV infection, its incidence varies with its key risk factors, which are advanced age and immune status. A study in 2007 suggested that based on age- and sex-adjusted estimates of the incidence of shingles extrapolated to the general population of the United States ("U.S.") that there are nearly 1 million cases annually. Shingles incidence rates in the European Union and Japan, when extrapolated to the size of the current population suggest that there are approximately 1.5 and 0.5 million annual shingles cases, 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% 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% of all persons in the U.S. will suffer from shingles at some point during their lifetime.

The symptoms associated with shingles generally include localized lesions, rash and pain. In certain cases the patient may notice localized prodomal pain prior to the appearance of any lesions; however, the first symptom of shingles is generally lesions that will continue to form for a week or more. While such lesions generally follow the path of nerves that emanate from the spinal cord around the torso, the infection is also commonly found on the face, neck, and in certain cases, systemically. Within several weeks, the lesions in the infected areas will typically begin to crust over and heal, and these dermatological symptoms generally will resolve within a month. 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 attributed to damage caused to the nerve fibers 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 contact with the infected area. The majority of shingles patients experience acute pain for several weeks in connection with their active infection. For 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 is more prevalent 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 or lesions, and the presence and greater severity of a painful prodrome preceding the lesions or rash.

Valacyclovir, acyclovir and famciclovir are oral antivirals currently indicated and approved by the FDA, and regulatory agencies in many other countries, to treat shingles. These drugs are referred to as "pan-herpetic" drugs, as they are used to treat infections caused by various herpes viruses, including herpes simplex 1 and 2, and VZV. IMS data indicates that the majority of the approximately $2.3 billion in annual sales these drugs generate in the U.S. in 2008 was for use in treating infections caused by herpes simplex 1 and 2, and not VZV. Unlike those drugs, FV-100 only demonstrates antiviral activity against VZV, and not the other herpes viruses. Based upon an analysis by IMS Health, Inc. ("IMS") data, we estimate that approximately 15-20% of all retail prescriptions for valacyclovir, acyclovir and famciclovir are for the treatment of herpes zoster, and that the size of the market for oral antivirals to treat shingles is in excess of $350 million per year in the U.S.

Limitations of Current Therapies

Data from various clinical trials demonstrate that a seven day administration of valacyclovir, acyclovir, or famciclovir, beginning less than 72 hours after the first appearance of a shingles-related rash or lesion, can lessen the duration of the dermatological symptoms associated with shingles, and the average duration of shingles-related pain. However, these currently approved 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 or PHN. There is also no cure for PHN per se; rather, treatment of PHN is accomplished through pain management. The most commonly prescribed medications are opioids, antidepressants, anticonvulsants, or a topical lidocaine or

capsaicin patch. Previously published clinical data demonstrate that antiviral therapy can reduce the duration of shingles-related pain and PHN, and we believe a more potent, faster acting anti-VZV compound, such as FV-100, has the potential to more rapidly inhibit the replication of VZV, thus reducing shingles-related nerve damage and therefore further reducing acute pain and PHN. We believe an antiviral therapy that can further reduce the severity and/or duration of acute pain and the prevalence of PHN may have a significant competitive advantage relative to the currently available 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 for the treatment of shingles 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, are taking other medications, and may have difficulty ingesting large tablets or caplets, such dosing regimens are inconvenient and can result in non-compliance, resulting in less than optimal treatment outcomes. We believe that an effective antiviral therapy that can be administered via convenient, once-a-day oral administration may have a competitive advantage relative to current shingles therapies.

- *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 in the ongoing Phase II trial and any future clinical trials we may conduct, we believe the dosing of FV-100 will not need to be adjusted for patients with insufficient renal function. We believe that an oral antiviral therapy that has a similar or better safety profile to valacyclovir, famciclovir and acyclovir, and 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, faster acting, once-a-day oral antiviral agent, such as FV-100, which 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 in vitro, we also believe that the amount of FV-100 necessary to fully inhibit the 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 in preclinical studies and our Phase I trials, may provide for less frequent oral dosing than valacyclovir, acyclovir and famciclovir.

FV-100 Clinical Trials

Phase II. In May 2009, we initiated a well-controlled, double-blind study Phase II clinical trial comparing two doses of FV-100 to an active control (valacyclovir). The trial protocol calls for the enrollment and randomization of approximately 350 patients, aged 50 years and older with shingles-associated pain, who will be equally randomized to one of three treatment arms: 200 mg FV-100 administered once daily; 400 mg FV-100 administered once daily; and 1,000 mg valacyclovir administered three times per day. In addition to further evaluating its safety, the primary objectives of the trial are to evaluate the therapeutic benefit of FV-100 in reducing the severity and duration of shingles-related acute pain, the incidence of PHN, the time to lesion healing, and the use of concomitant pain medications.

There are planned safety assessments by an independent Data Safety and Monitoring Board ("DSMB") when each quartile of patients has been enrolled and has completed 30 days of follow-up, as well as an interim efficacy analysis on the primary endpoint when the second quartile of patients has completed 30 days of follow up. In January 2010, we indicated that the DSMB had reviewed safety data from the first quartile of subjects and recommended to continue the trial as planned. We expect the second quartile DSMB review and interim efficacy analysis to occur shortly. Further, we anticipate completing enrollment in and having top-line data available from this trial in the fourth quarter of 2010.

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. Further, pharmacokinetic data demonstrated that all doses studied maintained mean plasma levels of CF-1743, the active form of FV-100, which exceeded its EC_{50} for at least 24 hours, supporting the evaluation of once-a-day dosing of FV-100 in future clinical trials. The EC_{50} represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*.

In January 2009, 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 twice daily for seven consecutive days and two of whom received placebo. The results of this trial demonstrated no significant safety 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 EC_{50} 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 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 EC_{50}, with the 40 mg dose maintaining such levels for approximately eight hours.

HCV Nucleoside Polymerase Inhibitors

Modified nucleoside inhibitors (nucleoside analogues) is a class of small molecule compounds that have a proven record of success as antiviral agents. These natural small chemical compounds function as the building blocks of human and viral genetic material, commonly referred to as deoxyribonucleic acid ("DNA") or ribonucleic acid ("RNA"). Modified nucleoside inhibitors are small molecules that effectively target viral polymerases, the enzymes that replicate viral genetic information. Mimicking the role of natural or unmodified nucleosides, nucleoside inhibitors are incorporated by viral polymerases into replicating viral genomes. This event leads to chain termination, preventing the virus from reproducing its genetic material. Modified nucleosides need to be phosphorylated to their corresponding 5'-triphosphates by the host cell kinases. In many cases, however, nucleoside analogues are poor substrates for the kinases and the pharmacologically active triphosphate species cannot be considered as possible drug candidates due to their high instability and poor cellular permeation. In many cases, the limiting step in this process is represented by the conversion to the corresponding 5'-monophosphate.

Our collaborators at Cardiff University in Wales, United Kingdom ("Cardiff") have developed the aryloxy-phosphoramidate ProTide approach, which allows the delivery of the monophosphorylated nucleoside analogue ("nucleotide") into the cell, bypassing the first phosphorylation step. Cardiff has previously reported the successful application of this ProTide approach to 2'-methyl purines (adenosine and guanosine). Through our ongoing research and collaboration with Cardiff, we have synthesized an extensive array of ProTide derivatives of 2'-*C*- methyl guanosine nucleotide analogues that target the RNA-dependent RNA polymerase ("NS5b") of

HCV. In the first half of 2009 we selected INX-189 as our lead compound and initiated IND-enabling studies. We have completed the requisite good laboratory practices ("GLP") preclinical studies needed to support the filing of an IND for INX-189 with the FDA. We anticipate filing an IND for INX-189 shortly, and subject to FDA review, anticipate initiating a Phase I clinical trial of INX-189 in the first half of 2010.

INX-189 has demonstrated in the HCV genotype 1a (EC_{90}= 42 nM), 1b (EC_{90}= 38 nM), and 2a (EC_{90}= 7 nM), cell-based replicon assays. In addition, INX-189 exhibited a high degree of synergy in combination with ribavirin in the HCV genotype 1b replicon assay. *In vitro* data from primary human hepatocytes indicated that INX-189 is rapidly and efficiently converted to the active triphosphate with a half-life of approximately 26 hours. Furthermore, oral dosing studies in multiple animal species indicate that INX-189 is effectively extracted by the liver through first-pass metabolism and converted to levels of active triphosphate predicted to exceed those required to exhibit antiviral activity. The pharmacokinetics in these studies support evaluating INX-189 under once-a-day dosing in future clinical trials.

Market Opportunity for the Treatment of HCV

HCV is a virus that is a common cause of viral hepatitis, an inflammation of the liver. HCV infection is contracted by contact with blood or other body fluids of an individual infected with HCV. HCV disease progression occurs over a period of 20 to 30 years, during which patients generally do not exhibit any symptoms of the disease. 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 U.S. HCV is often found among hemodialysis patients, hemophiliacs and recipients of blood transfusions before 1992. HCV is now transmitted primarily through the sharing of needles used for injection drug use and by pregnant women infecting their children *in utero*. The World Health Organization estimates that approximately 170 million people worldwide are infected with HCV as of 2004. Of these individuals, it is estimated that approximately 130 million are chronically infected 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. The Center for Disease Control ("CDC") estimates that approximately 4 million people in the U.S. are chronically infected with HCV as of 2006, yet projects that only about 100,000 of these patients are currently under treatment. Because symptoms of this chronic disease do not typically appear until its later stages, carriers often do not realize they are infected, and therefore do not seek treatment. Current therapies to treat HCV infections generated worldwide sales of approximately $2.2 billion in 2005, and sales of these products and new approved products are forecast to increase to more than $4.4 billion by 2010 and $8.8 billion by 2015.

There are several genotypes and subtypes of HCV. At least six major genotypes of HCV have been identified, each with multiple subtypes. Genotypes are designated with numbers (genotypes 1-6) and subtypes with letters. HCV genotypes 1, 2, 3, and 4 are found worldwide, but their prevalence varies among geographic regions. Genotype 1 and its subtypes (1a and 1b) are the most common genotype globally, accounting for approximately 70% of infections. Patients with genotype 2 or 3 represent approximately 25% of the worldwide chronically infected HCV population and the remaining 5% is comprised of genotypes 4 through 6.

Limitations of Current Therapies for the Treatment of HCV Infection

The current standard of care for the treatment of chronic hepatitis C infection is a combination of once-weekly pegylated interferon-alpha and twice-daily oral administration of ribavirin for up to 48 weeks, depending on the HCV genotype. Interferon-alpha is administrated by injection and results in abnormally high levels of this cytokine circulating systemically throughout the body. Therapy with interferon-alpha causes a number of side effects in many patients, including depression, a drop in blood cell count and flu-like symptoms. These symptoms may be experienced during the entire 48-week course of therapy that is standard for treatment of patients infected with HCV genotype1, who are the most difficult patient group to treat. These side effects may make patients feel worse than the foregoing treatment, which reduces their motivation to initiate or continue therapy. Many patients take additional drugs to treat these side effects, further increasing the cost and the risk of additional side effects. As a result, poor compliance with the current standard of care may decrease the patient response rate.

In addition to these side effects, current therapies do not cure the disease or provide sustained elimination of the virus, called sustained virologic response ("SVR"), for a large proportion of chronically infected patients.

For example, approximately 50 percent of the genotype 1 patients, which represent the largest portion of HCV patients in the U.S., Europe and Japan, do not achieve a SVR six months after the end of the treatment with the current standard of care. Due to the lack of alternative treatments, patients without a SVR response have no other treatment option but to undergo a second 48-week course of interferon-alpha-based therapy with a different brand of interferon-alpha, the outcome of which is generally sub-optimal.

In order to improve the treatment outcomes of patients with chronic hepatitis C and reduce or eliminate the side effects and toxicities associated with the current standard of care, there are a number of pharmaceutical and biopharmaceutical companies pursuing the development of various classes of antiviral compounds that can directly inhibit the replication of HCV by specifically targeting different proteins and enzymes of the virus. Accordingly, direct acting antiviral, or DAA, therapy is now emerging as a potential complement, or possibly an alternative, to the current standard of care. Several classes of DAA compounds are currently in clinical development, including protease inhibitors, which are the most clinically advanced class, nucleoside and non-nucleoside polymerase inhibitors, and other emerging novel antivirals that inhibit different molecular targets of HCV. To date, data from a number of clinical trials evaluating various direct acting antivirals in combination with standard of care demonstrate superior SVR rates as compared to standard of care alone. Notwithstanding the improved treatment outcomes reflected by these trials combining a single DAA with standard of care, it is believed that two or more classes of direct acting antivirals will ultimately be used in combination with the current standard of care, or possibly as its replacement, in order to optimize the potential of direct antiviral therapy. This would be akin to what has evolved in the treatment of HIV/AIDS.

There are currently two approaches to inhibiting the activity of the HCV polymerase. In general, polymerase inhibitors can be assigned to two broad categories on the basis of their chemical structure and mechanism of action: nucleoside analogue inhibitors and non-nucleoside analogue inhibitors. Nucleoside analogues are generally converted to nucleotide analogues by host cell kinases. Nucleoside analogues target the active site of the polymerase and they can either compete with natural nucleoside triphosphate ("NTP") substrates or/and act as 'chain terminators', or cause of a mutational 'error catastrophe' by being incorporated into the elongating nascent RNA molecule. The second category of compounds is the non-nucleoside analogue inhibitors, which typically bind to allosteric surface cavities of the HCV polymerase. 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 cannot occur properly. The probability of this happening tends to be higher with non-nucleoside than with nucleoside/nucleotide analogues.

We are focused on developing the use of ProTide nucleotide analogues that mimic nucleotides normally recognized by the enzyme as it builds a new copy of the viral genome. Similar to current HIV/AIDS therapy, where nucleosides have become a cornerstone of combination therapy, we believe NS5b nucleoside/nucleotide polymerase inhibitors will play a similar role in the treatment of chronic hepatitis C infections.

Certain potential advantages that nucleoside/nucleotide analogues have over protease inhibitors, as well as non-nucleoside polymerase inhibitors, are as follows:

- Nucleoside/nucleotide polymerase analogues have the highest genetic barrier to resistance due to their ability to bind in the active site of the HCV polymerase and mutations in the active site significantly reduce the fitness of the virus.

- Nucleoside/nucleotide polymerase analogues exhibit antiviral activity against all the various genotypes of HCV. Protease and non-nucleoside inhibitors have typically shown variable potency against HCV genotypes 1a and 1b, and reduced or no activity against genotypes 2a, 3a or 4. This genotype specificity suggests that protease and non-nucleoside inhibitors would need to be combined with a nucleoside analogue to provide therapeutic coverage across the breadth of HCV genotypes found globally.

- Nucleoside/nucleotide polymerase analogues do not require boosting with ritonavir. Several of the protease inhibitors currently in development require boosting with ritonavir to enhance their pharmacokinetics. The addition of ritonavir to the treatment regimen for HCV may require extensive drug-drug interactions studies prior to licensure.

The FDA has not yet approved any direct acting antivirals for the treatment of infections caused by HCV, but a number of pharmaceutical and biotechnology companies are developing nucleoside/nucleotide and non-nucleoside HCV polymerase inhibitors. To our knowledge, the most advanced nucleoside/nucleotide and non-nucleoside polymerase inhibitors are currently in Phase II clinical trials.

Staphylococcal Vaccine

In 2001, we entered into an exclusive worldwide license and collaboration agreement with Wyeth (since acquired by Pfizer, Inc. ("Pfizer") in 2009) for the development of active vaccines against staphylococcus from our MSCRAMM protein platform. In consideration for this license, we received an upfront payment and the right to receive future milestone payments, financial support of certain research and development activities, and royalty payments on product sales. Pfizer is responsible for all clinical development, manufacturing and marketing of the vaccine.

In January 2010, we announced that Pfizer had initiated recruitment for a randomized, double-blind Phase I clinical trial to evaluate the safety, tolerability, and immunogenicity of three ascending dose levels of a 3-antigen *S. aureus* vaccine (SA3Ag) in 408 healthy adults. Upon the initiation of this trial we received a milestone payment of $0.7 million and are eligible to receive future regulatory milestone payment, as well as royalties on any future net sales.

Market Opportunity for Staphylococcal Vaccine

The Centers for Disease Control and Prevention ("CDC") as of 2007 estimates that each year, approximately 1.7 million infections and 99,000 associated deaths occur in U.S. hospitals, making nosocomial infections one of the leading overall causes of death. Nosocomial infections constitute a significant economical burden, as they cause a large range of additional costs to health services, patients and society. These include material and personnel costs as well as costs related to lost productivity, disability or caring activities. Most of these costs are directly related to the prolonged hospital stay that becomes inevitable for many patients suffering from a nosocomial infection. The number of extra days a patient has to spend in the hospital varies depending on the type of infection he or she is suffering from, and can extend from days to weeks. In 2000, the CDC estimated the prolonged stay at 1 — 4 days for a urinary tract infection, 7 — 8 days for an infection at the site of a surgery procedure, 7 — 21 days for a bloodstream infection, and 7 — 30 days for pneumonia. Further, the CDC estimated the total additional costs of hospital-associated infections at nearly $5 billion per year, ranging from $600 for a urinary tract infection to $50,000 or more for prolonged bloodstream infections.

S. aureus is the most frequent pathogen in nosocomial infections, associated with many different types of infection and a worse clinical outcome in a wide range of patients. The emergence of the hard-to-treat MRSA, in both the hospital and more recently, the community setting, and the additional costs of treatment have provided a strong rationale to investigate preventive strategies against *S. aureus* infection. From a practical point of view, vaccination appears to be highly feasible for several key target groups such as patients undergoing planned surgeries, the approximately 500,000 patients receiving end stage renal disease therapy in the U.S. as of 2006, patients receiving chronic long-term care, and the elderly.

Staphylococcal Vaccine Clinical Trials

Phase I. In January 2010, we announced that Pfizer had initiated recruitment for a randomized, double-blind Phase I clinical trial to evaluate the safety, tolerability, and immunogenicity of three ascending dose levels of a 3-antigen *S. aureus* vaccine ("SA3Ag") in 408 healthy adults. The SA3Ag vaccine contains an antigen originating from our MSCRAMM protein platform. The primary outcome measures of the trial are an assessment of safety and tolerability as determined by local reactions, systemic events, and adverse events. The secondary outcome measures include an assessment of immunogenicity one month post-vaccination and the effect of the SA3Ag vaccine on the number of *S. aureus* bacteria that naturally occur on the skin and within the nose.

Aurexis

Aurexis is a humanized monoclonal antibody we have evaluated 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 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 a single dose of Aurexis, administered intravenously, 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 developing oral antivirals, and more specifically advancing the development of FV-100, INX-189 and other compounds in our HCV polymerase program, we currently do not intend to allocate any additional resources to advance the clinical development of Aurexis. 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

As of 2007, it was estimated that approximately 94,000 invasive MRSA infections occurred in the United States in 2005 and these infections were associated with death in almost 19,000 cases. The economic burden of MRSA infections is substantial. MRSA hospitalizations cost nearly double that for non-MRSA stays — $14,000 for MRSA stays compared with $7,600 for non-MRSA stays. The average length of stay in the hospital for a patient with MRSA infection was more than double that for non-MRSA stays — 10.0 days versus 4.6 days. These data support the need for the development of newer therapies with novel mechanisms of action designed to either prevent or mitigate the progression of SAB.

There are at least four categories of benefits that may be realized by adjunctive Aurexis therapy: first, reduced mortality and morbidity (complications) associated with MRSA and methicillin sensitive *S. aureus* bacteremia; second, reduced length of stay in the ICU, thereby reducing the costs associated with the overall hospital stay; third, reduced antibiotics utilization consistent with CDC and NIH guidelines, thereby reducing the pressure on the development of antibiotic resistance; and fourth, reduced rates of relapse of infection. Moreover, the ability to be used prophylactically in high-risk patients gives Aurexis a unique advantage over antibiotics where their prophylactic use is discouraged.

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.

HIV Integrase Inhibitors

In September 2007, we obtained an exclusive worldwide license from the University of Georgia Research Foundation, ("UGARF") for intellectual property covering a series of HIV integrase inhibitors. In August

2008, we announced that we had assigned our HCV nucleoside polymerase inhibitor preclinical program a higher priority than our HIV preclinical program and had realigned our internal resources in order to maximize the potential of accelerating our HCV program. In July, 2009 we terminated the license agreement, and all intellectual property covering HIV integrase inhibitors reverted back to UGARF. The conclusion of this agreement did not have a material effect on our financial position or operations.

Our Strategy

Our goal is to become a leading biopharmaceutical company that develops differentiated products that can 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.* In the near-tern, we plan to focus our resources on further developing our most advanced antiviral compounds, FV-100 for the treatment of shingles and INX-189 for the treatment of chronic hepatitis C, through the completion of their respective proof of concept clinical trials. More specifically, we plan to:
  - Complete a Phase II proof of concept clinical trial of FV-100 in shingles patients in the fourth quarter of 2010; and
  - file an IND and initiate a Phase I clinical trial for INX-189 in the first half of 2010, with the goal of completing a Phase Ib trial of INX-189 in HCV infected patients in 2011.
- *Conduct preclinical studies on potential back-up and follow-on HCV nucleotide polymerase inhibitors that possess different chemical structures and properties than INX-189.* We have a number of potential back-up and follow on HCV nucleotide polymerase inhibitors that we are evaluating in various stages of research and preclinical development.
- *Continue to support our existing MSCRAMM programs, including our MSCRAMM based license and collaboration agreement with Pfizer for the development of staphylococcal vaccines as needed.* Pfizer recently initiated a Phase I trial of a staphylococcal vaccine, which includes intellectual property covered under our license agreement with them. Pfizer is responsible for all preclinical, clinical and commercial activities relating to the program, while we maintain intellectual property covered under the license and provide additional research support as needed. Further, we currently do not plan to allocate any additional developmental resources to our MSCRAMM protein and antibody platform, including Aurexis. However, we do intend to continue to maintain the intellectual property and to pursue licensing, co-development collaborations or other business arrangements that can provide financial and other synergistic capabilities to support the further development and commercialization of our MSCRAMM protein and antibody platform.
- *Accelerate and Sustain Growth Through Collaborations.* We intend to establish strategic licenses and collaborations, partnerships or alliances with leading pharmaceutical or biopharmaceutical companies with greater financial, clinical development, manufacturing and commercialization capabilities that we believe can accelerate the development and/or commercialization of our antiviral product candidates after we have independently established their clinical proof of concept.

Research and Development

Our research and development expense in 2009 and 2008 was $15.4 million and $12.5 million, respectively. We plan to focus our resources primarily on the clinical development of our most advanced antiviral compounds, namely FV-100, which we are developing for the treatment of shingles, and INX-189, our nucleotide polymerase inhibitor for the treatment of chronic hepatitis C.

Sales and Marketing

We currently do not have any commercialization or sales and marketing capabilities, and currently have no plans to invest in or build such capabilities internally. At this time, we anticipate partnering or collaborating with, or licensing certain rights to, other larger pharmaceutical or biopharmaceutical companies to support the

development of our antiviral product candidates through late-stage clinical development, and if successful, commercialization. However, other than our existing license agreement with Pfizer, 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 facilities in which we could formulate and manufacture our product candidates. We currently rely on contract manufacturers to produce all materials required to conduct preclinical studies and clinical trials under current good manufacturing practices, ("cGMP") with oversight by our management team. We currently rely on a single group of manufacturers for the preclinical and clinical trial materials of each of our product candidates. However, we have identified alternate sources of supply and other contract manufacturers that can produce materials for our preclinical and clinical trial requirements. If a contract manufacture fails to deliver on schedule, or at all, it could delay or interrupt the development process and affect our operating results.

We have used contract manufacturers to produce clinical trial material for use in the clinical trials of FV-100. As of December 31, 2009, we have a maximum purchase commitment of $0.1 million under these agreements and have no other long-term, non-cancellable financial obligations under these agreements.

We have recently begun to use a different group of contract manufacturers to produce clinical trial material for use in our planned clinical trials of INX-189. As of December 31, 2009, our maximum purchase commitment is $0.4 million under these agreements, and we have no other long-term, non-cancellable financial obligations under these agreements.

Competition

Our industry is highly competitive and characterized by rapid technological change and government regulation. 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; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity; manufacturing costs; intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, FV-100, INX-189, 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 could become available in the future for the treatment of shingles, chronic hepatitis C and the prevention of staphylococcal infections . Some of the large pharmaceutical companies that currently market products that would compete with our product candidates, if approved, include, but are not limited to: GlaxoSmithKline, Novartis and Merck in the shingles market and Merck and Roche in the hepatitis C market.

In addition to existing therapies, there are many other pharmaceutical and biopharmaceutical companies developing numerous direct acting antiviral product candidates across various classes of compounds for the treatment of chronic hepatitis C, including, but not limited to, Abbott, Anadys Pharmaceuticals, Bristol Myers Squibb, Gilead, Idenix Pharmaceuticals, Johnson and Johnson, Merck, Novartis, Pfizer, Pharmasset, Roche, and Vertex, which may compete with INX-189 or any other HCV nucleotide polymerase inhibitor we may develop in the future. Most of the product candidates being developed by these companies, and in particular those that belong to the class of compounds referred to as protease inhibitors, are further advanced in their clinical development than INX-189. Further, Idenix Pharmaceuticals and Pharmasset are developing nucleotide analogues, which are similar to the approach we are using for INX-189. Moreover, their compounds have advanced further in clinical development and are currently in Phase II clinical trials.

While there are many direct acting antiviral compounds in various stages of clinical development, none have been approved for sale by the FDA or EMEA. Accordingly, the competitive landscape for the treatment of chronic hepatitis C is expected to be highly dynamic over the next five to ten years. In order to compete effectively in this market in the future, we believe a direct acting antiviral will need to demonstrate a favorable

toxicity profile, superior potency, high resistance barriers, and be amenable to combination with other direct acting antivirals in a low fixed oral dose.

Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that could compete with FV-100 or INX-189, have substantially more capital resources than we have, and much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, manufacturing drug substances and drug products, and 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 classes of drugs from 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 them. 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.

We anticipate that our product candidates, and in particular FV-100 if successfully developed and approved, will compete directly or indirectly with existing generic drugs, or drugs that will be generic by the time our product candidates may 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 intellectually 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

Patents and other proprietary intellectual rights are crucial in our business, and are essential to justify 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 for our product candidates. 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.

As patent applications in the U.S. are maintained in secrecy until patents are issued, unless earlier publication is required under applicable law or in connection with patents filed under the Patent Cooperation Treaty ("PCT") or as publication of discoveries in the scientific or patent literature often lags behind the actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions described in these pending patent applications or that we or our licensors were the first to file patent applications for such inventions. Furthermore, the patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions, and therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that any patents will be issued or that patents licensed to us will be issued from any of these patent applications or, should any patents issue, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that patents issued or licensed to us will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent our patent position in the U.S. or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

Pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of 20 years from the date of filing, irrespective of the period of time it may take for the patent to ultimately issue. This may shorten the period of patent protection afforded to our products as patent applications in the biopharmaceutical sector often take considerable time to issue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were used to support the marketing application for the drug. The Drug Price Competition and Patent Term Restoration Act of 1984 also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding New Drug Application ("NDA") plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. We cannot be sure that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of this law.

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success depends, in part, on our ability to develop and maintain a strong patent position for our intellectual property and product candidates in clinical development, both in the U.S. and in other countries. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents, or to protect our trade secrets, and could result in substantial cost to us and diversion of our efforts. We intend to file applications as appropriate for patents describing the composition of matter of our drug candidates, the proprietary processes for producing such compositions, and the uses of our products and drug candidates. 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 there under may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential drug product 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 will remain in force for only a short period following commercialization. Expiration of patents or rights we directly 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 an exclusive global license to an issued patent and pending patent applications with respect to FV-100 in the U.S. and internationally. The earliest projected expiration date for patents which may issue from those patent applications is approximately 2018, while many of the patent applications will not expire until at least 2027.

We have an exclusive global license to multiple pending patent applications, including a corresponding PCT application, relating to INX-189 and a number of our preclinical HCV nucleotide polymerase inhibitors. The earliest projected expiration date for any patents that may issue with claims related to INX-189 is approximately 2029.

We currently own or are licensed under numerous patents and patent applications in the U.S. and foreign countries related to our MSCRAMM protein platform. 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. We have two issued U.S. patents and corresponding foreign rights relating to multi-component vaccines for staphylococci. These patents will expire in 2019 if not extended.

Licenses

In 2007, we acquired the rights to an exclusive worldwide license from Cardiff, which includes FV-100, a bicyclic nucleoside analogue for the treatment of VZV infections. 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 intellectual property. We may terminate this agreement upon 90 days notice. Cardiff may terminate upon 90 days following certain specified breaches of the license agreement by us.

In 2007, we entered into an exclusive worldwide license agreement with Cardiff and Katholieke Universiteit in Leuven, Belgium for intellectual property covering a series of HCV nucleotide 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 intellectual property. We may terminate this agreement upon 90 days notice. Cardiff and Katholieke Universiteit may terminate upon 90 days following certain specified breaches of the license agreement by us.

In October 2009, we entered into a second exclusive worldwide license agreement with Cardiff for intellectual property covering certain HCV nucleotide polymerase inhibitors in exchange for 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 intellectual property. We may terminate this agreement upon 90 days notice. Cardiff may terminate upon 90 days following certain specified breaches of the license agreement by us. Pursuant to this license agreement, we entered into a cooperative research agreement with Cardiff under which we have agreed to collectively pay Cardiff approximately $0.3 million in annual sponsored research payments over approximately two years. Christopher McGuigan, a member of our Board of Directors, holds the following positions at Cardiff University' Welsh School of Pharmacy: Professor, Chairman, Department Research Committee; Director of Research; and Head of Medicinal Chemistry.

In 2000, we executed an exclusive license from the Texas A&M University System ("Texas A&M") for a number of issued U.S. patents, their related pending U.S. divisional applications and corresponding international filings with claims to MSCRAMM nucleic acids, proteins, antibodies, and vaccines. BioResearch Ireland/Trinity College Dublin is a co-owner of certain issued patents and patent applications. We may terminate the license without cause upon 60 days written notice. Otherwise, this agreement will terminate upon the expiration of all licensed patents. We have agreed to pay Texas A&M a royalty based on net sales for any product sold utilizing these licenses. We are obligated to pay a minimum royalty of $25,000 annually.

In 1996, we obtained an exclusive license from BioResearch Ireland ("BRI") under two issued U.S. patents and a pending U.S. patent application directed to the ClfA nucleic acid, protein, and antibodies. This license will terminate upon the expiration of all licensed patents. We may terminate the license agreement as to any patent or patent application upon 90 days notice. We have agreed to pay BRI a royalty based on net sales for any product sold utilizing these licenses.

Pfizer, Inc.

In August 2001, we entered into an exclusive worldwide license and development collaboration agreement with Wyeth (subsequently acquired by Pfizer in 2009) under which we granted Pfizer exclusive rights to our MSCRAMM proteins for use in the development and commercialization of human vaccines against staphylococcal organisms. Under the agreement, the development, manufacture and sale of any products resulting from the collaboration are the responsibility of Pfizer. We may terminate this agreement if Pfizer fails to use reasonable commercial efforts to bring related products to market. Pfizer 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 $7.3 million in an upfront license fee and annual research support payments from Pfizer as of December 31, 2009. We are entitled to receive minimum research support payments of $1.0 million per year until commercial sales reach a targeted threshold for any product developed under this agreement. We are also entitled to receive milestone payments upon the commencement of each Phase I, Phase II and Phase III clinical trial, the filing of a biologic drug application and regulatory approval of a licensed product. If all such milestones are achieved relative to at least one licensed product, we would be entitled to receive a minimum of $10.0 million in milestone payments under the agreement. 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 related products manufactured, sold or distributed by Pfizer. In January 2010, we announced that Pfizer had commenced enrollment in a Phase I study with a staphylococcal vaccine that includes an antigen covered under this license agreement, which resulted in a milestone payment to us.

Pharmaceutical Pricing and Reimbursement

In the U.S. and most foreign markets, any revenue associated with the sale of our product candidates, 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 U.S., 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 U.S. and foreign governments periodically propose and pass legislation designed to reduce the cost of healthcare and pharmaceutical products. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals may change before any of our product candidates are ever approved for sale. In addition, the adoption of new legislation could further limit reimbursement for pharmaceuticals. Further, an increasing emphasis on managed care in the U.S. 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, and our existing 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 U.S., principally the U.S. 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.

U.S. Regulatory Approval

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

- the completion of satisfactory preclinical studies under the FDA's GLP regulation;
- the submission and acceptance of an IND that must become effective before human clinical trials may begin;
- obtaining the approval of an Institutional Review Board ("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 NDA or a 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 that this process will result in the granting of an approval for any of our product candidates on a timely basis, if at all or that we will have sufficient financial resources to see the process through to completion.

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 *in vivo* animal studies to assess its potential safety and biologic activity. We must submit the results of these preclinical studies, together with other information, including manufacturing records, 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 will be required to resolve any outstanding issues to the satisfaction of the FDA before we could begin, or continue, clinical trials of such product candidates. 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 GLP regulations and the U.S. 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 trial phase of drug development follows a successful IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy and dosage of an investigational new drug substance in humans, as well as the ability to produce the drug substance 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, with limited exceptions, requires the patient's informed consent to participate in the trial. Sponsors, investigators, and IRBs also must satisfy extensive GCPs, 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 serious 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.

Clinical trials to support a NDA or BLA for marketing approval are typically conducted in three sequential phases: Phase I, II and III, with Phase IV clinical trials often conducted after marketing approval has been granted. The FDA may require sponsors to conduct Phase IV clinical trials to study certain safety issues. Data from these activities are compiled in a 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 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 dose 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 are generally 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 HCV, Phase I trials may be conducted in patients with the respective disease rather than in healthy volunteers. These studies may provide initial evidence of activity or efficacy traditionally obtained in Phase II clinical trials, and therefore these trials may be referred to as Phase I/II or Phase Ib clinical trials.

A company may request an "end-of-Phase II Meeting" with the FDA to assess the safety of the dose regimen to be studied in the Phase III clinical trial, to evaluate the planned design of a Phase III trial, and to identify any additional information that will be needed to support a NDA. If a Phase III clinical trial has been the subject of discussion at an "end-of-Phase II Meeting," the trial 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 deemed to be adequate to meet the scientific and regulatory requirements identified by the sponsor. If the FDA and the sponsor reach agreement on the design and size of a Phase III clinical trial intended to form the primary basis of an efficacy claim in a NDA or BLA, the FDA may 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 various phases of clinical development, samples of the product candidate made in different batches are tested for stability to establish any 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 development 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, the sponsor, or an IRB may suspend or terminate a clinical trial 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 or advancement to the next stage of development. 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. 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.

Clinical trials performed outside the U.S. under an IND must meet the same requirements that apply to studies conducted in the U.S. 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.

Certain information about clinical trials, including a description of the study, participation criteria, location of study sites, and contact information, is required to be sent to the National Institutes of Health, ("NIH") for inclusion in a publicly-accessible database that is available at 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 directed 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 we believe that all the requisite clinical trials for a product candidate have been completed with satisfactory and supporting 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 in the U.S. Among many other items, a NDA or BLA typically includes the results of all 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 it believes all applicable regulatory criteria are not satisfied, or it may require additional data, including clinical, toxicology, safety or manufacturing data prior to approval. 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 a 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 potentially significant improvement in the treatment, prevention or diagnosis of a life threatening or serious 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 also receive accelerated approval 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's 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 it cannot approve the application in its present form, it generally issues what is referred to as a complete response letter. 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 are met to the FDA's satisfaction, the FDA will typically re-review the application and possibly 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 to be approved may vary substantially, depending upon the nature, complexity and novelty of the product candidate.

We cannot assure you that the FDA, or any other similar regulatory agency in another country, 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 to be marketed and sold, 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 for our current and future product candidates, failure of the FDA to grant approval for marketing of such product candidates, 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 formulation 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 an approved 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 U.S. 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 U.S. 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 whether FDA regulations, guidance or interpretations will change 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 an 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 appears to be significantly superior to existing 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 U.S., 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 above. 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, 2009, we had 32 full-time employees, 24 of whom were engaged in research and development, clinical, regulatory, chemistry and manufacturing, and eight of whom were engaged in administration, finance, and business development activities. 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 that contains the reports, proxy and information statements, and other information filed electronically. Our website address is www.inhibitex.com. Please note that these website addresses are provided as inactive textual references only. We make available free of charge through our website our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information provided on our website is not part of this report, and is therefore not incorporated by reference unless such information is otherwise specifically referenced elsewhere in this report.

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 their commercial viability remains subject to future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in these activities. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

In the near-term, failure to successfully advance the development of one or more of our product candidates may have a material adverse effect on us. To date, we have not successfully developed or commercially marketed, distributed or sold any product candidates. The success of our business depends primarily upon our ability to successfully advance the development of our product candidates through preclinical studies and clinical trials, have these product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately, have our product candidates successfully commercialized by us or a strategic collaborator. We have initiated a Phase II trial for FV-100, a product candidate we are developing to treat shingles and anticipate completing this trial in the fourth quarter. Further, we plan to file an IND for INX-189, a nucleotide polymerase inhibitor we are developing to treat chronic hepatitis C infections, and, subject to FDA review, initiate a Phase I clinical trial in the first half of 2010. We cannot assure you that the results of planned or ongoing preclinical studies or clinical trials will support or justify the continued development of one or both of these product candidates, or that we will receive approval from the FDA, or a similar regulatory authority in other countries, to the advance the development of our product candidates.

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

- offer therapeutic or other benefits over existing comparable drugs or other product candidates in development;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects (or may include undesirable or unexpected effects);
- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of later stage clinical trials will be favorable and continue to support the development of our product candidates. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, 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 of our product candidates may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of an IND application, the

initiation or continuation of human clinical trials, or a NDA or BLA to obtain regulatory approval from the FDA in the U.S. to market and sell the product.

Our product candidates will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. We cannot assure you that any of our product candidates will successfully progress through the drug development process or will result in 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 the results of preclinical studies or clinical trials for our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

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 regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, may take many years to complete, and have highly uncertain outcomes. Delays, setbacks or failures can occur at any time, or in any phase of preclinical or clinical development, and can result from 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 formulation or 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 observe in later stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety and efficacy characteristics despite having favorably demonstrated such characteristics 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 advance the development, receive regulatory approval, or commercialize our product candidates, including, but not limited to:

- communications with the FDA, or comparable regulatory authorities in different countries, regarding the scope or design of the trial;
- regulatory authorities or independent review boards ("IRBs") not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being 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;
- our third party contractors, upon whom we rely for conducting preclinical studies and clinical trials, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- 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 non-compliance with regulatory requirements; and
- the supply or quality of drug material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of an IND application, the initiation or continuation of human clinical trials, or a New Drug Application ("NDA") or Biologics License Application ("BLA") to obtain regulatory approval from the FDA in the U.S. to market and sell the product.

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

Product candidates that we may receive regulatory approval to advance through clinical development and ultimately market and sell are subject to extensive and rigorous domestic and foreign government regulation. In the U.S., the FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical and biopharmaceutical products. Our product candidates are also subject to similar 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, as well as data supporting an acceptable manufacturing process, 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 U.S. 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, and involves post-marketing surveillance and vigilance and 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, 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 potential 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 suspend or terminte the preclinical or clinical development of a 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 U.S. 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 and requirements associated with the FDA regulatory process for drug development 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.

Our two lead antiviral product candidates, FV-100 and INX-189, are chemical compounds, also referred to as small molecules. We have limited experience in the discovery, development and manufacturing of small molecule antiviral compounds. In order to successfully develop these product candidates, we must supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing capabilities through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we do not possess. 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 or manage our antiviral pipeline, our business could be materially harmed.

If we are unable to retain or attract key employees, advisors or consultants, we may be unable to successfully develop our product candidates in a timely manner, if at all, or otherwise manage our business effectively.

We have adopted an operating model that largely relies on the outsourcing of a number of responsibilities and activities to third-party consultants and contract organizations in order to advance the development of our product candidates. Therefore, our success depends in part on our ability to retain qualified key management, personnel, and directors to develop, implement and execute our business strategy and operate the company, as well as academic and corporate advisors or consultants to assist us. We are currently highly dependent upon the efforts of our management team. In order to develop our product candidates, we need to retain or attract certain personnel, consultants or advisors with experience in a number of disciplines, including research and development, clinical trials, medical matters, 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 key personnel, directors, advisors or consultants, the development of our product candidates could be delayed or terminated and 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 delayed, terminated, or fail, or we could incur significant additional expenses.

We have limited resources dedicated to designing, 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 designing, managing, monitoring and conducting our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring 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 in the U.S., or our third-party vendors' sites, to determine if our clinical trials are being conducted according to good clinical practices ("CGP"). 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 formulate and 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 could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any formulation or manufacturing facilities. We have historically contracted with third-party contract manufacturers and organizations to formulate and manufacture the preclinical and clinical materials we use to test our product candidates in development. We intend to continue to rely on third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical 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 our preclinical studies or clinical trials, or 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:

- our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;
- our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, current good manufacturing procedures ("cGMP"), or otherwise manufacturing material that we or the FDA may deem to be unusable in our clinical trials;
- our contract manufacturers being 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 product candidates. 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 contract manufacturers placing a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers failing to perform as agreed or may not remain in the contract manufacturing business; and
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. 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 may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

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

Due to regulatory restrictions inherent in an IND, NDA or BLA, various steps in the manufacture of our product candidates may be sole-sourced. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. 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 and therefore a delay in the development of our product candidates. Further, in order to maintain our development time lines in the event of a change in our third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates.

Our product candidates may exhibit undesirable side effects when used alone or in interaction with other approved pharmaceutical products, which may delay or preclude their further development or regulatory approval, or limit their use if approved.

Throughout the drug development process, we must continually demonstrate the safety of our product candidates to obtain regulatory approval to advance their clinical development or to market them. Even if our product candidates demonstrate biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh their potential benefit. In preclinical studies and clinical trials we have conducted to- date, our product candidates have demonstrated an acceptable safety profile and no unacceptable drug-drug interactions, although these studies and trials have involved a small number of subjects or patients over a limited period of time. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trials of these product candidates, which could result in the delay or termination of their development, prevent regulatory approval, or limit their market acceptance if they are ultimately approved.

The safety or efficacy profile of INX-189 may differ in combination with other existing or future drugs used to treat chronic hepatitis C, and therefore may preclude its further development or approval, which could materially harm or business.

It is anticipated that in the future, the optimized treatment of chronic hepatitis C will involve the combination of three or more antiviral compounds. Accordingly, Phase II and Phase III clinical trials of other direct acting antiviral agents similar to INX-189 are now being conducted in combination with the current standard of care and increasingly, with other direct acting antivirals in clinical development. Therefore, the clinical development and commercialization pathway for INX-189, or any other product candidate we may develop in the future for the treatment of chronic hepatitis C, will require that it be evaluated in clinical trials in combination with other existing or future antivirals. Even if INX-189 demonstrates meaningful therapeutic benefits equal to or better than our competitor's compounds, an acceptable safety profile, and a dose amenable to combination therapy in Phase I and other early-stage clinical trials, INX-189 when combined with other HCV therapies, it may demonstrate unexpected side effects. We cannot assure you that INX-189 will be amenable for use in combination with some, or any, existing therapies or those in clinical development. Further, to evaluate INX-189 in combination therapy with other antivirals may require us to establish collaborations, licensing arrangements or alliances with third parties in the future. There is no assurance we will be able to enter into such arrangements on favorable terms, or at all.

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.

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; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity; manufacturing costs; intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, FV-100, INX-189, 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 potentially become available in the future for the treatment of shingles, chronic hepatitis C and the prevention of staphylococcal infections. Some of the large pharmaceutical companies that currently market products that would compete with our product candidates, if approved, include, but are not limited to: GlaxoSmithKline, Novartis and Merck in the shingles market and Merck and Roche in the hepatitis C market.

In addition to existing therapies, there are many other pharmaceutical and biopharmaceutical companies developing numerous direct acting antiviral product candidates across various classes of compounds for the

treatment of chronic hepatitis C, including, but not limited to, Abbott, Anadys Pharmaceuticals, Bristol Myers Squibb, Gilead, Idenix Pharmaceuticals, Johnson and Johnson, Merck, Novartis, Pfizer, Pharmasset, Roche, and Vertex , which may compete with INX-189 or any other HCV nucleotide polymerase inhibitor we may develop in the future. Most of the product candidates being developed by these companies, and in particular those that belong to the class of compounds referred to as protease inhibitors, are further advanced in their clinical development than INX-189. Further, Idenix Pharmaceuticals and Pharmasset are developing nucleotide analogues, which are similar to the approach we are using for INX-189. Moreover, their compounds have advanced further in clinical development and are currently in Phase II clinical trials.

While there are many direct acting antivirals in various stages of clinical development, none has yet to be approved for sale by the FDA or EMEA. Accordingly, the competitive landscape for the treatment of chronic hepatitis C is expected to be highly dynamic over the next five to ten years. In order to compete effectively in this market in the future, we believe a direct acting antiviral will need to demonstrate a favorable toxicity profile, superior potency, high resistance barriers, and be amenable to combination with other direct acting antivirals in a low fixed oral dose.

Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that would compete with FV-100 or INX-189, have substantially more capital resources than we have, and much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, manufacturing drug substances and drug products, and 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 classes of drugs from 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 them. 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.

We anticipate that our product candidates, and in particular FV-100 if successfully developed and approved, 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 intellectually 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.

We also face, and will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biopharmaceutical companies, and for attracting investigators and clinical sites capable of conducting our preclinical studies and 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 can 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 do not have significant internal drug discovery capabilities, and therefore we are primarily dependent on in-licensing or acquiring development programs from third parties in order to obtain additional product candidates.

While we are currently focused on developing our existing product candidates, if we sought to expand our pipeline, we would be largely dependent on in-licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely, on obtaining discoveries, new technologies, intellectual property and product candidates from third-parties through sponsored research, in-licensing arrangements or acquisitions. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources then we have, in obtaining these in-licensing, sponsored research or acquisition opportunities. Additional in-licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In-licensed compounds that appear promising in discovery, or research or preclinical studies may fail to progress into further preclinical studies 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. Three is a great deal of uncertainty inherent in our research efforts and as a consequence, our ability to expand our development pipeline with additional product candidates may not be successful.

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, decided on March 4, 2009, the U.S. 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 that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant 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 the amount of 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 product liability 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 activities involve the controlled use of certain hazardous materials and medical waste. Notwithstanding the regulations controlling the use and disposal of these materials as well as 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 at any time if we believe 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 have conducted or may conduct in the future may support further development of one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, nor gain meaningful acceptance, 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 currently 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 generic drugs currently used to treat shingles patients. Generic drugs are compounds that have no remaining patent protection, and generally have an average selling price substantially lower than drugs protected by patents and 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 may impose significant pricing pressure on patented 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 the ongoing Phase II trial or later-stage clinical trials of FV-100 will demonstrate any meaningful therapeutic benefits over existing generic drugs sufficient to justify its continued development. Further, if we successfully develop FV-100 and it is approved for sale, we cannot assure you that any real or perceived therapeutic benefits of FV-100 over generic drugs will result in a price higher than the existing generic drugs.

If the actual or perceived therapeutic benefits or the safety profile of INX-189 are not equal to or better than other direct anti-viral treatments in clinical development, or if the dosing of INX-189 is not amenable to combination with other existing or future anti-viral therapies for the treatment of chronic hepatitis C, we may terminate the development of INX-189 at any time, or our ability to generate significant revenue from the sale of INX-189, if approved, may be limited and our potential profitability could be harmed.

We are aware of a number of companies developing various classes of direct acting antiviral product candidates for the treatment of chronic hepatitis C, some of which are of a similar class to INX-189. Since many of these product candidates are further advanced in clinical development than INX-189, their time to approval and commercialization timelines may be sooner than those for INX-189. Accordingly, if at any time we believe that INX-189 may not provide meaningful therapeutic benefits, perceived or real, equal to or better than our competitor's compounds, or we believe that INX-189 may not have as favorable a safety profile as potentially competitive compounds, or we believe INX-189 may not be amendable for use in a combination therapy with existing or future treatments for chronic hepatitis C, we may delay or terminate the future development of INX-189 at any time. We cannot provide any assurance that future preclinical studies or clinical trials of INX-189 will demonstrate any meaningful therapeutic benefits over potentially competitive compounds in development, an acceptable safety profile sufficient to justify its continued development, or whether INX-189 is amenable to combination therapy.

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 ultimately approved for sale, our future profitability will depend largely on our ability to access or develop suitable marketing and sales 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 U.S. 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 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.

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 U.S. 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 organizations, 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. Further, the comparative effectiveness of new compounds over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by these payers to establish reimbursement rates. We may also 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 resources. We cannot assure you that any products we successfully develop will be reimbursed in part, or at all, by any third-party payers in any countries.

Domestic and foreign governments continue to propose legislation designed to expand the coverage, yet reduce the cost of healthcare including pharmaceutical drugs. In some foreign markets, governments control prescription drugs' pricing and profitability. In the U.S., significant changes in federal health care policy have been approved. Some of the legislation could result in reduced reimbursement rates. We expect that there will continue to be federal and state proposals to implement more governmental control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products domestically. 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. Further, pressure from social activist groups, whose goal it is to reduce the cost of drugs, particularly in less developed nations, also may put downward pressure on the price of drugs, which could result in downward pressure on the prices of our products in the absence of generic competition.

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 collaborator obtain the requisite regulatory approvals to commercialize them in the future, they may not gain market acceptance or utilization

among physicians, patients or third party payers. 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 relative to existing therapies, if they exist;
- the timing of market approval and existing marketed competitive drugs;
- the level of reimbursement provided by payers to cover the cost of the product;
- the cost of the product to the user or payer;
- the convenience and ease of administration of our products;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, prevalence and severity of side effects;
- 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 prescribe or administer our products, if approved, 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 a collaborator achieve market acceptance for our products, we may experience downward pricing pressure on the price of our products due to generic competition or social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability.

Many approved products are already available in generic form in certain markets and indications that we are developing our product candidates for, particularly for the treatment of shingles. If FV-100 is successfully developed and approved, 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, also may put downward pressure on the price of drugs, which could result in downward pressure on the prices of our products in the absence of generic competition.

If conflicts arise between our collaborators and us, our collaborators may act in their best interest and not in ours, which could delay or terminate the development of a product candidate and adversely affect our business.

Conflicts may arise with our existing or future collaborators if they pursue alternative therapies for the same diseases or indications that are targeted by compounds or intellectual property rights we have licensed to them. Potentially 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- or jointly-developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the collaboration, we may not be able to obtain certain development support or revenues that we anticipated receiving.

We may be unable to successfully develop a product candidate that is the subject of collaboration if our collaborator does not perform, terminates our agreement, or delays the development of our product candidate.

We 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 upon or anticipated, 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. For example, if an existing or future collaborator does not devote sufficient time and resources to our collaboration arrangement, we may not realize the full potential benefits of the arrangement, and our results of operations may be adversely affected.

A majority of the potential revenue from existing and future collaborations will likely consist of contingent payments, such as payments for achieving development or regulatory milestones and royalties payable on the sales of approved products. The milestone and royalty revenues that we may receive under these collaborations will depend primarily upon our collaborator's ability to successfully develop and commercialize our product candidates. In addition, our collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly involved in the development or commercialization of our product candidates and accordingly, will depend entirely on our collaborators. Our collaboration partners may fail to develop or effectively commercialize our product candidates because they:

- do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to fully support the product candidate through clinical development, regulatory approval and commercialization;
- are unable to obtain the necessary regulatory approvals, or re-evaluate the importance and their support for developing our product candidate in light of a revised pipeline, business or financial strategy.

In addition, a collaborator may decide to pursue the development of a competitive product candidate developed outside of our collaboration with them. If a collaboration partner fails to develop or effectively commercialize our product candidates for any of these reasons, we may not be able to replace them with another partner willing to develop and commercialize our product candidates under similar terms, if at all. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate. We cannot assure you that any product candidates will emerge from our relationships with Pfizer or any other future collaboration agreements we may enter into for any of our product candidates.

If we are unable to adequately protect or expand our intellectual property related to our current or future product candidates, our business prospects could be harmed.

Our success depends in part on our ability to:

- obtain and maintain intellectual property rights;
- 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 pharmaceutical 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 otherwise have intellectual property 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. Our future patent position will be influenced by the following factors:

- we or our licensors may not have been the first to discover 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, may not provide us with any competitive advantages, or may be challenged by third parties; and
- third parties may develop intellectual property around our or our licensors' patent claims to design competitive intellectual property and ultimately product candidates that fall outside the scope of our or our licensors' patents.

Because of the extensive time required for the development, testing and regulatory review and approval 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 approval and 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 U.S. 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 U.S. 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.

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, U.S. Patent and Trademark Office ("USPT") interference proceedings and related legal and administrative proceedings, both in the U.S. 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 protracted and expensive 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 U.S. are, in most cases, maintained in secrecy until approximately 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 that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding in the USPT office, or similar proceedings in other countries to determine the priority of invention. 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.

We are aware of other companies having filed patent applications attempting to cover broad classes of compounds to treat chronic hepatitis C in the U.S. and other countries. In the future, the USPT or a foreign patent office may grant patent rights to our product candidates or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may 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 need to obtain such licenses or sublicenses, but are unable to do so, 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.

It is becoming common for third parties to challenge patent claims on any successful product candidate or approved drug. If we become involved in any patent litigation, interference or other legal proceedings, we could 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.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Related to Owning Our Common Stock

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, 2009, we have incurred a cumulative deficit of approximately $245 million. Our losses to date have resulted principally from:

- costs related to supporting our research programs and the preclinical and 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 laboratory and preclinical testing and conduct extensive and expensive clinical trials for our product candidates. We cannot assure you that we will ever generate direct or royalty revenue from the sale of products, or ever become profitable.

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

Until we, or a collaborator, have 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, our existing collaboration arrangement allows our partner to terminate the agreement on relatively short notice. 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. Therefore, our historical and current revenues may not be indicative of our ability to achieve additional payment-generating milestones or events 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 formulation and 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.

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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") 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. Further effective as of the fiscal year of 2010 and onward, our independent auditor will attest on our internal control over financial reporting. 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 board of directors and management, as well as administrative, operational, and financial 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 affects our business. We will continue to incur additional expenses as a result of being a publicly-traded company.

In order to develop our product candidates and support our operations beyond 24 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 the price of our common stock could suffer a decline in value.

We anticipate that our existing cash and cash equivalents and short-term investments on hand as of the date of this filing, together with proceeds we expect to receive from our existing license and collaboration agreement will enable us to operate through 2011. We have no other committed sources of additional capital at this time. This guidance assumes that we completes our ongoing Phase II proof of concept trial of FV-100 in 2010 and initiate a Phase I clinical trial of INX-189 in the first half of 2010. This estimate does not include the direct costs associated with continuing the clinical development of FV-100 or INX-189 beyond these ongoing or planned clinical trials, or the impact of any other significant transaction or change in strategy or development plans in the future. 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 on any or all of our product candidates. We may also be forced to curtail, restructure, sell, or merge 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, assuming any such arrangements are available at all.

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 may be beyond our control, including:

- our development plans for our product candidates, including any changes in our strategy;
- 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 variability, timing and costs associated with conducting preclinical studies;
- the cost of formulating and manufacturing preclinical and clinical trial materials to evaluate our product candidates;
- receiving FDA approval to advance the clinical development of our product candidates in a timely manner, if at all
- the cost to obtain regulatory approvals required to advance the development of our product candidates:
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- future payments we may receive or make under existing or future license or collaboration agreements, if any;
- 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.

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;
- disclosure of any favorable or unfavorable data from our preclinical studies or clinical trials, or other regulatory developments concerning our clinical trials, the formulation and manufacturing of our 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 compounds;
- 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 U.S. or abroad;
- changes in patent legislation in the U.S. 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, or the perception that such future sales may occur;
- 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 and the Sarbanes-Oxley Act of 2002; and
- general economic conditions and capital markets.

In addition, the stock market in general, and more specifically the NASDAQ Capital Market, upon which our common stock trades, and the market for smaller 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 losses.

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.

Any issuance of equity we may undertake in the future to raise additional capital 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 newly issued 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, 2009, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 24.8% 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.

A significant number of shares of our common stock are subject to issuance upon exercise of outstanding warrants, which upon such exercise could result in dilution to our security holders.

As of December 31, 2009, there were outstanding warrants to purchase an aggregate of 14,053,318 shares of our common stock, which warrants had a weighted average exercise price of $1.19. The exercise price and/or the number of shares issuable upon exercise of our outstanding warrants may be adjusted in certain circumstances and subject to certain limitations, including upon the occurrence of certain reclassifications or mergers or certain subdivisions or combinations of the common stock, and the issuance of certain stock dividends. Although we cannot determine at this time which of these warrants may ultimately be exercised, it is reasonable to assume that a warrant may be exercised if the exercise price thereof is below the market price of our common stock at the time of exercise. To the extent any of our outstanding warrants are exercised in the future, additional shares of our common stock will be issued that will be eligible for resale in the public market, which could result in dilution to our security holders. The issuance of additional securities upon the exercise of warrants could also have an adverse effect on the market price of our common stock.

We do not anticipate paying cash dividends, and accordingly, stockholders must rely on appreciation in the price of our common stock for any return on their investment in us.

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation in the price of our common stock will provide a return to stockholders.

Our amended and restated certificate of incorporation, our amended and restated bylaws, as well as 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 a 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 10, 2010, the Company had 80 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, 2008.

	2009	
	High	Low
First Quarter	$ .37	$.21
Second Quarter	.56	.24
Third Quarter	1.33	.36
Fourth Quarter	1.25	.67
Year End Close		$.92

	2008	
	High	Low
First Quarter	$.90	$.65
Second Quarter	.80	.57
Third Quarter	.76	.35
Fourth Quarter	.40	.18
Year End Close		$.26

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 or treat serious infections. Our research and development efforts are currently focused on small molecule antiviral compounds, and in particular, orally-available therapies to treat herpes zoster, also referred to as shingles and chronic infections caused by hepatitis C virus ("HCV"). Currently available antiviral therapies have a number of therapeutic limitations that include inadequate potency, 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 antiviral product candidates have the potential to address a number of these limitations as well as unmet clinical needs in their respective intended indications. In addition to our antiviral programs, we have also licensed the rights to certain intellectual property from our

MSCRAMM protein platform to Pfizer for the development of active vaccines to prevent staphylococcal infections.

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 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, 2009, we had an accumulated deficit of $245 million.

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 primarily 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, milestone payments, royalties, or other product revenue agreements. In 2010, we expect our revenues will slightly increase from 2009 due to a milestone payment from Pfizer, Inc. (formerly, Wyeth) in connection with our collaboration agreement with them.

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 preclinical studies and supplies associated with development activities by internal staff; research chemistry; professional fees paid to third-party service providers in connection with conducting preclinical studies and 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 benefits and share-based compensation; the cost to formulate and manufacture product candidates; legal fees associated with patents and intellectual property; consulting fees; license and sponsored research fees paid to third parties; depreciation and laboratory facility costs. We charge all research and development expenses to operations as incurred.

The following table summarizes our research and development expense for the years ended December 31, 2009 and 2008. 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 and maintain licensed programs, payments to third parties for toxicological studies, 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, consulting fees, formulation and manufacturing materials for preclinical studies and clinical trials. All remaining research and development expenses, such as salaries and personnel-related expenses, legal fees associated with patents and intellectual property, supplies, depreciation, 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.

	Years Ended December 31,	
	2009	2008
	(In millions)	
Direct external costs:		
FV-100	$ 4.0	$ 3.7
HCV	3.3	0.9
Other preclinical programs	0.4	(0.5)
Unallocated costs and overhead	7.7	8.4
Total research and development expenses	$15.4	$12.5

We anticipate that our research and development expense will increase in 2010, as compared to 2009, due to our clinical development plans for FV-100 and INX-189. Due to the uncertainty regarding the timing and regulatory approval of preclinical studies and clinical trials, our future expenditures are likely to be highly volatile in future periods depending on the results of these trials and studies. 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 reflects the costs incurred to manage and support our research and development activities and corporate infrastructure. 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 2010, we expect our general and administrative expense to remain relatively consistent with our 2009 expenses.

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

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 U.S. 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 U.S. 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 accomplish 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, we will recognize such payments as earned when all of the conditions 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, or for employee services that have not been paid. This process primarily 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 connection with the formulation or manufacture of materials for our preclinical studies and clinical trials. In order to estimate costs incurred to date, but for which we 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.

Recent Accounting Pronouncements

On October 1, 2009, we adopted the amended guidance for the fair value measurement of investments in certain entities that calculate net asset value per share (or its equivalent). This amendment permits us to measure the fair value of certain investments, including those with fair values that are not readily determinable, on the basis of the net asset value per share of the investment (or its equivalent) if such net asset value is calculated in a manner consistent with the measurement principles as of our measurement date. This amendment also requires enhanced disclosures about the nature and risks of investments within its scope that are measured at fair value on a recurring or nonrecurring basis. The adoption of this amendment did not have a significant impact on our consolidated financial position or results of operations.

In October 2009, Financial Accounting Standards Board ("FASB") amended the guidance for revenue recognition in multiple-element arrangements. The guidance will require an entity to provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and the consideration allocated, and allocates revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence ("VSOE") or third-party evidence of selling price. The guidance also eliminates the use of the residual method and requires an entity to allocate revenue using the relative selling price method. This amendment is effective for us beginning January 1, 2011 and can be applied prospectively or retrospectively. We are currently evaluating the impact of this accounting amendment on our consolidated financial statements.

Results of Operations

Fiscal Years Ended December 31, 2009 and 2008

Summary. For 2009, we reported a net loss of $17.6 million, as compared to a net loss of $13.2 million in 2008 and basic and diluted net loss per share of $0.38 in 2009 as compared to $0.31 in 2008. The increase in net loss and net loss per share, as compared to 2008, was principally due to higher research and development expense associated with the clinical development of FV-100 and the preclinical development of INX-189 and the Company's HCV nucleoside polymerase inhibitor program, lower revenues from a collaborative license and development agreement and lower net interest income and other income, offset in part by a reduction in general and administrative expense. We expect to incur losses for the foreseeable future as we intend to continue to support the clinical development of FV-100, INX-189 and the preclinical development of other HCV nucleoside polymerase inhibitors.

Revenue. Revenue decreased to $1.2 million in 2009 from $3.2 million in 2008. This $2.0 million decrease was primarily the result of upfront license fees received by the Company in 2007 and 2008 being fully amortized to revenue as of the end of 2008, and to a lesser extent, lower periodic research-associated support fees received by the Company in 2009.

Research and Development Expense. Research and development expense increased to $15.4 million in 2009 from $12.5 million in 2008, representing an increase of $2.9 million, or 23%. The following table summarizes the components of our research and development expense for 2009 and 2008.

	December 31,	
	2009	2008
	(In millions)	
Direct preclinical, clinical and manufacturing expenses	$ 7.6	$ 4.1
Salaries, benefits and share-based compensation expenses	3.8	4.0
License fees, legal and other expenses	2.1	2.3
Depreciation and facility related expenses	1.9	2.1
Total research and development expense	$15.4	$12.5

Direct preclinical, clinical, and manufacturing costs increased due to a $2.4 million increase in costs related to preclinical studies and clinical trial material for INX-189 and our HCV program, a $0.3 million increase related to the initiation of the Phase II clinical trial of FV-100, and a $1.4 million increase related to a reduction in expense in 2008 associated with the favorable settlement of litigation, offset by $0.6 million decrease in other costs. Salaries, benefits and share-based compensation expense decreased slightly due to lower share-based compensation expenses and lower benefit costs. License fees, patent-related legal fees and other expenses decreased slightly due to reduced spending. Depreciation and facility related expenses decreased slightly due to a reduction in our facility costs as a result of partially subleasing our facility and lower operating costs.

General and Administrative Expense. General and administrative expense decreased to $3.6 million in 2009 from $5.1 million in 2008, representing a decrease of $1.5 million, or 29%. The following table summarizes the components of our general and administrative expense for 2009 and 2008.

	December 31,	
	2009	2008
	(In millions)	
Salaries, benefits and share-based compensation expenses	$1.6	$2.3
Professional and legal fees expenses	0.9	1.1
Other expenses	0.9	1.1
Depreciation and facility related expenses	0.2	0.6
Total general and administrative expense	$3.6	$5.1

Salaries, benefits and share-based compensation expense decreased primarily due to lower share-based compensation expense. Professional and legal fees decreased by $0.2 million due to lower consulting, legal and auditing expenses in 2009 than 2008. Other expenses decreased slightly due to lower insurance premiums and various other expenses. Depreciation and facility related expenses decreased due to a $0.3 million loss on rent accrual in 2008 that did not recur in 2009, and a reduction in our facility as a result of partially subleasing our facility and lower operating costs.

Interest and Other Income, net. Interest and other income, net decreased to $0.2 million for 2009 from $1.3 million in 2008. The decrease of $1.1 million was largely the result of a decrease in net interest income in 2009 primarily due to lower interest rates in 2009 than 2008.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in May 1994 through December 31, 2009, we have funded our operations primarily with $237.4 million in gross proceeds raised from a series of five private equity financings, our IPO in June 2004, and three private investment in public equity financings ("PIPE").

From inception through December 31, 2009, 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 $16.0 million in license fees, collaborative research payments and grants, of which $0.3 million and $0.7 million were recorded as deferred revenue as of December 31, 2009 and December 31, 2008, respectively.

At December 31, 2009, cash, cash equivalents and short-term investments were $37.9 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 U.S. treasury securities, U.S. government agency securities, commercial paper, corporate debt and money market accounts that have an average maturity date of less than 12 months.

Cash Flows

For the year ended December 31, 2009, cash, cash equivalents, and short-term investments increased by $4.8 million, from $33.1 million to $37.9 million. This increase was primarily the result of the net proceeds from the issuance of common stock and warrants of $21.5 million, offset by net cash used for operating activities and to a lesser extent, the repayment of capital lease obligations and notes payable.

Net cash used for operating activities was $16.1 million in 2009, which reflects our net loss for the period of $17.6 million, offset in part by a net increase in operating liabilities over operating assets of $0.1 million and non-cash charges of $1.4 million. Our net loss resulted largely from the cost of funding our clinical trials, preclinical studies, 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 net increase in operating liabilities over operating assets reflects a $0.6 million increase in accrued expenses and a $0.1 million increase in accounts payable, offset in part by a $0.2 million increase in prepaid expenses and other assets and a $0.4 million decrease in deferred revenue.

Net cash used for investing activities was $5.2 million, which primarily consisted of net proceeds from short-term investments of $5.2 million and $0.1 million in proceeds from sale of equipment, offset in part by $0.1 million in cash paid for capital expenditures.

Net cash from financing activities was $21.2 million, which consisted of $21.5 million of net proceeds from the issuance of common stock and warrants during 2009, offset by $0.3 million in scheduled payments on our capital leases and notes payable.

Funding Requirements

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

- our development plans for our product candidates, including any changes in our strategy;
- 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 variability, timing and costs associated with conducting preclinical studies;
- the cost of formulating and manufacturing preclinical and clinical trial materials to evaluate our product candidates;
- receiving regulatory approval to advance the clinical development of our product candidates in a timely manner, if at all;
- the cost to obtain regulatory approvals required to advance the development of our product candidates;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- future payments we may receive or make under existing or future license or collaboration agreements, if any;

- 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 product candidates on our planned timelines, we believe that our existing cash, cash equivalents and short-term investments of $37.9 million as of December 31, 2009, including anticipated proceeds from our existing license and collaboration agreements, will enable us to operate for a period of at approximately 24 months. Our estimate assumes that we complete the ongoing Phase II proof of concept trial of FV-100 and initiate a Phase I clinical trial of INX-189 in the first half of 2010. This estimate does not include the direct costs associated with continuing the clinical development of FV-100 or INX-189 beyond these ongoing or planned clinical trials, or the impact of any other significant transaction or change in strategy or development plans in the future.

We currently do not have any commitments for future funding, nor do we anticipate that we will generate significant revenue from the sale of any products in the foreseeable future. Therefore, in order to meet our anticipated liquidity needs beyond 24 months 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, or 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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Atlanta, Georgia
March 26, 2010

INHIBITEX, INC.

Consolidated Balance Sheets

	December 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,290,332	$ 11,507,137
Short-term investments	26,625,496	21,634,880
Prepaid expenses and other current assets	831,196	621,797
Accounts receivable	61,062	108,558
Total current assets	38,808,086	33,872,372
Property and equipment, net	1,621,392	2,328,707
Other assets	40,290	31,876
Total assets	$ 40,469,768	$ 36,232,955
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,590,804	$ 1,276,215
Accrued expenses	1,537,637	1,001,047
Current portion of notes payable	78,125	312,500
Current portion of capital lease obligations	207,100	254,291
Current portion of deferred revenue	191,667	441,667
Other current liabilities	202,531	224,922
Total current liabilities	3,807,864	3,510,642
Long-term liabilities:		
Notes payable, net of current portion	546,875	390,625
Capital lease obligations, net of current portion	180,792	387,892
Deferred revenue, net of current portion	87,500	237,500
Other liabilities, net of current portion	1,096,629	1,279,994
Total long-term liabilities	1,911,796	2,296,011
Total liabilities	5,719,660	5,806,653
Stockholders' equity:		
Preferred stock, $.001 par value; 5,000,000 shares authorized at December 31, 2009 and 2008, none issued and outstanding at December 31, 2009 and 2008	—	—
Common stock, $.001 par value; 150,000,000 and 75,000,000 shares authorized at December 31, 2009 and 2008, respectively; 61,559,782 and 43,380,570 shares issued and outstanding at December 31, 2009 and 2008, respectively	61,560	43,381
Additional paid-in capital	267,432,572	243,825,057
Accumulated other comprehensive income	8,977	111,450
Warrants	12,133,216	13,742,630
Accumulated deficit	(244,886,217)	(227,296,216)
Total stockholders' equity	34,750,108	30,426,302
Total liabilities and stockholders' equity	$ 40,469,768	$ 36,232,955

See accompany notes to the consolidated financial statements

INHIBITEX, INC.

Consolidated Statements of Operations

	Year Ended December 31,	
	2009	2008
Revenue:		
License fees and milestones	$ 150,000	$ 1,650,000
Collaborative research and development	1,000,000	1,500,000
Total revenue	1,150,000	3,150,000
Operating expense:		
Research and development	15,393,066	12,548,430
General and administrative	3,551,682	5,075,048
Total operating expense	18,944,748	17,623,478
Loss from operations	(17,794,748)	(14,473,478)
Other income, net	36,535	87,651
Interest income, net	168,212	1,224,584
Net loss	$(17,590,001)	$(13,161,243)
Basic and diluted net loss per share	$ (0.38)	$ (0.31)
Weighted average shares used to compute basic and diluted net loss per share	46,664,811	43,090,432

See accompany notes to the consolidated financial statements

INHIBITEX, INC.

Consolidated Statement of Stockholders' Equity

	Series A Preferred Stock		Common Stock Subscription		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Common Stock Warrants	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value	Shares	Par Value	Shares	Par Value					
Balance at January 1, 2008	—	$—	—	$—	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
Exercise of stock options and issuances of restricted stock and employee stock purchase plan	—	—	—	—	221,175	221	34,971	—	—	—	35,192
Expiration of common stock warrants	—	—	—	—	—	—	5,548,103	—	(5,548,103)	—	—
Repurchase of common stock and retirement	—	—	—	—	(10,710)	(11)	(3,202)	—	—	—	(3,213)
Share-based compensation expense	—	—	—	—	—	—	515,386	—	—	—	515,386
Net issuance of common stock and warrants in connection with private placement	—	—	—	—	17,968,747	17,969	17,512,257	—	3,938,689	—	21,468,915
Net loss	—	—	—	—	—	—	—	—	—	(17,590,001)	(17,590,001)
Other comprehensive loss	—	—	—	—	—	—	—	(102,473)	—	—	(102,473)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(17,692,474)
Balance at December 31, 2009	—	$—	—	$—	61,559,782	$61,560	$267,432,572	$ 8,977	$12,133,216	$(244,886,217)	$ 34,750,108

See accompany notes to the consolidated financial statements

INHIBITEX, INC.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2009	2008
Cash flows from operating activities:		
Net loss	$(17,590,001)	$(13,161,243)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	806,152	837,094
Share-based compensation expense	515,386	1,491,119
Gain on sale of property and equipment	(39,890)	(74,076)
Amortization of investment premium or discount	84,224	(647,417)
Changes in operating assets and liabilities, net of acquisition:		
Prepaid expenses and other assets	(217,813)	411,812
Accounts receivable	47,496	(63,570)
Accounts payable and other liabilities	108,833	335,098
Accrued expenses	536,590	(5,367,203)
Deferred revenue	(400,000)	(150,000)
Net cash used in operating activities	(16,149,023)	(16,388,386)
Cash flows from investing activities:		
Purchases of property and equipment	(98,837)	(468,507)
Purchases of investments	(34,367,313)	(45,913,947)
Proceeds from maturities and sales of investments	29,190,000	61,019,763
Proceeds from sale of property and equipment	39,890	81,730
Cash paid in connection with the acquisition	—	(179,222)
Net cash provided by (used in) investing activities	(5,236,260)	14,539,817
Cash flows from financing activities:		
Proceeds from capital lease financing	—	368,121
Payments on promissory note and capital leases	(332,416)	(1,075,153)
Repurchase of common stock	(3,213)	(130,583)
Proceeds from the issuance of common stock	35,192	15,178
Proceeds from the issuance of common stock and warrant in connection with private placement	22,999,996	—
Financing costs in connection with private placement	(1,531,081)	—
Net cash provided by (used in) financing activities	21,168,478	(822,437)
Decrease in cash and cash equivalents	(216,805)	(2,671,006)
Cash and cash equivalents at beginning of period	11,507,137	14,178,143
Cash and cash equivalents at end of period	$ 11,290,332	$ 11,507,137
Supplemental cash flow information:		
Interest paid	$ 64,054	$ 67,972
Non-cash investing and financing activities:		
Fixed assets capitalized using capital lease	$ —	$ 269,854

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 focused on small molecule antiviral compounds, and in particular, orally-available therapies to treat herpes zoster, also referred to as shingles and chronic infections caused by HCV. Currently available antiviral therapies have a number of therapeutic limitations that include inadequate potency, significant adverse side effects, complex dosing schedules, inconvenient methods of administration, and diminishing efficacy due to the emergence of drug-resistant viruses. The Company believes that its antiviral drug candidates have the potential to address a number of these limitations as well as unmet clinical needs in their respective intended indications. In addition to the Company's antiviral programs, it has also licensed the rights to certain intellectual property from its MSCRAMM protein platform to Pfizer for the development of active vaccines to prevent staphylococcal infections.

The Company has not received regulatory approval for any of its product candidates, and the Company does not have any commercialization capabilities; therefore, it is possible that the Company may never successfully derive any significant revenues from any of its existing or future product candidates.

The Company plans to continue to finance its operations with its existing cash, cash equivalents and short-term investments, or through future equity and/or debt financings; with proceeds from existing or potential future collaborations or partnerships; or through 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 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. The Company includes Inhibitex, Inc., a subsidiary FermaVir Pharmaceuticals and its subsidiary FermaVir Research Corp. The accompanying consolidated financial statements include all accounts of the Company and its subsidiaries. All intercompany 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. 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 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.

Available-for-sale securities as of December 31, 2009 and 2008 consisted primarily of U.S. treasury bills, commercial paper, U.S. government agency obligations, corporate debt and money market funds.

Fair Value Measurements. In 2008, the Company adopted the guidance related to fair value measurements pertaining to financial assets and liabilities. On January 1, 2009, the Company adopted guidance related to fair value measurements pertaining to nonfinancial assets and nonfinancial liabilities. This guidance establishes the authoritative definition of fair value, which sets out a framework for measuring fair value and expands the required disclosures about fair value measurement. The Company's nonfinancial assets are not required to be carried at fair value on a recurring basis, but if certain triggering events such that a nonfinancial asset is required to be evaluated for asset impairment the nonfinancial asset will be recorded at the lower of cost or fair value. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Fair Value of Financial Instruments. Cash, cash equivalents and short-term investments are reported at fair value. The Company believes the recorded values of all of our other financial instruments approximate their current fair values. The Company may expand opportunities to use fair value measurement in financial reporting and permits the Company to choose to measure many financial instruments and certain other items at fair value. The Company did not elect to measure any new assets or liabilities at the respective fair values pursuant to the fair value option.

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

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

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.

Revenue Recognition. To date, the Company has not generated any significant revenue from the sale of products. Revenue relates to fees recovered or received for licensed intellectual property, collaborative research and development agreements, and materials transfer agreements to the Company. 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 or accomplished pursuant to the terms of the related agreements. Development milestone payments are recognized as revenue when the Company has achieved the specific milestone and collectability is assured. Any amounts received in advance of the performance of the related activities are recorded as deferred revenue until earned.

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 or earned internal services that have not been paid. 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. In order to estimate costs incurred to date, but have not been invoiced, the Company will 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. The Company 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 prepaid expenses and other assets that the Company has made an advance payment for and that services to be

performed or asset utilization will occur in the future. As services are performed or asset utilization occurs the Company recognizes the expense and the prepaid or other asset are amortized by the corresponding amount.

Share-based Compensation. The Company uses the Black-Scholes method to estimate the value of share-based awards granted. The Company's forfeiture rate is based on historical experience as well as anticipated future 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 graded vesting awards is recognized on the straight-line method.

Concentrations of Credit Risk. Cash, cash equivalents and short-term investments 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 formulate or manufacture its product candidates, due to inherent FDA current good manufacturing practices, ("cGMP") requirements. 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 affect the Company's operating results.

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 preclinical studies and supplies associated with development activities by internal staff; research chemistry; professional fees paid to third-party service providers in connection with conducting preclinical studies and 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 benefits and share-based compensation; the cost to formulate and manufacture product candidates; legal fees associated with patents and intellectual property; consulting fees, license and sponsored research fees paid to third parties; depreciation and laboratory facility costs. The Company charges all research and development expenses to operations as incurred.

General and Administrative Expense. General and administrative expense reflects the costs incurred to manage and support our research and development activities. 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 as a result of being publicly-traded, and depreciation and facility expenses.

Income Taxes. The Company utilizes the liability method of accounting for income taxes. 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. The Company has no uncertain tax positions and 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.

Comprehensive Loss. 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 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 expense over ten 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 liability. The balance of these deferred rent liabilities are classified in the balance sheet as other liabilities.

Recent Accounting Pronouncements. On October 1, 2009, the Company adopted the amended guidance for the fair value measurement of investments in certain entities that calculate net asset value per share (or its equivalent). This amendment permits the Company to measure the fair value of certain investments, including those with fair values that are not readily determinable, on the basis of the net asset value per share of the investment (or its equivalent) if such net asset value is calculated in a manner consistent with the measurement principles as of the Company's measurement date. This amendment also requires enhanced disclosures about the nature and risks of investments within its scope that are measured at fair value on a recurring or nonrecurring basis. The adoption of this amendment did not have a significant impact on the Company's consolidated financial position or results of operations.

In October 2009, the FASB amended the guidance for revenue recognition in multiple-element arrangements. The guidance will require an entity to provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and the consideration allocated; and allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence ("VSOE") or third-party evidence of selling price. The guidance also eliminates the use of the residual method and requires an entity to allocate revenue using the relative selling price method. This amendment is effective for the Company beginning January 1, 2011 and can be applied prospectively or retrospectively. We are currently evaluating the impact of this accounting amendment on our consolidated financial statements.

3. Net Loss Per Share

Basic and diluted net loss per share have been computed based on net loss and the weighted-average number of common shares outstanding during the applicable period. For diluted net loss per share, common stock equivalents (common shares issuable upon the exercise of stock options, restricted stock and warrants) are excluded from the calculation of diluted net loss per share if their effect is antidilutive. The Company has excluded all options, restricted stock and warrants to purchase common stock, as such potential shares are antidilutive.

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

	Year Ended December 31,	
	2009	2008
Historical		
Numerator:		
Net loss	$(17,590,001)	$(13,161,243)
Denominator:		
Weighted average common shares outstanding	46,664,811	43,090,432
Basic and diluted net loss per share	$ (0.38)	$ (0.31)

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 antidilutive.

	December 31, 2009	December 31, 2008
Common stock options	5,740,908	4,820,459
Restricted common stock	—	140,000
Common stock warrants	14,053,318	8,022,863
Total	19,794,226	12,983,322

4. Fair Value Measurements

A fair value hierarchy has been established which requires the Company to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The fair value hierarchy 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, 2009, by level within the fair value hierarchy. The 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.

December 31, 2009	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	$10,380,463	$10,380,463	$ —	$—
Short-term investments available-for-sale	26,625,496	504,023	26,121,473	—
Total	$37,005,959	$10,884,486	$26,121,473	$—

Cash equivalents consist primarily of money market funds and commercial paper with original maturity dates of three months or less. Short-term investments consist of U.S. agency securities, U.S. Treasury securities and corporate debt, 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 had no realized gains or losses from the sale of investments for the twelve months ended December 31, 2009. The following table shows the unrealized gains and losses and fair values for those investments as of December 31, 2009 and December 31, 2008 aggregated by major security type:

December 31, 2009	At Cost	Unrealized Gains	Unrealized (Losses)	At Fair Value
Certificates of deposit and money market funds	$10,380,463	$ —	$ —	$10,380,463
Commercial paper	9,635,631	9,145	—	9,644,776
Corporate debt	9,183,702	956	(5,006)	9,179,652
Debt securities of U.S. government agencies	7,293,200	5,273	(1,428)	7,297,045
US Treasury securities	503,986	103	(66)	504,023
Total	$36,996,982	$15,477	$(6,500)	$37,005,959

December 31, 2008	At Cost	Unrealized Gains	Unrealized (Losses)	At Fair Value
Certificates of deposit and money market funds	$11,603,992	$ —	$ (386)	$11,603,606
Commercial paper	845,999	1,551	—	847,550
Corporate debt	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	754,641	157	(36)	754,762
Total	$32,785,691	$120,780	$(9,330)	$32,897,141

As of December 31, 2009, the Company had investments in an unrealized loss position. The Company has determined that the unrealized losses on these investments at December 31, 2009 are temporary in nature and expects the security to mature at its stated maturity principal. All available-for-sale securities held at December 31, 2009 will mature within one year or less.

5. Prepaid Expenses

The components of prepaid expenses are as follows:

	December 31, 2009	December 31, 2008
Interest receivable	$166,967	$ 78,004
Prepaid direct preclinical, clinical and manufacturing	392,797	102,756
Prepaid other	271,432	441,037
Total	$831,196	$621,797

6. Property and Equipment

The components of property and equipment are as follows:

	December 31, 2009	December 31, 2008
Laboratory equipment	$ 2,044,804	$ 3,034,990
Leasehold improvements	2,455,321	2,455,321
Computer software and equipment	671,227	574,798
Office furniture and fixtures	115,002	115,002
Sub-total	5,286,354	6,180,111
Less accumulated depreciation and amortization	(3,664,962)	(3,851,404)
Total property and equipment, net	$ 1,621,392	$ 2,328,707

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 and amortization expense was $806,152 and $966,345 for the years ended December 31, 2009 and 2008, respectively.

In 2009, the Company retired $912,594 of laboratory equipment with a net asset value of $71,664. In 2008, the Company retired $653,330 in various equipment and software with a net asset value of $21,601. Remaining net asset value is charged to depreciation expense upon retirement.

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 $413,521 and $616,821 as of December 31, 2009 and 2008.

7. Accrued Expenses

The components of accrued expenses are as follows:

	December 31, 2009	December 31, 2008
Preclinical, clinical and manufacturing development expense	$ 410,207	$ 149,019
Payroll and benefits expense	481,765	306,694
Professional fee expense	252,802	309,022
Other operating expense	392,863	236,312
Total	$1,537,637	$1,001,047

8. Commitments

Lease Commitments. In May 2005, the Company began a non-cancelable ten year agreement to lease a 51,000 square foot research and office facility. 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 the life of the 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 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 period 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 ten 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 liability. The balance of these deferred 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. 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 was $181,012 and $231,445 as of December 31, 2009 and 2008, respectively, and is classified in the balance sheet as other liabilities (See Note 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, 2009 and 2008, gross rent expense totaled approximately $932,000 and $920,000, respectively; these amounts were offset against sublease rental receipts of $119,000 and $104,000, respectively. Future minimum payments and receipts under these operating leases at December 31, 2009 are as follows:

Year Ending December 31,	Payments	Receipts
2010	$ 926,555	$ 97,500
2011	948,710	102,000
2012	967,940	106,500
2013	992,137	111,000
2014 and after	1,358,697	—
Total minimum lease payments and receipts under operating leases	$5,194,039	$417,000

Other Commitments. In October 2009, the Company entered into a second exclusive royalty-bearing worldwide license agreement with Cardiff University in Wales, United Kingdom for intellectual property covering a HCV nucleoside polymerase inhibitor in exchange for 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 intellectual property. The Company may terminate this agreement upon 90 days notice. Pursuant to the above license agreements, the Company entered into a series of cooperative research agreements with Cardiff University for which the Company has a future minimum purchase commitment of approximately 205,000 pounds sterling in annual cooperative research agreement funding as of December 31, 2009. However, the Company may terminate the collaboration agreement on three months written notice and Cardiff 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 August 2011 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.

Future payments under capital lease agreements as of December 31, 2009 are as follows:

Year Ending December 31,	
2010	$ 238,658
2011	188,913
2012	—
Total future minimum lease payments	427,571
Less amount representing interest	(39,679)
Present value of future minimum lease payments	387,892
Less current portion of capital lease obligations	(207,100)
Long-term portion of capital lease obligations	$ 180,792

Notes Payable. On August 3, 2009, the Company entered into a second amendment to its interest free loan agreement with a local development authority for laboratory — related leasehold improvements at the Company's research and headquarters' facility. Under the amended agreement the Company will make one payment of $78,125 on January 1, 2010 and then make eight quarterly installments of $60,764 beginning January 1, 2011 with a final payment $60,763 payable on January 1, 2013. As of December 31, 2009 and December 31, 2008, $625,000 and $703,125 were outstanding under this note payable, respectively. The loan is secured by leasehold lab improvements of the Company's facility.

Future minimum payments due under notes payable as of December 31, 2009 are as follows:

Year Ending December 31,	
2010	$ 78,125
2011	243,056
2012	243,056
2013	60,763
Total future payments	$625,000

10. Other Liabilities

The components of other liabilities are as follows:

	December 31,	
	2009	2008
Deferred amortization of leasehold improvements and deferred rent	$1,106,873	$1,240,764
Other	192,287	264,152
Less current portion of other liabilities	(202,531)	(224,922)
Long term portion of other liabilities	$1,096,629	$1,279,994

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

the 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, respectively. In addition, the Company took possession 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 ten year life of the lease. Further, the Company recognizes rent expense on a straight-line basis over the life of the lease. The difference between cash rent payments and rent expense is recorded as deferred rent. The balance of these deferred rent liabilities are classified in the balance sheet as other liabilities.

11. Income Taxes

At December 31, 2009, the Company had available federal net operating loss ("NOL") carry forwards of approximately $195,301,959 and state NOL carry forwards of $186,110,455 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 stockholders' equity. The Company also has approximately $4,062,560 of research and development ("R&D") tax credit carry forwards as of December 31, 2009 which begin to expire in the year 2017. Included in the Company's carry forwards 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.

The Company has no uncertain tax positions. As of December 31, 2009 and 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, 2009. 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.

The Company's income tax expense was $0 for years ended December 31, 2009 and 2008. The primary factors causing income tax expense to be different than the federal statutory rates are as follows:

	December 31,	
	2009	2008
Income tax benefit at statutory rate	$(5,980,600)	$(4,474,823)
State income tax benefit, net of federal tax benefit	(644,536)	(548,995)
IPR&D expense	—	(43,945)
General business credit	(456,792)	(425,273)
Other	446,713	(194,829)
Valuation allowance	6,635,215	5,687,865
Income tax expense	$ —	$ —

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

	December 31, 2009	December 31, 2008
Deferred tax assets:		
Net operating loss carry forwards	$ 73,770,008	$ 67,294,096
Research and development tax credit carry forwards	4,062,559	3,605,767
Depreciation and amortization	1,826,603	1,809,081
Accruals and reserves	405,314	138,765
Compensation accruals	929,661	1,133,880
Deferred revenue	105,972	257,812
Other, net	(32,981)	192,520
Total deferred tax assets	81,067,136	74,431,921
Less valuation allowance	(81,067,136)	(74,431,921)
Net deferred tax assets	$ —	$ —

For financial reporting purposes, a valuation allowance is 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 assets due to uncertainties with respect to the Company's ability to generate sufficient taxable income in the future. The valuation allowance increased by $6,635,215 and $8,931,986 in 2009 and 2008, respectively, as follows:

	December 31, 2009	December 31, 2008
Deferred tax valuation allowance at beginning of year	$74,431,921	$65,499,935
Change in cumulative tax due to FermaVir acquisition	—	3,244,121
Change in cumulative tax differences	6,635,215	5,687,865
Deferred tax valuation allowance at end of year	$81,067,136	$74,431,921

12. Stockholders' Equity

Common Stock. In June 2009, the Company's stockholders approved an amendment to the Company's Eighth Amended and Restated Certificate of Incorporation to increase the Company's authorized common stock, $0.001 par value per share, from 75,000,000 shares to 150,000,000 shares. As of December 31, 2009 and 2008, the Company was authorized to issue 150,000,000 and 75,000,000 shares of common stock, respectively. Each holder of common stock is entitled to one vote for each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

Private Placement. On October 28, 2009, the Company completed a private placement ("offering") in which it raised $22,999,996 in gross proceeds through the sale of units, at a price of $1.28 per unit. Each unit consisted of one share of common stock and a warrant to purchase 0.45 of a share of common stock. In connection with the offering, the Company incurred financing costs of $1,531,081 resulting in net proceeds of $21,468,915, exclusive of any proceeds that might be received upon exercise of the warrants. Pursuant to the offering, the Company issued an aggregate of 17,968,747 shares of its common stock and warrants to purchase an aggregate of 8,085,932 shares of its common stock. The warrants expire on October 28, 2013 and have an exercise price of $1.46 per share.

Pursuant to the terms of the offering, the Company filed a registration statement with the Securities Exchange Commission. If the Company fails to keep the registration statement effective for three years by not filing periodic reports with the Securities Exchange Commission it has agreed to pay the offering investors liquidated damages equal to 1% (up to a maximum of 10%) of the aggregate purchase price paid for each 30 day period the registration statement ceases to be effective.

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, 2009. 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 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, 2009, the Company had 2,824 shares committed to be released to employees and had granted 94,704 shares out of the plan. The Company recorded $2,873 of share-based compensation expense on all discounts to the fair market value during the purchase period of 2009.

Common Stock Warrants. In 2009, a total of 2,055,477 warrants expired with a weighted average exercise price of $8.81. The total Black-Scholes value of those warrants was $5,548,103 and such amount was reclassified from warrants to additional paid-in capital. Additionally in 2009, the Company issued a total of 8,085,932 warrants with an exercise price of $1.46 and a total Black-Scholes value of $3,938,689 in connection with the private placement.

As of December 31, 2009 and 2008, there were 14,053,318 and 8,022,863 warrants outstanding, respectively. As of December 31, 2009, all of the outstanding warrants are exercisable and expire from January 18, 2010 to September 26, 2018. The weighted average strike price as of December 31, 2009 and 2008 was $1.19 and $2.87, respectively.

Share-Based Award Plans

The Company has two active share-based award plans as described below. For the twelve months ended December 31, 2009 and 2008, the Company recorded share-based compensation expense related to grants from these plans of $515,386 and $1,491,119, or $0.01 and $0.03 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, 2009 and 2008.

1998 Equity Ownership Plan. In May 1998, the Board of Directors approved the 1998 Equity Ownership Plan (the "Plan"), which provided for the grant of stock options to directors, officers, employees and consultants. Under the Plan, both incentive stock options and non-qualified stock options, among other equity related awards, could be granted. The Board of Directors determined the term and vesting dates of all options at their grant date, provided that such price shall not be less than the fair market value of the Company's stock on the date of grant. Under the Plan, the maximum term for an option grant is ten years from the grant date, and options generally vest ratably over a period of four years from the grant date. As discussed below, upon the adoption of the 2002 Stock Incentive Plan ("2002 Plan"), no additional grants of stock option grants or equity awards were authorized under the 1998 Equity Ownership Plan. All options outstanding under the Plan remain in full force and effect until they expire or are exercised. However, future forfeitures of any stock options granted under the 1998 Equity Ownership Plan are added to the number of shares available under the 2002 Plan.

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 is 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 the maximum term for an award is ten years from the grant date. As of December 2009, an aggregate of 8,718,428 shares of common stock were reserved for issuance under the 2004 Plan. As of December 31, 2009, there were 5,740,908 outstanding option awards to purchase the Company's common stock, with 628,890 shares available for grant under the 2004 Plan.

The following is a summary of all share-based activity and related information about the Company's share-based award plans for 2009 and 2008.

Stock Options. The fair value of each time-based stock award was estimated at the date of grant using the Black-Scholes method in 2009 and 2008 with the following assumptions:

	December 31,	
	2009	2008
Risk-free interest rate	1.51%	2.72%
Expected life	3.1 years	4 years
Weighted average fair value of options granted	$ .44	$ .43
Volatility	.71	.68

The risk-free interest rate is based on the expected life of the option and the corresponding U.S. Treasury bond. The expected life of stock options granted is derived from actual and forecasted option exercise patterns and represents the period of time that options granted are expected to be outstanding. The Company uses

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

	Number of Options	Weighted-Average Exercise Price per Option	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value ($000)
Balance at December 31, 2008	4,820,459	$2.33		
Granted	1,530,500(1)	$0.97		
Exercised	(35,349)	$0.68		
Forfeited or expired	(574,702)	$2.62	—	—
Balance at December 31, 2009	5,740,908(1)	$1.95	5.02	$88
Vested or expect to vest at December 31, 2009	5,591,512	$1.97	5.02	$87
Exercisable at December 31, 2009	3,154,042	$2.61	4.65	$38

(1) Includes performance-based options of 910,000, subject to specific performance conditions.

Time-based stock options granted during the twelve month period ended December 31, 2009 were 620,500 with a weighted-average exercise price of $0.92. The weighted-average grant date fair value of time-based stock options granted during the twelve month period ended December 31, 2009 was $0.44, using the assumptions in the above table. As of December 31, 2009, there was $985,924 of total unrecognized share-based compensation expense related to unvested stock option awards (excluding performance-based options as discussed below), not discounted for future forfeitures. This unrecognized expense is expected to be recognized over a weighted-average period of 1.7 years.

Performance-based stock options granted during the twelve month period ending December 31, 2009 were 910,000 with an exercise price of $1.00 with total unrecognized share-based compensation expense of $377,650. Vesting is contingent upon meeting specific performance goals with respect to FV-100 and INX-189. As of December 31, 2009, no share-based compensation expense related to performance-based options has been recognized as it is not probable that the performance condition will be achieved. The Company will evaluate the probability of achieving these performance goals quarterly, and if the Company determines that it is probable that a performance goal will occur, the effect of the change in estimate will be accounted in the period of change by recording a cumulative catch-up adjustment to retroactively apply the new estimate. As of December 31, 2009, all performance-based options are unvested and expire five-years from the grant date or will be forfeited upon not achieving performance goals.

The total intrinsic value of stock options exercised during the twelve month period ended December 31, 2009 was $32,121, from which the Company received cash proceeds of $24,037. 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, 2009:

	December 31, 2009				
	Outstanding			Exercisable	
Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$0.29 — $0.97	357,062	5.41	$0.66	200,812	$0.72
$1.00	1,460,000	4.35	1.00	—	—
$1.22 — $1.36	592,500	5.11	1.36	585,000	1.36
$1.45	1,912,900	6.93	1.45	958,950	1.45
$1.62 — $2.27	891,234	3.67	2.05	891,234	2.05
$2.91 — $9.38	526,687	1.88	7.80	517,521	7.87
$9.69	525	.03	9.69	525	9.69
	5,740,908	5.02	$1.95	3,154,042	$2.61

Restricted Stock Awards. A summary of the Company's restricted stock as of December 31, 2009 is presented below:

Restricted Stock	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2008	140,000	$1.76
Granted	—	—
Released	(140,000)	$1.76
Forfeited	—	—
Outstanding at December 31, 2009	—	$ —

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

	December 31, 2009	December 31, 2008
Common stock options	5,740,908	4,820,459
Restricted common stock	—	140,000
Common stock warrants	14,053,318	8,022,863
Total	19,794,226	12,983,322

13. Comprehensive Loss

The components of comprehensive loss for the twelve months ended December 31, 2009 and 2008 are as follows:

	Twelve Months Ended December 31	
	2009	2008
Net loss	$(17,590,001)	$(13,161,243)
Change in net unrealized gains (losses) on investments	(102,473)	4,970
Comprehensive loss	$(17,692,474)	$(13,156,273)

14. 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 intellectual property.

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 Company has an obligation to pay a minimum payment of $15,000 annually until the license agreement expires or is terminated. 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 intellectual property.

In October 2009, the Company entered into a second exclusive royalty-bearing worldwide license agreement with Cardiff University in Wales, United Kingdom, for intellectual property for a HCV nucleoside polymerase inhibitor in exchange for 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 intellectual property. The Company has an obligation to pay a minimum payment of $7,500 annually until the license agreement expires or is terminated. Pursuant to the agreements, the Company entered into a series of cooperative research agreements with Cardiff University for annual sponsored research payments.

Texas A&M University Health Science Center. The Company has licensed, on an exclusive basis, from the Texas A&M University System ("Texas AM") a number of issued U.S. patents, their related pending U.S. divisional applications and corresponding international filings with claims to MSCRAMM nucleic acids, proteins, antibodies, and vaccines. BioResearch Ireland/Trinity College Dublin is a co-owner of certain issued patents and patent applications. 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. The Company has an obligation to pay a minimum payment of $25,000 annually until the license agreement expires or is terminated.

BioResearch Ireland. The Company obtained an exclusive royalty-bearing license from BioResearch Ireland ("BRI") under two issued U.S. patents and a pending U.S. patent application directed to the ClfA nucleic acid, protein, and antibodies. The Company may terminate the license agreement as to any patent or patent application upon 90 days notice. We have agreed to pay BRI a royalty based on net sales for any product sold utilizing these licenses.

University of Georgia Research Foundation. 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 future milestone payments and royalties on future net sales. In addition, the Company entered into a cooperative research agreement with UGARF for annual sponsored research payments that expired on August 31, 2009. The Company terminated the license agreement effective August 31, 2009.

Out-licensing Agreements

Pfizer (Wyeth). In August 2001, the Company entered into an exclusive worldwide license and development collaboration agreement with Wyeth Pharmaceuticals, Inc., ("Wyeth"), which has since been acquired by Pfizer, Inc. ("Pfizer") for the development of staphylococcal vaccines for humans. Under the terms of this agreement, the Company granted Pfizer 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 Pfizer. The Company must commit two full-time equivalent employees to the collaboration. The Company may terminate the agreement if Pfizer fails to use reasonable commercial efforts to bring related products to market. Pfizer 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 $7,250,000 in an upfront license fee and annual research support payments from Pfizer as of December 31, 2009. 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 commencement of a Phase I trial, 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 Pfizer. 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 Pfizer.

3M Company. In January 2007, the Company entered into an exclusive worldwide license and commercialization agreement with 3M Company ("3M") for the development of various diagnostic products using its MSCRAMM protein platform. Under the terms of the agreement, the Company granted 3M exclusive global licenses to use MSCRAMM protein intellectual property in the development of diagnostic products in exchange for license fees, future milestone payments, financial support of future research and development activities and royalty payments on net product sales. 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 reverted back to the Company. Pursuant to this agreement, the Company received a total of $4,000,000 in an upfront license fee and annual research support payments from 3M as of December 31, 2009.

15. 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 $127,000 and $124,000 in 2009 and 2008, 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-employments benefits upon termination. These benefits cannot be reasonably estimated and no measurable event has occurred as of December 31, 2009.

16. Quarterly Financial Data (Unaudited)

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

	Revenue	Loss from Operations	Net Loss	Net Loss Attributable To Common Stockholders per Share - Basic and Diluted
Year Ended December 31, 2009				
First Quarter	$287,500	$(4,281,050)	$(4,195,683)	$(0.10)
Second Quarter	287,500	(4,330,402)	(4,229,258)	(0.10)
Third Quarter	287,500	(4,489,228)	(4,471,737)	(0.10)
Fourth Quarter	287,500	(4,694,068)	(4,693,323)	(0.08)
Year Ended December 31, 2008				
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)

17. Subsequent Event

On January 11, 2010, the Company announced that Pfizer had initiated a Phase I trial of a staphylococcal vaccine that contained an antigen licensed by Pfizer from the Company's MSCRAMM intellectual property. The Company received a milestone payment of $666,667 from Pfizer.

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

None.

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, 2009. 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, 2009, 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 26, 2010

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2009 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

Exhibit No.	Description
3.1	Eighth Amended and Restated Certificate of Incorporation, as amended through June 9, 2009 (incorporated by reference to Exhibit 3.4 of the Quarterly Report on Form 10Q filed with the Securities and Exchange Commission on August 12, 2009).
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 field 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 Registration Statement on Form S-1 Securities and Exchange filed with the Commission on March 3, 2004 (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).

Exhibit No.	Description
10.21	Amendment No. 2 to License Agreement, dated April 29, 2002, between the registrant and The Texas A&M University System (incorporated by reference to Exhibit 10.21 of the March 2004 S-1).
10.22†	Exclusive License Agreement, dated April 8, 1999, between the registrant and Enterprise Ireland, trading as BioResearch Ireland (incorporated by reference to Exhibit 10.22 of the March 2004 S-1).
10.23†	License Agreement, dated December 23, 2002, between the registrant and Lonza Biologics PLC (incorporated by reference to Exhibit 10.23 of Amendment No. 3).
10.24†	Non-Exclusive Cabilly License Agreement, dated June 30, 2003, between the registrant and Genentech, Inc (incorporated by reference to Exhibit 10.24 of the March 2004 S-1).
10.35	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).
10.39†	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 field 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 field 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 field 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 field 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).
10.53	Form of Stock and Warrant Purchase Agreement dated October 22, 2009 between the registrant and each of the investors signatory thereto (incorporated by reference to Exhibit 10.53 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 28, 2009).
10.54	Form of Warrant pursuant to Securities Purchase Agreement dated October 22, 2009 between the registrant and each of the investors signatory thereto (incorporated by reference to Exhibit 10.54 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 28, 2009).

Exhibit No.	Description
10.55*	License Agreement, dated October 1, 2009, by and between registrant and University College Cardiff Consultants Limited.
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.

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

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Alpharetta, Georgia on this 26th day of March, 2010.

Inhibitex, Inc.

By: /s/ Russell H. Plumb
Russell H. Plumb
President, Chief Executive Officer,
Chief Financial Officer, Secretary and Treasurer

Pursuant to the requirements the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/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 26, 2010
/s/ Michael A. Henos Michael A. Henos	Chairman of the Board of Directors	March 26, 2010
/s/ M. James Barrett, Ph.D. M. James Barrett, Ph.D.	Director	March 26, 2010
/s/ Chris McGuigan, M.Sc., Ph.D. Chris McGuigan	Director	March 26, 2010
/s/ A. Keith Willard. A. Keith Willard.	Director	March 26, 2010
/s/ Russell M. Medford, M.D., Ph.D. Russell M. Medford, M.D., Ph.D.	Director	March 26, 2010
/s/ Marc L. Preminger Marc L. Preminger	Director	March 26, 2010
/s/ Gabriele M. Cerrone. Gabriele M. Cerrone	Director	March 26, 2010

Exhibit 23.1

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 26, 2010, with respect to the consolidated financial statements of Inhibitex, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2009.

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

Registration Statement No. 333-163132 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 26, 2010

Exhibit 31.1

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, 2009 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

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

Date: March 26, 2010

Exhibit 32.1

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, 2009, 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 26, 2010

Inhibitex Leadership

OFFICERS

Russell H. Plumb
President, Chief Executive Officer and Chief Financial Officer

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

Geoffrey W. Henson, Ph.D.
Senior Vice President of Drug Development

BOARD OF DIRECTORS

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

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

Gabriele M. Cerrone
Managing Partner – Panetta Partners, Ltd.

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

Headquarters
Inhibitex, Inc.
9005 Westside Parkway
Alpharetta, Georgia 30009
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 23, 2010, at 9:00 am EST at the company's headquarters in Alpharetta, Georgia.

Investor Information Requests
Copies of the Inhibitex, Inc. 2009 Annual Report and Form 10-K and additional information may be obtained through the corporate website, by email or by letter.

Website
www.inhibitex.com

Email
IR@inhibitex.com

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

9005 Westside Parkway • Alpharetta, Georgia 30009
P: 678.746.1100 • F: 678.746.1299
www.inhibitex.com