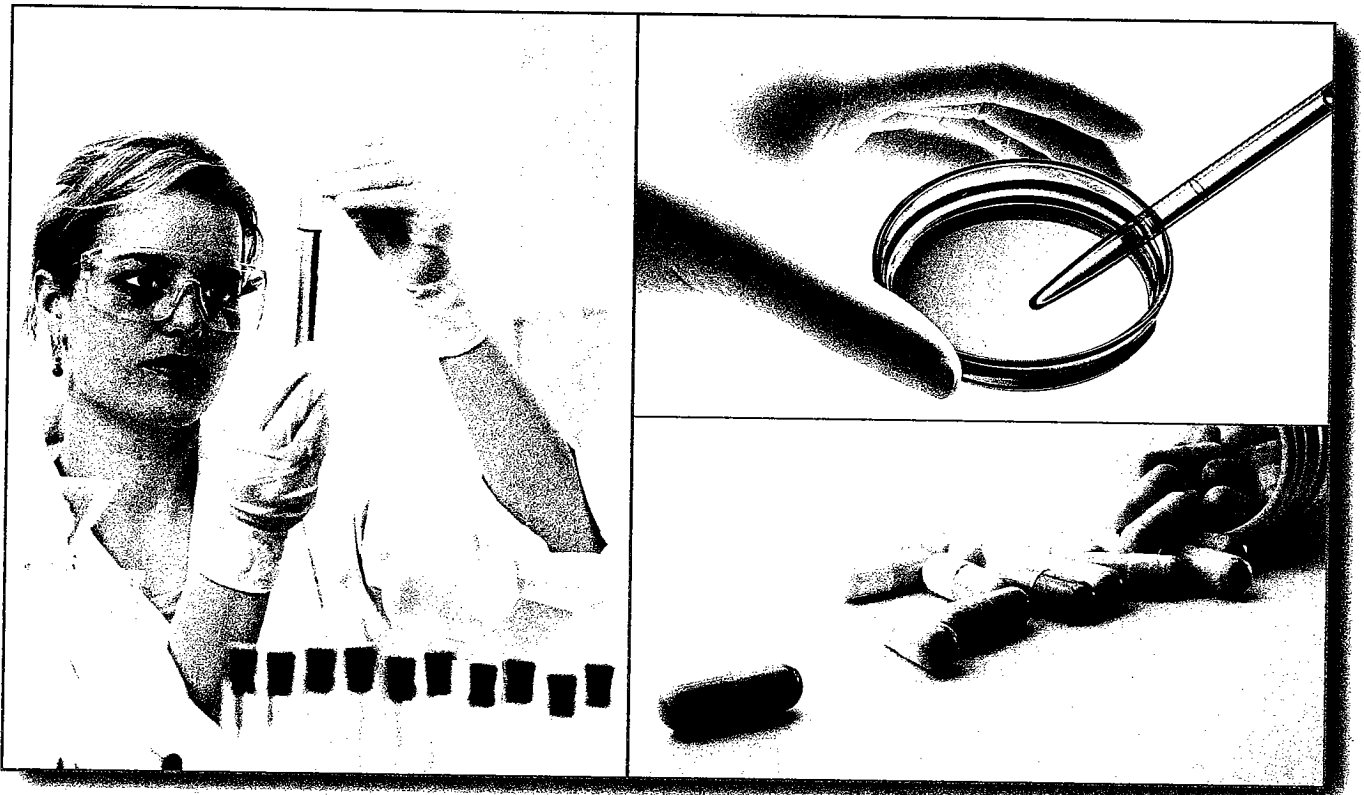




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Inhibitex, Inc.

2010 Annual Report



Received SEC
MAY 11 2011
Washington, DC 20549



Fellow Shareholders,

The past year has been exciting as well as transformational for Inhibitex. At this time last year, I indicated that we were poised to make great strides during 2010, based on the anticipation of establishing clinical proof of concept for both INX-189, our lead nucleotide polymerase inhibitor in development for the treatment of chronic hepatitis C infection, and FV-100, an oral, highly potent and rapid-acting compound in development for the treatment of shingles. I am very pleased to report that we achieved and exceeded these and other key corporate goals for the year by:

- Successfully completing both a Phase 1a and 1b clinical trial of INX-189. INX-189, when administered at low, once-daily oral doses, demonstrated potent antiviral activity by significantly reducing the viral loads of patients infected with chronic hepatitis C;
- Successfully completing a robust, well-controlled, randomized 350-patient Phase 2a clinical trial of FV-100 in shingles patients. FV-100, taken orally once-daily, demonstrated the potential to reduce the incidence of sub-acute and chronic pain, also known as post-herpetic neuralgia, or PHN, often associated with shingles infections, as compared to current standard of care, and;
- Securing financial and strategic flexibility to further advance our clinical development programs by raising approximately \$51 million in net proceeds in an underwritten public offering and also executing an at-the-market offering product to selectively raise capital on a cost-effective, flexible, as-needed basis.

Achievement of these key milestones, as well as other favorable corporate developments added to the year's success. These other developments include Pfizer completing a 408-subject Phase I clinical trial with a multi-component vaccine against *Staphylococcus aureus* that contains a protein antigen licensed from our proprietary MSCRAMM[®] protein platform. Additionally, nucleotide polymerase inhibitors are increasingly being perceived as the back-bone of future direct acting antiviral HCV therapy, and as such, INX-189 has gained considerable visibility over the past year as a promising and highly relevant product candidate. This potential of INX-189 was recently recognized by the FDA when they designated it with Fast Track Status. Taken together, these important developments have led to a marked increase in shareholder value from a year ago.

Our goal in 2011 is to build upon this momentum by continuing to successfully implement our strategic and operating plan. Specifically, we plan to:

- Initiate an extensive Phase 2 clinical development program for INX-189 in HCV genotype 1,2 and 3 patients that will highlight and utilize the compound's pan-genotypic antiviral activity and high genetic barrier to resistance and provide the opportunity to evaluate INX-189 in combination with other direct acting antivirals;
- Nominate a second HCV nucleotide polymerase inhibitor for advancement into IND-enabling preclinical development in the second half of 2011;
- Determine a commercial, regulatory and strategic pathway for the clinical advancement of FV-100 as a product candidate with the potential to reduce shingles-associated PHN and sub-acute chronic pain, which remain significant unmet medical and commercial needs.

We continue to believe that our development programs are well positioned to ultimately provide significant benefits to the millions of patients who suffer from hepatitis C and shingles, and the physicians that treat them. I offer a sincere thank you to our shareholders for your continued support and look forward to another successful year for Inhibitex.

Sincerely,



Russell Plumb
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, 2010

or

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

For the transition period from to

Commission file number: 000-50772

Inhibitex, Inc.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

**9005 Westside Parkway
Alpharetta, GA**

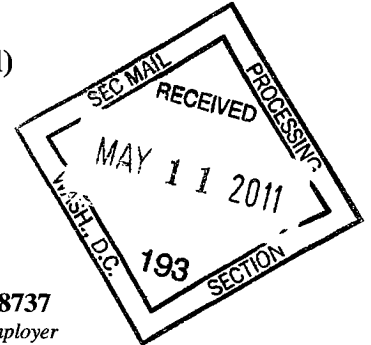
(Address of Principal Executive Offices)

74-2708737

(I.R.S. Employer
Identification Number)

30009

(Zip Code)



(678) 746-1100

(Registrant's telephone number, including area code)

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

Title of Each Class

Name of Each Exchange on Which Registered

Common Stock, par value \$.001 per share

Nasdaq Capital Market

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

None

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

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

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

Indicate by check mark 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, 2010 was \$126,536,217.

Number of shares of Common Stock outstanding as of March 10, 2011: 62,423,358

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive Proxy Statement with respect to the 2011 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 the clinical development of INX-189 and FV-100;
- the expected timing of future milestones and events, and our development plans associated with INX-189 and FV-100 or any of our product candidates;
- our ability to successfully execute our strategy;
- the expected time to complete our ongoing Phase 1b trial of INX-189;
- the timing and our plans to initiate a Phase 2 clinical trial for INX-189 to further assess the safety, tolerability and antiviral activity of INX-189 in certain hepatitis C virus (“HCV”) patient populations;
- the timing and our plans to nominate another HCV nucleotide polymerase inhibitor for advancement into an investigational new drug application (“IND”) enabling preclinical studies;
- the timing and our plans to complete a full evaluation of the Phase 2 FV-100 data set and post hoc analyses, conduct additional market research, including reimbursement, pricing, and competitive analyses, etc. and finalize our potential future developmental plans for FV-100;
- our belief that NS5b nucleotide polymerase inhibitors will play a significant role in the treatment of chronic HCV infections in the future;
- our belief that the 400 mg once-daily dose of FV-100 demonstrated clinically meaningful numerical differences from valacyclovir with respect to reducing shingles-associated pain and the incidence of post herpetic neuralgia (“PHN”);
- our belief that an antiviral therapy that can further reduce the severity and/or duration of shingles-associated pain and the incidence of PHN may have a competitive advantage relative to the currently available shingles therapies.
- our estimate that the market opportunity for a differentiated oral antiviral to reduce the incidence of shingles-associated pain and PHN is in excess of \$500 million per year in the U.S.;
- our belief that an effective therapy that can be administered via convenient, once-a-day oral administration may have a competitive advantage relative to current shingles therapies;
- our belief 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;
- our plan to support our existing collaboration with Pfizer, Inc. (“Pfizer”);
- 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;
- the number of months that our current cash, cash equivalents, and short-term investments will allow us to operate without raising additional capital;
- 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
- our 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: that we, the United States Food and Drug Administration (“FDA”), or an investigational review board might delay, suspend or terminate the clinical development of FV-100 or INX-189 for lack of safety, manufacturing issues or other clinical reasons; the safety or efficacy results of ongoing or future preclinical studies and clinical trials of INX-189 not supporting its further development; FV-100 not demonstrating sufficient efficacy in reducing the incidence and severity of shingles-related symptoms, including shingles-associated pain and post herpetic neuralgia, to be clinically relevant or commercially viable; Pfizer not terminating our license and collaborative research agreements; our ability to maintain sufficient resources, including executive management and key employees; our ability to successfully develop current and future product candidates either in collaboration with a partner or independently; our ability to secure and use qualified third-party clinical and preclinical research and data management organizations; third party manufacturers not fulfilling their contractual obligations or otherwise performing satisfactorily in the future; our ability to manufacture and maintain sufficient quantities of preclinical and clinical trial material on hand to complete our preclinical studies or clinical trials on a timely basis; our ability, or that of our clinical investigators, to enroll patients in our clinical trials or on a timely basis; our failure to obtain regulatory approval to advance the clinical development of or 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 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 that was incorporated in the state of Delaware in May 1994. We are currently focused on the development of differentiated anti-infective products to prevent or treat serious infections. Our research and development efforts are currently focused on oral, small molecule compounds to treat viral infections, and in particular, chronic infections caused by HCV and herpes zoster, also referred to as shingles, which is caused by the varicella zoster virus ("VZV"). Currently available antiviral therapies that are used to treat these and other infections have a number of therapeutic limitations, including inadequate potency, significant adverse side effects, complex and inconvenient dosing schedules 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 medical 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 not received regulatory approval to sell or market any of our current or past product candidates, nor do we currently have any commercialization capabilities. Therefore, it is possible that we may never successfully derive any commercial revenues from any of our existing or future product candidates.

Background

Infectious diseases are caused by pathogens that are present in the environment, such as viruses and bacteria, which enter the body through various means and overwhelm its natural defenses. The severity of an infectious disease 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 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 adverse or toxic side effects, complex dosing schedules and inconvenient methods of administration, such as injection or infusion. These factors often lead to patients prematurely discontinuing treatment or failing to fully comply with treatment dosing schedules, resulting in a treatment failure. Moreover, a patient's failure to comply fully with a recommended 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 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, HCV 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 deoxyribonucleic acid ("DNA") or Ribonucleic acid ("RNA"). Viruses generally must invade healthy, 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 or inhibit the replication of the responsible virus, which results in persistent and ongoing 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 chronic or acute. Chronic infections, such as those caused by HIV or HCV, do not typically self-resolve with time and can cause disease to remain for months or years if left untreated. Acute infections associated with viruses, such as influenza or VZV, generally lasts for a relatively short period of time, and in most cases can ultimately self-resolve in most immuno-competent individuals.

Viruses can also be characterized as either active or latent. An active virus can cause a persistent infection or disease over an extended period of time, such as infections caused by HCV. A latent virus, such as most

herpes viruses, including VZV, will remain in the body for very 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, allowing the virus to once again replicate. Vaccines have been widely used 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.

Viruses that develop resistance to antiviral drugs are increasingly becoming a major challenge in the treatment of viral infections, particularly those that are chronic in nature. The ability of viruses to mutate spontaneously during replication allows drug-resistant strains to emerge when patients are using drugs that are not potent enough to quickly and completely inhibit viral replication. Drug resistance occurs because viruses continually replicate and can make millions of copies of themselves every day, some of which will contain mutations in their genetic material. Mutations that emerge in the presence of a suppressive antiviral drug will give rise to mutant strains that are wholly or partially resistant to that drug. These mutant viruses, while initially low in number, eventually become the predominant strain in an infected patient as those strains that remain susceptible to the drug are inhibited from replicating. Once this occurs, the treatment benefit of that particular 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 HIV or 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 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 chemical 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 in many cases overuse of antibiotics over time, and the ability of bacteria to develop drug resistance, many antibiotics now have diminished or limited efficacy. The inability to effectively treat certain serious infections caused by drug-resistant bacteria with antibiotics has led to increased risk of mortality, 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 an approach to broaden the ability to prevent serious infectious diseases caused by both viruses and bacteria. In addition to many antiviral vaccines available for sale or in clinical development, there are ongoing efforts to develop vaccines to prevent bacterial infections such as those caused by *S. aureus*. *S. aureus* is one of the most common pathogens to cause hospital-acquired infections, and also affects a wide range of different patient groups, including those that acquire a *S. aureus* infection outside of the hospital setting. Hospital-associated *S. aureus* infections are typically associated with a longer hospital stay, poorer clinical outcome and higher treatment costs and mortality rates.

Due mainly to the broad use of many antibiotics, a number of resistant strains of *S. aureus* have emerged. The most notable of these is known as methicillin-resistant *S. aureus*, ("MRSA. The high incidence of *S. aureus* infections and MRSA are key drivers for the development of vaccines to prevent *S. aureus* infections. The increasing incidence of MRSA has led to a high interest in preventing such infections. In the hospital setting, the vaccination of patients who are highly susceptible to serious *S. aureus* infections could potentially prevent

a large number of such infections and their related morbidity and mortality. Further, the emergence of certain MRSA strains, such as USA300, in the community setting indicate that vaccination may also be beneficial in high-risk community groups including athletes or prison inmates.

Our Pipeline

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

<u>Drug Candidate</u>	<u>Indication</u>	<u>Stage of Development</u>	<u>Marketing Rights</u>
Antivirals			
INX-189	<i>Treatment of Chronic Hepatitis C Infection</i>	Clinical (Phase 1b)	Inhibitex
HCV Nucleotide Polymerase Inhibitors	<i>Treatment of Chronic Hepatitis C Infection</i>	Preclinical	Inhibitex
FV-100	<i>Treatment of Herpes Zoster (shingles)</i>	Clinical (Phase 2)	Inhibitex
Antibacterials			
Staphylococcal Vaccines	<i>Active Vaccine to Prevent S. aureus infections</i>	Clinical (Phase 1)	Pfizer
Aurexis	<i>Treatment of S. aureus Bloodstream Infections</i>	Clinical (Phase 2)	Inhibitex

HCV Nucleotide Polymerase Inhibitors

Modified nucleoside inhibitors, also known as nucleoside analogues, are a class of small molecule compounds that have a proven record of potent antiviral activity against numerous viruses. These natural chemical compounds function as the building blocks of human and viral genetic material, commonly referred to as DNA or RNA. Modified nucleoside inhibitors are small molecules that are designed to target viral RNA-dependent RNA polymerase (“RdRp” or “NS5b”), which are enzymes within the genes of the virus that facilitate the ability of the virus to replicate. Mimicking the role of a natural or unmodified nucleoside, nucleoside inhibitors are designed to be incorporated by viral polymerases into replicating viral genomes just as a natural nucleoside would. However, due to its engineered modifications, once incorporated, the modified nucleoside inhibitor will cause the chain of events that result in the virus reproducing its genetic material to terminate, thus preventing the virus from further replicating.

The HCV inhibitory activity of 2'-C-modified nucleosides have been well studied and have been shown to specifically inhibit HCV RNA replication both in biochemical assays and in cell-based replicon assays. The corresponding intracellular triphosphates of these 2'-substituted nucleosides were shown to be potent, competitive inhibitors of NS5b-catalyzed reactions *in vitro*. Incorporation of the 2'-modified monophosphates onto the 3'-end of the RNA strand resulted in efficient termination of elongation of the growing RNA chain. Despite the potential of 2'-C-modified nucleosides, they have generally failed to progress as product candidates into late stage development due to one or more of the following shortcomings: lack of oral bioavailability; poor pharmacokinetic characteristics; lack of cell penetration; and inefficient intracellular conversion to the active triphosphate.

In an effort to unlock the potential of nucleoside NS5b inhibitors we have employed a phosphoramidate prodrug approach to improve upon the characteristics of cellular uptake and intracellular activation. This approach is designed to bypass the rate limiting initial phosphorylation step of activation by delivering the monophosphate, or nucleotide form of the nucleoside analog to the liver where it can be efficiently converted to the active triphosphate. INX-189 is referred to as a nucleotide analogue and is a phosphoramidate of 0-6-methyl-2'-C-methyl guanosine. This compound was selected from a number of phosphoramidate candidates because of its significant potency in replicon assays and its ability to efficiently generate intracellular triphosphate in primary human hepatocytes. In addition to its potency, INX-189 has demonstrated a high genetic barrier to resistance *in vitro*, a significant differentiating factor when compared to non-nucleoside polymerase or protease inhibitors.

We are currently conducting a Phase 1b, multiple ascending dose (“MAD”) clinical trial in HCV genotype 1 treatment-naïve patients to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of INX-189 as monotherapy and in combination with ribavirin. In January 2011, we reported interim top-line safety and antiviral data from the first two monotherapy cohorts of this ongoing trial, where INX-189 demonstrated potent antiviral activity with a mean HCV RNA reduction from baseline levels of -0.71 and -1.03 log₁₀ IU/mL for the 9 mg and 25 mg doses, respectively, following seven oral once a day doses. Preliminary assessments of the data available from the first two cohorts in the study also indicate that INX-189 was well tolerated. We expect to complete the Phase 1b study around the end of the first quarter of 2011, and are developing plans to further evaluate its safety and antiviral activity in a Phase 2 program that we anticipate could begin in the third quarter of 2011.

On February 11, 2011, the FDA designated the investigation of INX-189 as a Fast Track development program. Under the FDA Modernization Act of 1997, Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life threatening conditions and that demonstrate the potential to address unmet medical needs.

In addition to INX-189, we also anticipate conducting advanced preclinical studies on another HCV nucleotide polymerase inhibitor in the second half of 2011 which, if successful, could support the filing of an IND with the FDA in 2012.

Market Opportunity for the Treatment of Chronic HCV Infections

HCV is a virus that is a common cause of viral hepatitis, an inflammation of the liver. HCV is typically contracted by contact with the blood or other body fluids of another individual infected with HCV. HCV disease progression occurs over a period of 20 to 30 years, the majority of which patients generally do not exhibit any symptoms of the disease. Therefore many patients are unaware they are infected, are undiagnosed and do not seek treatment. 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. More recently, HCV is primarily transmitted through the sharing of needles used for injection drug use and by pregnant women infecting their children *in utero*. As of 2004, the World Health Organization (“WHO”) estimated that approximately 170 million people worldwide are infected with HCV. Of these individuals, it is estimated that approximately 130 million, or about 75%, are chronically infected with an increased risk of eventually developing liver cirrhosis or liver cancer. As of 2006, the Center for Disease Control (“CDC”) estimated that approximately 4 million people in the U.S. are chronically infected with HCV, and that only about 3% of these patients receive treatment in any given year.

There are several genotypes and subtypes of HCV. Worldwide, 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 all HCV infections. Patients with genotype 2 or 3 represent approximately 25% of the worldwide chronically infected HCV population, with the remaining 5% being comprised of genotypes 4 through 6.

Currently available therapy to treat HCV infection, which is a combination of pegylated interferon-alpha plus ribavirin, generated worldwide sales of approximately \$2.2 billion in 2005, and sales of these products and future approved products are forecast to increase to more than \$8.8 billion by 2015.

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 a once-weekly injection of pegylated interferon-alpha and twice-daily oral administration of ribavirin for up to 48 weeks, depending on the HCV genotype.. Therapy with pegylated interferon-alpha causes a number of noticeable side effects in many patients, including depression, a drop in blood cell count and flu-like symptoms. These symptoms may be experienced during part, or all, of the 48-week course of therapy that is

standard for treatment of patients infected with HCV genotype 1. These side effects can make patients feel worse than foregoing their treatment altogether, which in many cases 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 is believed to decrease the patient response rate to therapy.

In addition to these side effects, current standard of care does not cure the disease, referred to as a sustained virologic response ("SVR"), for a significant portion of chronically infected HCV 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 treatment with the current standard of care. Due to the lack of alternative treatments, patients without a SVR response currently have no other treatment option but to undergo a second course of pegylated interferon-alpha-based therapy with a different brand of pegylated interferon-alpha, the outcome of which is generally sub-optimal as well.

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 ("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, nucleotide and non-nucleoside polymerase inhibitors, and other emerging antivirals that seek to inhibit different molecular targets of HCV. To date, data from a number of clinical trials evaluating various DAAs 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, it is believed that two or more classes of DAAs 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. The goal and focus of many current DAA development programs is to either materially reduce the duration of current standard of care therapy, or eliminate the need for pegylated interferon-alpha from standard of care.

Our Approach for the Treatment of HCV Infection

There are currently two approaches to inhibiting the activity of the HCV polymerase.: nucleoside analogue inhibitors and non-nucleoside analogue inhibitors. Nucleoside analogues are generally converted to nucleotide analogues by host cell kinases. Nucleotide analogues target the active site of the polymerase and they can either compete with natural nucleoside triphosphate ("NTP") substrates 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 are 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 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 nucleotides, leading to a lower barrier to the formation of resistant mutations of non-nucleoside inhibitors.

We are focused on developing the use of proline modified nucleotide analogues that mimic nucleotides normally recognized by the polymerase 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 nucleotide polymerase inhibitors will play a significant role in the treatment of chronic hepatitis C infections in the future.

We believe NS5b nucleoside/nucleotide polymerase inhibitors have certain potential advantages that over protease inhibitors, as well as other classes of DAA, including NS5b non-nucleoside polymerase and NS5a inhibitors, as follows:

- Nucleoside/nucleotide polymerase inhibitors exhibit a very high genetic barrier to resistance relative to other classes of DAAs due to their ability to bind in the active site of the HCV polymerase and any mutations that

do occur in the active site significantly reduce the fitness of the virus to replicate. To our knowledge, there are also no known pre-existing resistant strains to these nucleoside/nucleotide inhibitors.

- Nucleoside/nucleotide polymerase inhibitors exhibit robust antiviral activity against all genotypes of HCV. Protease, non-nucleoside and NS5a inhibitors have typically shown variable potency against HCV genotypes 1a and 1b, and reduced or minimal antiviral activity against genotypes 2, 3 or 4. This genotype specificity suggests that these other inhibitors would need to be combined with a nucleoside/nucleotide inhibitor to provide broad therapeutic coverage across the breadth of all HCV genotypes found globally.
- Nucleoside/nucleotide polymerase inhibitors 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 necessitate extensive drug-drug interactions studies prior to licensure.

The FDA has not yet approved any DAAs for the treatment of infections caused by HCV, but it is anticipated that two protease inhibitors could be approved for sale in the U.S. in 2011. Additionally, numerous Phase 2 and Phase 3 clinical trials of various protease, non-nucleoside and NS5a inhibitors are currently being conducted by a number of pharmaceutical and biotechnology companies worldwide. Further, several pharmaceutical and biotechnology companies are also developing nucleoside and nucleotide polymerase inhibitors. To our knowledge, the most advanced nucleoside inhibitor has successfully completed a Phase 2b trial and there are several nucleotide polymerase inhibitors currently in Phase 2 clinical trials.

INX-189 Clinical Trials

Phase 1b. We are currently conducting a Phase 1b, multiple ascending dose clinical trial of INX-189 under an IND in the United States. The trial is a double-blind, placebo-controlled, dose escalation study designed to evaluate the safety, tolerability, pharmacokinetics and antiviral activity of INX-189, administered orally once daily for seven days, in treatment naïve patients with HCV genotype 1. Each treatment cohort includes 10 patients, eight of which receive INX-189 and two of which receive placebo. We plan to evaluate five cohorts of INX-189 as monotherapy. In addition, we are evaluating both 9 and 25 mg of INX-189, administered once daily for seven days, in combination with ribavirin, which is one of the drugs currently approved for the treatment of HCV. We expect to complete the Phase 1b study around the end of the first quarter of 2011.

In January 2011, we reported interim top-line safety and antiviral data from the first two monotherapy cohorts of this ongoing trial, which demonstrated potent antiviral activity with a mean HCV RNA reduction from baseline levels of -0.71 and -1.03 log₁₀ IU/mL for the 9 mg and 25 mg doses of INX-189, respectively, following seven once-daily oral doses. Preliminary assessments of the data available from the first two cohorts in the study also indicated that INX-189 was well tolerated.

Phase 1a. In September 2010, we completed a Phase 1a, single ascending dose trial of INX-189. In this trial, 42 healthy volunteers received either a single oral dose of INX-189, ranging from 3 mg to 100 mg, or placebo. Data from the Phase 1a trial indicated that INX-189 was generally well tolerated at all dose levels; there were no drug-related serious adverse events, no dose-related trends in frequency or type of adverse events, and no grade II or higher laboratory abnormality adverse events or clinically significant changes in ECGs; and pharmacokinetic data supports INX-189's potential for once daily (QD) dosing.

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 more rapid onset of antiviral activity, and may fully inhibit the replication of VZV more rapidly than these drugs at significantly lower concentration levels. In addition, pharmacokinetic data from our

Phase 1 and 2 clinical trials suggests that FV-100 has the potential to demonstrate antiviral activity when dosed orally once-a-day at significantly lower levels than valacyclovir, acyclovir, and famciclovir.

We completed a Phase 2 clinical trial for FV-100 in December, 2010. This trial represented the first clinical trial of FV-100 in shingles patients. The Phase II trial was a well-controlled, double-blind study comparing two different dosing arms of FV-100 to an active control (valacyclovir). We enrolled 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 and tolerability, the main objectives of the trial were 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. Numerically favorable treatment differences, and in particular in those patients that received 400 mg FV-100, were observed for FV-100 as compared to valacyclovir for the primary endpoint of the study, which was the reduction in the severity and duration of shingles-associated pain over the first 30 days after lesion appearance. The treatment differences observed between either of the FV-100 treated arms and the valacyclovir-treated subjects for this primary endpoint were not statistically significant. There were also favorable treatment differences observed for key secondary pain endpoints, including the reduction in the severity and duration of shingles-associated pain over 90 days (a 14% relative reduction as compared to valacyclovir for 400mg FV-100) and the incidence of PHN (a 39% relative reduction as compared to valacyclovir for 400 mg FV-100). The secondary endpoints were not powered to demonstrate statistically significant treatment differences between the arms. FV-100 was generally well tolerated at both dose levels, and demonstrated a similar adverse event profile as compared to valacyclovir.

We are currently reviewing the clinical data from the Phase 2 trial and performing post hoc analyses, conducting additional market research, including reimbursement, pricing, and competitive analyses, etc. We are also evaluating a number of clinical, regulatory and commercial pathways for the potential future development of FV-100. Based upon the results of the recently-completed Phase 2 study, we are focusing this assessment on endpoints measuring a reduction in shingles-associated sub-acute pain and PHN. We anticipate concluding this evaluation in the first half of 2011.

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 and it is caused by exposure to another individual with an active infection. After the chickenpox infection subsides, VZV remains latent in the individual's dorsal root and cranial nerve ganglia, and can re-emerge later in life. Therefore, shingles is typically not transmitted from one individual to the next, and only those individuals who have had chickenpox are generally 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, immune status and being female. 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. A study in 2007 based upon data from 2000 implied that there were approximately 1 million new cases shingles cases that year. 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 has increased and is expected to continue to increase. A recent study from the Centers for Disease Control investigating medical claims data from MarketScan® databases from 1993-2006 indicated that the crude incidence of shingles case increased 259% over that period of time. Furthermore, a study conducted by the Mayo Clinic suggests that the recurrence rate for shingles is approximately 6.2%, which reflects a much higher rate than prior studies which assessed a shorter follow-up period. It is estimated that approximately 20-30% 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 and pain. In many cases the patient may notice localized prodromal pain prior to the appearance of any lesions; however, the first recognizable symptom of shingles is generally lesions that will continue to form for a week or two. Such lesions generally

follow the path of nerves that emanate from the spinal cord around the torso (thoracic); however, the infection is also commonly found on the face, neck, lower back and in certain cases, systemically. Within several weeks, the lesions in the infected areas will typically begin to heal, and these dermatological symptoms generally will resolve within a month or less after the appearance of the first lesion. In rare instances, lesions may never appear, but pain will be present.

The pain associated with an episode of shingles is attributed to both the damage caused to the affected nerves by the replication of VZV and the inflammatory response 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 such pain for several weeks in connection with their active infection, referred to as acute pain. For many patients, shingles-associated pain does not resolve when the lesions heal and the inflammation subsides, but, rather, continues for months, or possibly years. Persistent shingles-associated pain that lasts more than three to four weeks is referred to as sub-acute pain or neuralgia. Shingles-associated pain that persists more than three months is generally referred to as PHN, which is the most common and clinically relevant complication of shingles. Approximately 15-20% of all shingles patients experience PHN, although the incidence of PHN is more prevalent in patients over 50 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, for the treatment 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. Unlike those drugs, FV-100 only demonstrates antiviral activity against VZV, and not the other herpes viruses. Based upon an analysis by data compiled by IMS Health, Inc. (“IMS”) on our behalf, and a recent utilization study of the use of Valtrex® from 1994-2009 conducted by the FDA as well as other market research we have independently conducted, , we estimate that 15 -30% of the nearly 17 million retail prescriptions written for valacyclovir, acyclovir and famciclovir combined in 2009 were for the treatment of herpes zoster, and that the market opportunity for a differentiated oral antiviral to reduce the incidence of sub-acute shingles-associated pain and PHN is in excess of \$500 million per year in the U.S.

Limitations of Current Therapies

Data from various clinical trials conducted in the 1990’s 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 Shingles-Associated Pain and PHN.* Currently, there are no therapies indicated for the reduction of shingles-related pain or the prevention PHN. There is also no cure for PHN per se; rather, treatment of PHN is accomplished through analgesics, narcotics and pain management. The most commonly prescribed medications to treat PHN are opioids, antidepressants, anticonvulsants, or topical lidocaine or capsaicin patches. Previously published clinical data demonstrate that antiviral therapy can reduce the duration of shingles-related pain, 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 further reducing shingles-associated pain and PHN. In our recently completed Phase 2 study, the 400 mg once-daily dose of FV-100 demonstrated what we believe are clinically meaningful numerical differences from valacyclovir with respect to reducing sub-acute pain and PHN. We believe an antiviral therapy that can further reduce the severity and/or duration of shingles-associated pain and the prevalence of PHN may have a competitive advantage relative to the currently available shingles therapies.
- *Inconvenient Dosing.* Due to their pharmacokinetic properties and lower 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. Such dosing regimens are inconvenient and can result in non-compliance, resulting in less than optimal treatment outcomes. In our recently completed Phase 2 study, once-daily doses of 200 and 400 mg of FV-100 appeared to be comparable to valacyclovir dosed 1,000 mg three times per day with respect to reducing sub-acute pain and preventing PHN. We believe that an effective therapy that can be administered via convenient, once-a-day oral administration may have a competitive advantage relative to current shingles therapies.

- *The Dosage of Currently Available Antiviral Drugs for Shingles Must be Adjusted for Patients with Insufficient Renal Function.* Although current pan-herpetic oral antiviral therapies have been shown to be 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. Preclinical and clinical data to-date suggests that FV-100 is primarily metabolized and excreted via the liver and not through the kidney. Accordingly, we currently believe that 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 medical need for a more potent, faster acting, low dose once-daily oral antiviral agent, such as FV-100, which has the potential to further reduce the incidence, severity, and duration of shingles-associated pain and prevent PHN.

FV-100 Clinical Trials

Phase 2. We completed a Phase 2 clinical trial of FV-100 in December, 2010. The trial was a well-controlled, double-blind study comparing two different doses of FV-100 to an active control (valacyclovir). A total of 350 patients, aged 50 years and older who had shingles-associated pain and presented to the clinic within 72 hours of their first shingles lesion appearing were equally randomized to one of three treatment arms: 200 mg FV-100 administered once-daily for seven days; 400 mg FV-100 administered once-daily for seven days; or 1,000 mg valacyclovir administered three times per day for seven days. In addition to further evaluating its safety and tolerability, the objectives of the trial were to evaluate the potential therapeutic benefit of FV-100 in reducing (i) the severity and duration of shingles-associated pain, (ii) the incidence of PHN, (iii) the time to lesion crusting and healing and, (iv) the use of concomitant pain medications, as compared to valacyclovir. The primary efficacy analysis was conducted on the modified intent-to-treat population, which included all intent-to-treat patients except those whose lesions were PCR (-) for varicella zoster virus and PCR (+) for herpes simplex virus. The efficacy endpoints were calculated using a last observation carried forward methodology.

FV-100 Efficacy Summary

Shingles patients who received 200 mg or 400 mg FV-100 experienced numerically favorable treatment differences as compared to patients treated with valacyclovir, as measured by the primary endpoint, of 3% and 7%, respectively. In addition, patients treated with 200 mg and 400 mg FV-100 experienced a relative reduction in the amount of shingles-associated pain over the first 90 days after lesion appearance compared to those treated with valacyclovir, of -4% and 14%, respectively. Further, 18% and 12% of the patients receiving 200 mg and 400 mg FV-100, respectively, developed PHN as compared to 20% of the valacyclovir-treated patients, resulting in relative treatment differences of 12% and 39%, respectively. For patients receiving valacyclovir, the time to lesion crusting was faster than those patients receiving FV-100; however, no differences were noted between the treatment arms on time to full lesion healing. The three treatment arms were well-balanced with regard to demographics and baseline shingles-associated pain levels.

The following table reflects the treatment outcomes among the three treatment arms with respect to the key shingles-associated pain endpoints on the modified intent-to-treat population:

Cohort (N)	Primary Endpoint	Key Secondary Pain Endpoints	
	Least Squares Mean BOI30 days AUC ± S.E.	Least Squares Mean BOI90days AUC ± S.E.	Incidence of PHN (%)
3000 mg valacyclovir (N=109)	117.96 ± 6.25	229.59 ± 19.55	20.2
200 mg FV-100 (N=107)	114.49 ± 6.24	221.53 ± 19.51	17.8
400 mg FV-100 (N=113)	110.31 ± 6.08	196.94 ± 19.01	12.4

FV-100 Safety Summary

A comparison of adverse events between the three treatment arms in the Phase 2 trial demonstrated that the overall tolerability and side effect profile of both doses of FV-100 was comparable to valacyclovir. All three treatment arms showed a relatively low proportion of adverse events and serious adverse events. In the 400 mg FV-100 dose group, the most common adverse events were headache (reported in 13% of patients) and nausea (9%); no patient discontinued because of headache and one patient terminated due to nausea (grade 1). The most common adverse events in the valacyclovir cohort were nausea (6%) and upper abdominal pain (5%).

The following table summarizes the top-line adverse event findings from the trial:

Number (%) of Patients Reporting:	200 mg FV-100 (N=117)	400 mg FV-100 (N=117)	3000 mg valacyclovir (N=116)
Any AE	46.2	54.7	42.2
Treatment-Related AEs	20.5	25.6	19.8
Discontinuation of Drug for AE	1.7	1.7	1.7
SAEs	0	4.3	3.4
Treatment-Related SAEs	0	0	1.7

Phase 1. 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 EC₅₀ for at least 24 hours, supporting the evaluation of once-daily dosing of FV-100 in future clinical trials. The EC₅₀ represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*.

In January 2009, we also completed a blinded, placebo controlled Phase 1 trial to evaluate single and multiple doses of FV-100 in healthy subjects 65 years of age and older. One dose cohort consisted of 12 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 12 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 1 single ascending dose clinical trial of FV-100. The blinded, placebo-controlled trial evaluated the safety and pharmacokinetics of four doses of FV-100 in six cohorts of healthy volunteers (100, 200, 400, and 800 mg, as well as a two 400 mg food effect groups). Each cohort consisted of six subjects that received FV-100 and two that received placebo. There were no serious adverse events observed and the compound appeared to be generally well tolerated in the trial. In addition, pharmacokinetic data demonstrated that all doses evaluated in the trial maintained plasma levels of CF-1743, the active form of FV-100, which exceeded its EC₅₀ for at least 24 hours.

Staphylococcal Vaccine

In 2001, we entered into an exclusive worldwide license and collaboration agreement with Wyeth (since acquired by Pfizer) for the use of intellectual property from our MSCRAMM protein platform in the development of active vaccines against staphylococcus. 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 reported that Pfizer had initiated recruitment for a randomized, double-blind Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of three ascending dose levels of a 3-antigen *S. aureus* vaccine (“SA3Ag vaccine”) 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 payments, as well as royalties on any future net sales.

Market Opportunity for Staphylococcal Vaccine

As of 2007, the CDC estimated that each year, approximately 1.7 million infections and 99,000 associated deaths occur in U.S. hospitals, making hospital-associated, or nosocomial infections one of the leading overall causes of death. Nosocomial infections constitute a significant economic and healthcare burden, causing a large range of additional costs to health services, patients and society. Most of these costs are directly related to the prolonged hospital stay 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 following prolonged stays related to nosocomial infections: 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 cost 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 that causes nosocomial infections. It is associated with many different types of infection, and in general, patients that acquire a *S. aureus* infection have worse clinical outcomes. The emergence of hard-to-treat MRSA, in both the hospital and the community setting, and the additional costs of treatment have provided a strong rationale to investigate strategies to prevent *S. aureus* infections. 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 1. In January 2010, we reported that Pfizer had initiated recruitment in a randomized, double-blind Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of three ascending dose levels of the SA3Ag vaccine in 408 healthy adults. The SA3Ag vaccine contains clumping factor A (“ClfA”), a protein 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. We estimate that this trial could be completed in 2011.

Aurexis

Aurexis is a humanized monoclonal antibody we have clinically 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 the ClfA 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 current strategic focus, we currently do not have any plans to allocate additional resources to independently 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 U.S. during the year 2005, and that these infections were associated with death in approximately 19,000 cases. The economic burden of MRSA infections is substantial. MRSA hospitalizations cost nearly double that of non-MRSA hospitalizations; \$14,000 for MRSA compared with \$7,600 for non-MRSA. The average length of hospital stay for a patient with a 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 new therapies with novel mechanisms of action designed to either prevent or mitigate the progression of serious *S. aureus* infections.

We believe there are a number of medical benefits that may be realized by using Aurexis as adjunctive therapy with antibiotics: first, reduced mortality and morbidity (complications) associated with MRSA and methicillin sensitive *S. aureus* bacteremia; second, reduced length of stay in the intensive care unit, or ICU, thereby reducing the costs associated with a patient's overall hospital stay; third, reduced antibiotics utilization consistent with CDC and NIH guidelines, thereby reducing the likelihood of the development of antibiotic resistance; and fourth, reduced rates of relapse of infection. Moreover, the ability to be used prophylactically in high-risk patients may provide Aurexis with a unique advantage over antibiotics, as their prophylactic use is generally discouraged due to the potential for increased drug resistance.

Aurexis Clinical Trials

Phase 2. In May 2005, we reported the results from a 60-patient Phase 2 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 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, as well as in 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 2 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.

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-term, we plan to focus our resources primarily on further developing INX-189, and other HCV nucleoside polymerase

inhibitors, for the treatment of chronic hepatitis C, and FV-100 for the reduction of shingles-associated pain and the prevention of PHN. More specifically, we intend to:

- Complete our ongoing Phase 1b clinical trial of INX-189 and develop plans to further evaluate its safety and antiviral activity in a Phase 2 program that we anticipate could begin in the third quarter of 2011;
 - Nominate another HCV nucleotide polymerase inhibitor for advancement into IND-enabling GLP preclinical studies in 2011. We currently have several HCV nucleotide polymerase inhibitors that we are evaluating in non-GLP preclinical in vivo studies; and
 - Complete a full evaluation of the Phase 2 FV-100 data and post hoc analyses, conduct additional market research, including reimbursement, pricing, and competitive analyses, etc. and finalize our potential future developmental plans for FV-100.
- *Seek Strategic Collaborations to Accelerate the Development of Our Product Candidates to Optimize Economic Returns while Managing Risk.* We intend to establish strategic licenses and collaborations, partnerships, alliances or enter into other transactions in the future with pharmaceutical or biopharmaceutical companies with greater clinical development, manufacturing and commercialization capabilities that we believe can accelerate the development and/or commercialization of INX-189 and FV-100.
 - *Continue to support our existing license and collaboration agreement with Pfizer for the development of staphylococcal vaccines as needed.* In 2010, Pfizer initiated a Phase I trial of the SA3Ag 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.

Research and Development

Our research and development expense in 2010 and 2009 was \$21.0 million and \$15.4 million, respectively. In 2011, we plan to focus our resources primarily on the development of INX-189 and our HCV nucleotide polymerase inhibitor program and to a lesser extent, on FV-100 for the reduction of shingles-associated pain and the prevention of PHN.

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 can 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 management and oversight of these activities 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 on a timely basis. However, if an existing or future contract manufacturer fails to deliver on schedule, or at all, it could delay or interrupt the development process for our product candidates and affect our operating results and estimated time lines.

We have used contract manufacturers to produce clinical trial material for use in the clinical trials of INX-189 and FV-100. As of December 31, 2010, we have a maximum purchase commitment of \$0.4 million under these agreements and have no other long-term, non-cancellable financial obligations under these agreements.

Competition

Our industry is highly competitive and characterized by rapid scientific, medical and technological change, a reliance on establishing and maintaining intellectual property and patent rights, and government regulation. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through complex preclinical and clinical trials; the relative efficacy, toxicological, tolerability, safety, resistance or cross-resistance, and dosing profile of a product or product candidate as compared to other competing compounds; the timing and scope of regulatory approvals received, if ever; 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; establishing and maintaining intellectual property and patent rights and their protection; and sales and marketing capabilities.

If ultimately approved, INX-189, FV-100, or any of our product candidates 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 chronic hepatitis C, the reduction in shingles-associated pain, the prevention or treatment of PHN and the prevention of staphylococcal infections. Several of the large pharmaceutical companies that currently market products that would compete with our product candidates, if approved, include, but are not limited to: Merck and Roche in the hepatitis C market, and GlaxoSmithKline, Novartis and Merck in the shingles 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, Achillion, Anadys, Bristol Myers Squibb, Gilead, Idenix, 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, Pharmasset and Idenix are developing nucleotide analogues. Moreover, their lead nucleotide analogues have advanced further in clinical development than INX-189 and are currently in Phase 2 clinical trials.

While there are many direct acting antiviral compounds in various stages of clinical development for the treatment of HCV, none have been approved for sale by the FDA or European Medicines Agency ("EMA") as the date of this filing. However, it is widely anticipated that one or two protease inhibitors may be approved for sale by the FDA in 2011. 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, a high barrier to resistance, 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 and uncertain 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 INX-189 or FV-100, 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, more favorable reimbursement rates and coverage for their product candidates, and achieving broader 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 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 patents and intellectual property rights. Unless a patented drug can sufficiently differentiate itself from a directly-competing generic drug in a meaningful manner, the existence of generic competition in any indication will generally impose significant pricing pressure on competing patented drugs.

Intellectual Property Rights and Patents

Patents and other proprietary intellectual rights are crucial in our business, and establishing and maintaining these rights 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 published or 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 our 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.

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.

We have an exclusive global license to multiple pending patent applications, in the U.S. and internationally, relating to INX-189 and a number of our preclinical HCV nucleotide polymerase inhibitors. The earliest expiration date for any patents that may issue with claims related to INX-189 and our preclinical HCV nucleotide inhibitors is in approximately 2027.

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 expiration date for patents which may issue from those patent applications is approximately 2018.

We currently own or are licensed under numerous patents and patent applications in the U.S. and internationally related to our MSCRAMM protein platform. We have five issued U.S. patents relating to the ClfA protein found on *S. aureus* and antibodies to the protein. The patents will expire in 2014, 2016, and 2017. There are no corresponding foreign rights available for the ClfA protein and nucleic acid sequences. 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. 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.

Licenses

In 2007, we entered into an exclusive worldwide license agreement with Cardiff University in Cardiff, Wales (“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 the agreement upon 90 days notice 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 novel 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 the agreement upon 90 days notice 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 owe Cardiff approximately \$0.3 million in annual sponsored research payments over a three year period as of December 31, 2010. Christopher McGuigan, a member of our Board of Directors, holds the following positions at Cardiff University Welsh School of Pharmacy: Professor of Medicinal Chemistry and Deputy Pro Vice Chancellor (Research).

In 2007, we acquired the rights to an exclusive worldwide license from Cardiff, which included 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 the agreement upon 90 days notice following certain specified breaches of the license agreement by us.

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 U.S. divisional applications, now issued 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”) to U.S. patents and U.S. patent applications 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 use certain of our MSCRAMM proteins 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 \$8.3 million in an upfront license fee and annual research support payments and \$0.7 million in milestone payments from Pfizer as of December 31, 2010. 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 1, Phase 2 and Phase 3 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 1 study with a staphylococcal vaccine that includes intellectual property 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 for sale, 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, export, reporting and record-keeping of drug products and product candidates is subject to extensive regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state agencies, and regulatory agencies in foreign countries.

Non-compliance with applicable regulatory requirements can result in, among other things, total or partial suspension of the clinical development of a product candidate, manufacturing and marketing, failure of the FDA or similar regulatory agency in other countries 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 be reviewed by the FDA and 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, potency, efficacy and purity of any product candidate for its intended use, which conform to the FDA's good clinical practice ("GCP") regulations;
- the development and demonstration of manufacturing processes that conform to FDA-mandated current Good Manufacturing Practices ("cGMPs"); and
- the submission to, and review and approval by, the FDA of a New Drug Application ("NDA") or a Biologic License Application ("BLA") prior to any commercial sale or shipment of a product.

Successfully completing this development process requires a substantial amount of time and financial resources. We cannot assure you 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 for any of our product candidates 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 proposed clinical trial protocols, to the FDA as part of an IND, which must be reviewed and become effective before we may begin any human clinical trials. An IND generally becomes effective approximately 30 days after receipt by the FDA, unless the FDA, within this 30-day time period, raises material 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 may 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, biologic activity, 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 activity or 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 and the clinical protocol 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 any 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 or safety risk.

Clinical trials to support a NDA or BLA for marketing approval are typically conducted in three sequential phases: Phase 1, 2 and 3, with Phase 4 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 or other patient populations. 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 1:* After an IND becomes effective, Phase 1 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 1 trial is to assess a product candidate's safety and the ability of the human body to tolerate it at different dose levels. Absorption, metabolism, distribution and pharmacokinetic trials are also generally performed at this stage. Phase 1 trials typically evaluate these aspects of the investigational drug in both single doses, as well as multiple doses.
- *Phase 2:* During Phase 2 clinical 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 2 or Phase 3 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 is not treated with the product candidate but either receives a placebo or a drug already on the market for the same indication. Typically, two or more Phase 2 studies will be conducted for a product candidate prior to advancing to Phase 3.
- *Phase 3:* If and when one or more Phase 2 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 3 trials may be undertaken to further demonstrate or confirm the clinical efficacy and safety of the investigational drug in an expanded patient population, with the goal of evaluating its overall risk-benefit relationship. Phase 3 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 3 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 1 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 1/2 or Phase 1b clinical trials.

A company may request an "end-of-Phase 2 Meeting" with the FDA to assess the safety of the dose regimen to be studied in the Phase 3 clinical trial, to evaluate the planned design of a Phase 3 trial, and to identify any additional information that will be needed to support a NDA. If a Phase 3 clinical trial has been the subject of discussion at an "end-of-Phase 2 Meeting," the trial sponsor may be 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 3 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 1, 2, and 3 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 or safety 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 1 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 product candidate representing a potentially significant improvement in the treatment, prevention or diagnosis of a life threatening or serious disease may receive a 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 4 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 4 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 a specific clinical indication or use. 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 if applicable, 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 of 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 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 4 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. Two of our product candidates, INX-189 and Aurexis, have been granted Fast Track status by the FDA.

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.

Employees

As of December 31, 2010, we had 33 full-time employees, 25 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. 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 the successful outcome of current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. 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 cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will receive approval from

the FDA, or similar regulatory authorities in other countries, to 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 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 medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from 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 late-stage clinical trials will be favorable enough to support the continued development of our product candidates. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures 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 and clinical trials involving any of our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of a NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required 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 a commercially viable product. We do not expect any of our product candidates to be commercialized by us or collaborators for at least several years.

If the actual or perceived therapeutic benefits or the safety profile of INX-189 are not equal to or better than other competing anti-viral treatments approved for sale or 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. Many of these product candidates are further advanced in clinical development than INX-189, therefore their time to approval and commercialization may be sooner than that 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 with the current standard of care or future approved anti-virals for the treatment of hepatitis C.

Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, 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 and tolerability of our product candidates to obtain regulatory approval to further 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, 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 antiviral profile of INX-189 may differ in combination therapy 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 our business.

It is anticipated that in the future, the optimized treatment of chronic hepatitis C will involve the combination of at least two or more antiviral compounds. Accordingly, Phase 2 and Phase 3 clinical trials of other investigational direct acting antiviral agents, some similar to INX-189, are now being conducted in combination with the current standard of care. 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 likely require that it be evaluated in clinical trials in combination with other currently-approved antivirals or those still in development. Even if INX-189 demonstrates meaningful therapeutic benefits equal to or better than other similar compounds in development, an acceptable safety profile, and a dose amenable to combination therapy in Phase 2 and other future-stage clinical trials, when combined with other existing or HCV therapies, it may demonstrate unexpected side effects. We cannot assure you that INX-189 will be amenable for use in combination with existing or future antiviral HCV therapies in clinical development. Further, to evaluate INX-189 in combination therapy with other antivirals in clinical development may require us to establish collaborations, licensing arrangements or alliances with third parties. There is no assurance we will be able to enter into such arrangements on favorable terms, or at all.

The development of INX-189 in combination with other drugs may present additional risks beyond those inherent in the drug development of INX-189 administered alone.

We are developing INX-189 to treat chronic infections caused by HCV. Potential therapeutic regimens currently being tested, or anticipated to be tested in the future, include INX-189 in combination with:

- pegylated interferon and ribavirin, which in combination are considered to be the current standard of care;
- pegylated interferon alone;
- ribavirin alone;
- other yet-to-be-approved direct acting antiviral agents currently in clinical development; and

- pegylated interferon and/or ribavirin plus one or more direct acting antiviral agents in clinical development or approved for sale in the future.

These potential therapeutic regimens and planned clinic studies of INX-189 in combination with other approved and unapproved agents are subject to regulatory, commercial, manufacturing, and other risks that may be additional to the risks of developing a product candidate that is not used in combination. Regulatory guidelines for the use of direct acting antiviral drugs are evolving in the United States, Europe, and other countries. We anticipate that regulatory guidelines and regulatory agency responses to our and our competitors' development programs will continue to change, resulting in the risk that our activities may not meet unanticipated new standards or requirements, which could lead to delay, additional expense, or potential failure of our development activities. Our development program for INX-189 may involve the testing of it in combination with unapproved product candidates, which may increase the risk of significant adverse effects or clinical failure.

In order for us to pursue this combination strategy, we may need to engage the interest of other biopharmaceutical or pharmaceutical companies to do so, as we do not have another direct antiviral to combine with INX-189. Our ability to engage this interest will be impacted by other companies' perceived need to combine with an agent such as INX-189, as well as the risk involved in combining their agent with an unapproved product candidate such as INX-189. If they establish criteria for combination that we have not yet satisfied with INX-189, we could experience difficulties or delays in pursuing such combination trials. If we are unable to combine INX-189 with other unapproved direct acting antiviral agents, our business prospects could be harmed.

There is no assurance that in future clinical studies of INX-189, where it may be dosed for longer duration or in combination with other agents, that we will be able to identify safe and tolerable doses that result in clinical benefit, as measured by the clearance of the virus and sustainability of such clearance.

Future clinical development of INX-189 is anticipated to include trials where INX-189 will be dosed for up to 12 weeks, and potentially longer, with current standard of care and/ or other approved or unapproved direct acting antivirals. The ongoing Phase 1b study is evaluating the safety, tolerability and antiviral activity of several doses of INX-189 for seven days. It is possible that the safety and tolerability of INX-189 over longer durations of treatment may be inferior to that observed at the same dose levels at a shorter duration of treatment. If the tolerability of doses of INX-189 required for long-term treatment of HCV patients is unacceptable or unfavorable relative to competitive product candidates, then the prospects for developing INX-189 as a treatment for chronic hepatitis C may diminished, causing our business to be harmed.

If the actual or perceived therapeutic benefits of FV-100 are not sufficiently different from existing generic drugs currently used to treat shingles or reduce or prevent shingles-associated pain and PHN, 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 that are protected by patents and intellectual property rights. Unless a patented drug can differentiate itself from generic drugs treating the same condition or disease in a clinically 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 delay or terminate its future development. We cannot provide any assurance that 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 it being prescribed by physicians or commanding a price higher than the existing generic drugs.

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 similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can 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 testing, 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, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidates, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;
- regulatory authorities or 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, because we have difficulty recruiting patients 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, clinical trials and manufacturing of our trial materials, 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 or safety 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 a NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

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 of our product candidates may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

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 GCPs. 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.

We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete clinical trials of our product candidates and materially harm our business.

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio-pharmaceutical companies often have substantial staffs with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidates .

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 or our collaborators are developing require regulatory approval to advance through clinical development and to ultimately be marketed and sold, and 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 or our collaborators 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 candidate, requires the expenditure of substantial resources, and involves post-marketing surveillance and vigilance and ongoing requirements for post-marketing studies or Phase 4 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 impact our ability to raise sufficient capital to fund the development of the program candidates;
- 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 regulatory authorities 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, at any time we or our collaborators may voluntarily suspend or terminate 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, INX-189 and FV-100, are chemical compounds, also referred to as small molecules. We have limited experience in the discovery, development and manufacturing of these small molecule antiviral compounds. In order to successfully develop these product candidates, we must continuously 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 key activities to third-party consultants, and contract research and manufacturing organizations in order to advance the development of our product candidates. Therefore, our success depends in part on our ability to retain highly qualified key management, personnel, and directors to develop, implement and execute our business strategy, operate the company and oversee the activities of our consultants and contractors, as well as academic and corporate advisors or consultants to assist us in this regard. 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, formulation and chemistry, business development, accounting, finance, human resources and information systems. Although we have not experienced 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 managers or 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 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 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, cGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of 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 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 need to 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 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; establishing and maintaining intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, INX-189 or FV-100, or any other product candidate we may develop, 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 chronic hepatitis C, shingles-associated pain 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: Merck and Roche in the hepatitis C market and GlaxoSmithKline and Merck in the shingles market.

In addition to existing therapies, there are many other pharmaceutical and biopharmaceutical companies developing numerous direct acting antiviral product candidates across various classes for the treatment for chronic hepatitis C, including, but not limited to, Abbott, Achillion, Anadys, Bristol Myers Squibb, Gilead, Idenix, Pfizer, Johnson & Johnson, Pharmasset 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, Pharmasset and Idenix are developing nucleotide analogues, which are similar to the approach we are using for INX-189. Moreover, their lead nucleotide analogues have advanced further in clinical development and are currently in Phase 2 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 the EMEA. However, it is widely anticipated that one or two protease inhibitors may be approved for sale by the FDA in 2011. 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 across most or all HCV genotypes, 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 INX-189 or FV-100 have substantially more 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 resistance profile, or be more effectively marketed and sold than any drug we, or our potential collaborators, may develop or 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.

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. Generic drugs are drugs whose patent protection has expired, and generally have an average selling price substantially lower than drugs protected by intellectual property rights. Unless a patented drug can differentiate itself from a generic drug in a meaningful manner, the existence of generic competition in any indication may impose significant pricing pressure on competing patented 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.

Our research and development efforts may not result in additional HCV product candidates being discovered, which could limit our ability to generate revenues in the future.

Our research and development efforts may not lead to the discovery and development of any additional product candidates that would be suitable for further preclinical or clinical development to treat HCV. The discovery of additional HCV product candidates requires significant research and preclinical studies as well as a substantial commitment of resources. Many lead compounds that appear promising in preclinical studies fail to progress to become product candidates in clinical trials. There is a great deal of uncertainty inherent in the research and development process and, as a consequence, in our ability to advance the development of other promising HCV product candidates.

Our sponsored research with academic and commercial institutions may be subject to restriction and change, which could harm our ability to discover new HCV polymerase inhibitors.

We expect to continue to collaborate with chemists and biologists at academic and commercial institutions that assist us in our research and preclinical development efforts of HCV nucleotide polymerase inhibitors. Some of our product candidates were discovered with the research assistance of these chemists and biologists. Most of the scientists who have contributed to the discovery of our product candidates are not our employees and are employed by other institutions that may have other commitments or may elect not to contract with us in the future, which would limit their future availability to us.

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.

We are currently focused on developing additional HCV nucleoside polymerase inhibitor compounds. If in the future we decide to further expand our pipeline, we will 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 than 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 research or in preclinical studies may fail to progress into further preclinical studies or clinical trials. Our research and development efforts may not lead to the nomination of any additional product candidates that would be suitable for further preclinical or clinical development. The discovery of additional product candidates requires significant time, as well as a substantial commitment of personnel and financial resources. There is a great deal of uncertainty inherent in our research efforts and as a consequence our ability to expand our development pipeline with additional product candidates may not be successful.

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. 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. In the event any of our product candidates are approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. 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, gain meaningful market acceptance, generate a significant return to shareholders, or otherwise provide any competitive advantages in its intended indication or market.

If we fail to enter into collaborations, license agreements or other transactions with third parties to accelerate the development of our product candidates, we will bear the risk of developmental failure.

We plan to seek outlicensing opportunities as a way to accelerate the development of any of our product candidates. There is no guarantee that we will enter into a future transaction on favorable terms, or at all, or

that discussions will initiate or progress on our desired timelines. Completing transactions of this nature is difficult and time-consuming. Potentially interested parties may decline to re-engage or may terminate discussions based upon their assessment of our competitive, financial, regulatory or intellectual property position or for any other reason. Furthermore, we may choose to defer consummating a transaction relating to any of our product candidates until additional clinical data is obtained. If we decide do not actively pursue a transaction until we have additional clinical data, we and our stockholders will bear the risk that our product candidate fails prior to any future transaction.

If we fail to enter into or maintain 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 successfully developed and 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 the U.S. 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. In the event we develop a sales force and marketing capabilities, this may result in us incurring significant costs before the time that we may generate any significant product 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 similar 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, governmental agencies control prescription drugs' pricing and profitability. In the U.S. significant changes in federal health care policy have been recently approved and will mostly likely result in reduced reimbursement rates in the future. 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 that may be approved for sale 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, may also place 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 market for competitive drugs;
- the level of reimbursement provided by payers to cover the cost of the product to patients;
- the net cost of the product to the user or payer;
- the convenience and ease of administration of our product;
- 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 negative 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 social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability.

Pressure from social activist groups and future government regulations, 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 future.

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 met 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 other internal 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;
- re-evaluate the importance and their support for developing our product candidate pipeline due to a change in management, business operations 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. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the collaborative arrangement, or other licensing agreement terms. 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. 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 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, or otherwise be limited in scope. 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 also 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, 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 that have filed patent applications with respect to other nucleotide polymerase inhibitors 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 or our collaborators 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 the 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.

We cannot be sure that any patents will be issued or that patents licensed to us will be issued from any of our 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.

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, or prior to us filing patent applications on inventions we may make from time to time. 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 third-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, 2010, we have incurred a cumulative deficit of approximately \$268 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 plan to continue to conduct research, preclinical studies 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 or 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 and most likely, any future collaborations allow our partner to terminate the agreement on relatively short notice. Our quarterly and annual operating costs and revenues may become highly volatile, and comparisons to previous periods may 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 in the U.S., 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 and our independent auditor will perform their own assessment on our internal control over financial reporting. This testing is expensive and requires the attention of our limited management resources. The various financial reporting, legal, corporate governance and other obligations associated with being a publicly-traded company require us to incur significant expenditures and place additional demands on our board of directors and executive officers, as well as other 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 15 months from December 31, 2010 and continue as a going concern, 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.

We anticipate that our existing cash and cash equivalents and short-term investments on hand as of December 31, 2010, together with proceeds we expect to receive from our existing license and collaboration agreement will enable us to operate for approximately 15 months. We have no other committed sources of additional capital at this time. This estimate assumes that we complete our ongoing Phase 1b multiple ascending dose trial of INX-189 in the first quarter of 2011. This estimate does not include the direct costs associated with continuing the clinical development of INX-189 beyond the ongoing Phase 1b clinical trial or FV-100 beyond the recently completed Phase 2 trial 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 15 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 accelerate our development plans, we will need to secure additional capital. If we do not raise additional capital in the short term and continue with our development plans our liquidity guidance may be less than 15 months. We would expect to fund the Company 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 on acceptable terms 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 on acceptable terms, we may need to obtain funds through license agreements, or 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.

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 clinical development plans for INX-189, FV-100 and any of 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, and the results of these studies;
- the cost of formulating and manufacturing preclinical and clinical trial materials to evaluate our product candidates;
- whether we receive regulatory approval to advance the clinical development of our product candidates in a timely manner, if at all;
- the cost and time to obtain regulatory approvals required to advance the development of our product candidates;
- the scope and size of our research and development efforts;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish in the future;

- 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 or other listed markets;
- 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, including 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 or require us to relinquish rights.

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 debt financing 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. Any debt financing we enter into may include covenants that limit our flexibility in conducting our business. We also could be required to seek funds through arrangements with collaborators or others, which might require us to relinquish valuable rights to our intellectual property or product candidates that we would have otherwise retained.

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

As of December 31, 2010, our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 25.1% 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; and
- 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, 2010, there were outstanding warrants to purchase an aggregate of 12,868,100 shares of our common stock. These warrants had a weighted average exercise price of \$1.14. 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 in the foreseeable future, 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 \$1.0 million per annum for the remaining lease term of five 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 that are currently idle at this time.

ITEM 3. LEGAL PROCEEDINGS

Not Applicable

ITEM 4. REMOVED AND RESERVED

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, 2011, the Company had 64 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.

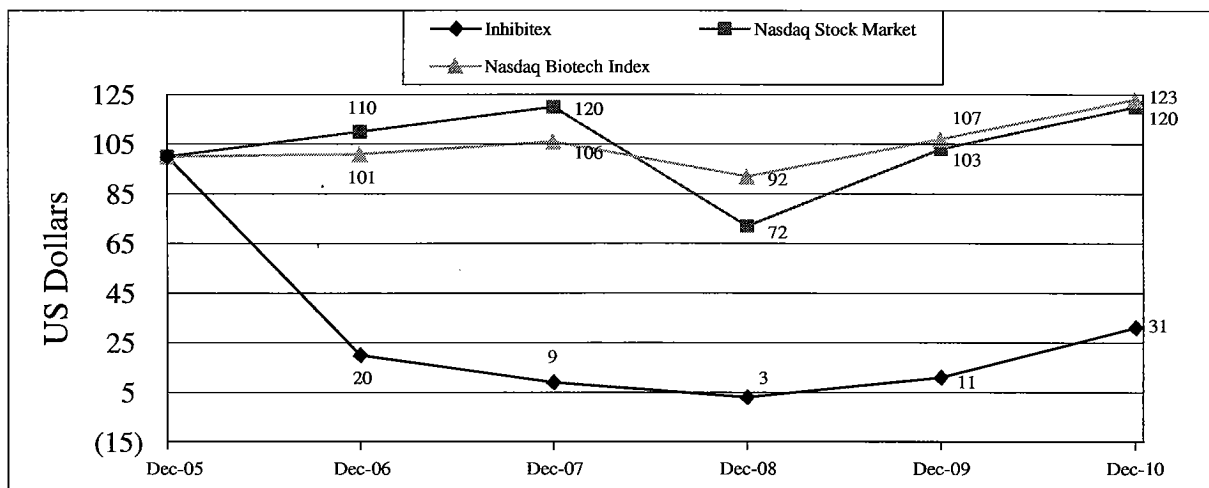
The following table shows the range of high and low prices and year-end closing prices for our common stock for each completed fiscal quarter since January 1, 2009.

	<u>2010</u>	
	<u>High</u>	<u>Low</u>
First Quarter	\$1.64	\$.88
Second Quarter	2.95	1.43
Third Quarter	2.71	1.31
Fourth Quarter	3.10	1.74
Year End Close		\$2.60
	<u>2009</u>	
	<u>High</u>	<u>Low</u>
First Quarter	\$.37	\$.21
Second Quarter56	.24
Third Quarter	1.33	.36
Fourth Quarter	1.25	.67
Year End Close		\$.92

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.

Comparative Stock Performance

The following graph and related information should not be deemed “soliciting material” or to be “filed” with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.



	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010
Inhibitex, Inc.	100	20	9	3	11	31
Nasdaq Stock Market	100	110	120	72	103	120
Nasdaq Biotech Index	100	101	106	92	107	123

Assumes \$100 invested on December 31, 2005

Assumes \$100 invested on December 31, 2005

ITEM 6. SELECT FINANCIAL DATA

The following selected financial data are derived from our audited consolidated financial statements. This data should be read in conjunction with our audited consolidated financial statements and related notes which are included elsewhere in this Annual Report on Form 10-K, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 below.

	Years Ended December 31,				
	2010	2009	2008	2007(1)	2006
	(In thousands, except share and per share data)				
Statement of Operations Data:					
Revenues	\$ 1,862	\$ 1,150	\$ 3,150	\$ 2,804	\$ 846
Cost and expenses:					
Research and development . . .	21,041	15,393	12,548	42,586	23,417
General and administrative . . .	4,059	3,552	5,075	6,301	12,758
Total costs and expenses	25,100	18,945	17,623	48,887	36,175
Operating loss	(23,238)	(17,795)	(14,473)	(46,083)	(35,329)
Interest income, net	65	168	1,224	2,655	3,124
Other income, net	504	37	88	1,969	1,060
Net loss	<u>(22,669)</u>	<u>(17,590)</u>	<u>(13,161)</u>	<u>(41,459)</u>	<u>(31,145)</u>
Net loss per common share:					
Basic and Diluted	<u>\$ (0.37)</u>	<u>\$ (0.38)</u>	<u>\$ (0.31)</u>	<u>\$ (1.22)</u>	<u>\$ (1.03)</u>
Weighted average number of shares used in per common share calculations:					
Basic and Diluted	<u>62,001,757</u>	<u>46,664,811</u>	<u>43,090,432</u>	<u>34,026,250</u>	<u>30,259,979</u>

(1) 2007 research and development expenses include \$10,016 for in-process research and development costs in connection with the FermaVir acquisition.

	As of December 31,				
	2010	2009	2008	2007	2006
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 8,554	\$11,290	\$11,507	\$14,178	\$19,682
Short-term investments	11,015	26,625	21,635	36,088	41,676
Working capital	13,870	35,000	30,362	41,997	52,678
Total assets	21,489	40,470	36,233	53,934	66,224
Long-term debt and capital leases	304	728	779	772	1,455
Total stockholders' equity (deficit)	\$13,841	\$34,750	\$30,426	\$42,200	\$53,077

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 oral, small molecule compounds to treat viral infections, and in particular, chronic infections caused by HCV, and herpes zoster, also referred to as shingles, which is caused by VZV. Currently, available antiviral therapies that are used to treat these and other infections have a number of therapeutic limitations, including inadequate potency, significant adverse side effects, complex and inconvenient dosing schedules 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 medical 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 for the foreseeable future our operations will result in a net loss on a quarterly and yearly basis. As of December 31, 2010, we had an accumulated deficit of \$268 million.

Financial Operations Overview

Revenue. We have generated revenue 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, milestone payments 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 2011, we expect our revenues will decrease from 2010 as we do not plan on receiving a milestone payment from Pfizer 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; and 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, 2010, 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 preclinical 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.

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
	(In millions)		
Direct external costs:			
FV-100	\$ 5.1	\$ 4.0	\$ 3.7
INX-189	6.6	3.3	0.9
Research programs	0.8	0.4	(0.5)
Unallocated costs and overhead	<u>8.5</u>	<u>7.7</u>	<u>8.4</u>
Total research and development expenses	<u>\$21.0</u>	<u>\$15.4</u>	<u>\$12.5</u>

We anticipate that our research and development expense will increase in 2011, as compared to 2010, assuming we continue the clinical development plans of INX-189 and FV-100. Due to the uncertainty regarding the timing and regulatory approval of clinical trials and preclinical studies, our future expenditures are likely to be highly volatile in future periods depending on the 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 and market research, as well as premiums for insurance, other expenses that result from being a publicly-traded company, and depreciation and facility expenses. In 2011, we expect our general and administrative expense to slightly increase from our 2010 expense levels.

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, research and development tax grants 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.

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. Revenues received for milestone payments are recognized 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 clinical research and data management organizations and investigators in conjunction with the conduct of our clinical trials, research organizations that perform preclinical studies, and fees owed to 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 United States generally accepted accounting principles.

Share-Based Compensation We use the Black-Scholes method to estimate the value of stock options granted to employees and directors. Our forfeiture rate is based on historical experience as well as anticipated turnover and other qualitative and quantitative factors, which may change over time. There may be adjustments to future periods if actual forfeitures differ from current estimates. Our time based awards are issued with graded vesting. The compensation cost for these graded vesting awards is recognized on the straight-line method. The Company has issued performance based options, for which at the time of grant the achievement of the performance condition is not probable. When achievement of the performance condition becomes probable, the Company records a change in estimate in the period of change by recording a cumulative catch-up adjustment over the implicit service period using the straight-line method.

Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board ("FASB") amended the guidance for applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, the Company may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. This amendment is effective on a prospective basis for research and development milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. This amendment is effective for the Company beginning January 1, 2011.

The adoption of this amendment is not expected to have a material 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. The adoption of this amendment is not expected to have a material impact on the Company's consolidated financial position or results of operations.

Results of Operations

Fiscal Years Ended December 31, 2010 and 2009

Summary. For 2010, we reported a net loss of \$22.7 million, as compared to a net loss of \$17.6 million in 2009 and basic and diluted net loss per share of \$0.37 in 2010 as compared to \$0.38 in 2009. The increase in net loss in 2010 was primarily the result of higher research and development expense associated with the Phase 2 clinical trial of FV-100, Phase 1 clinical trials of INX-189 and the company's HCV nucleotide polymerase inhibitor program, higher general and administrative expense and lower net interest income, offset in part by higher revenues from a collaborative license and development agreement and net other income. The slight decrease in net loss per share was due to a higher weighted average amount of shares outstanding, offset largely by the increase in net loss.

We expect to incur losses for the foreseeable future as we intend to continue to support the clinical development of INX-189, FV-100 and our HCV nucleoside polymerase inhibitor program.

Revenue. Revenue increased to \$1.9 million in 2010 from \$1.2 million in 2009. This \$0.7 million increase was primarily the result of a milestone payment earned in connection with our license and collaboration agreement with Pfizer.

Research and Development Expense. Research and development expense increased to \$21.0 million in 2010 from \$15.4 million in 2009, representing an increase of \$5.6 million, or 36.4%. The following table summarizes the components of our research and development expense for 2010 and 2009.

	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
	(In millions)	
Direct preclinical, clinical and manufacturing expenses	\$12.5	\$ 7.6
Salaries, benefits and share-based compensation expenses	4.2	3.8
License fees, legal and other expenses	2.5	2.1
Depreciation and facility related expenses	<u>1.8</u>	<u>1.9</u>
Total research and development expense	<u>\$21.0</u>	<u>\$15.4</u>

Direct preclinical, clinical and manufacturing costs increased due to a \$3.3 million increase in costs related to Phase 1 clinical trials for INX-189, a \$1.1 million increase related to the Phase 2 clinical trial of FV-100 and a \$0.5 million increase in our back-up or follow-on HCV nucleotide polymerase inhibitor program. Salaries, benefits and share-based compensation expense increased due to higher share-based compensation expenses and benefit expenses. License fees, patent-related legal fees and other expenses increased largely due an increase in regulatory consulting fees due to the clinical advancement of INX-189 and FV-100. Depreciation and facility related expenses decreased due to lower depreciation expense.

General and Administrative Expense. General and administrative expense increased to \$4.1 million in 2010 from \$3.6 million in 2009, representing an increase of \$0.5 million, or 13.9%. The following table summarizes the components of our general and administrative expense for 2010 and 2009.

	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
	(In millions)	
Salaries, benefits and share-based compensation expenses	\$1.7	\$1.6
Professional and legal fees expenses	1.2	0.9
Other expenses	1.0	0.9
Depreciation and facility related expenses	<u>0.2</u>	<u>0.2</u>
Total general and administrative expense	<u>\$4.1</u>	<u>\$3.6</u>

Salaries, benefits and share-based compensation expense increased primarily due to higher share-based compensation expense. Professional and legal fees increased due to higher legal and auditing expenses. Other expenses increased slightly due to higher shareholder service expenses.

Interest and Other Income, net. Interest and other income, net increased to \$0.6 million in 2010 from \$0.2 million in 2009. The net increase of \$0.4 million was largely the result of \$0.5 million in research and development grants under the Qualifying Therapeutic Discovery Project (“QTDP”), offset partially by a decrease of \$0.1 million in interest income earned.

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.

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.

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
	(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	<u>1.9</u>	<u>2.1</u>
Total research and development expense	<u>\$15.4</u>	<u>\$12.5</u>

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 backup 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.

	<u>December 31,</u>	
	<u>2009</u>	<u>2008</u>
	(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	<u>0.2</u>	<u>0.6</u>
Total general and administrative expense	<u>\$3.6</u>	<u>\$5.1</u>

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. 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 expenses 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 primarily due to lower interest rates in 2009 than in 2008.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in May 1994 through December 31, 2010, 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 investments in public equity financings.

From inception through December 31, 2010, 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 \$17.7 million in license fees, collaborative research payments and grants, of which \$0.1 million and \$0.3 million were recorded as deferred revenue as of December 31, 2010 and December 31, 2009, respectively. In 2010, the Company also received \$0.5 million in grants under the QTDP.

At December 31, 2010, cash, cash equivalents and short-term investments were \$19.6 million and we held no investments with a maturity greater than 12 months. Our cash, cash equivalents and short-term investments are generally held in a variety of interest-bearing instruments, consisting of 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, 2010, cash, cash equivalents, and short-term investments were \$19.6 million as compared to \$37.9 million as of December 31, 2009, a decrease of \$18.3 million. This decrease was primarily the result of net cash used for operating activities and, to a much lesser extent, the repayment of capital lease obligations and notes payable, offset in part by the proceeds from exercises of stock options and warrants.

Net cash used for operating activities was \$18.4 million in 2010, which reflects our net loss for the period of \$22.7 million, offset in part by a net increase in operating liabilities over operating assets of \$2.3 million and non-cash charges of \$2.0 million. Our net loss resulted largely from the cost of funding our clinical trials, preclinical studies, 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 \$1.4 million increase in accrued expenses, a \$1.0 million increase in accounts payable and other current liabilities, and a \$0.2 million decrease in prepaid expenses and other assets, offset in part by a \$0.1 million increase in accounts receivables and a \$0.2 million decrease in deferred revenue.

Net cash used for investing activities was \$15.1 million, which primarily consisted of net proceeds from short-term investments of \$15.2 million, offset by \$0.1 million in cash paid for capital expenditures.

Net cash from financing activities was \$0.6 million, which consisted of \$0.9 million of proceeds from the exercise of stock options and warrants during 2010, 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 INX-189, FV-100 and any of 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 and time to obtain regulatory approvals required to advance the development of our product candidates;
- the scope and size of our research and developmental efforts;
- 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 anticipated timelines, we believe that our existing cash, cash equivalents and short-term investments of \$19.6 million as of December 31, 2010, including anticipated proceeds from our existing license and collaboration agreements, will enable us to operate for a period of approximately 15 months. This estimate assumes that we complete our ongoing Phase 1b multiple ascending dose trial of INX-189 in the first quarter of 2011. This estimate does not include the direct costs associated with continuing the clinical development of INX-189 beyond the ongoing Phase 1b clinical trial or FV-100 beyond the recently completed Phase 2 trial 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 15 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. If we do not raise additional capital in the short term and continue with our development plans our liquidity guidance may be less than 15 months. We would expect to fund the Company 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.

Contractual Obligations and Commitments

We have entered into an operating lease for an office and laboratory space located in Alpharetta, Georgia through May, 2015. The annual occupancy expense under this lease is approximately \$1 million. We have a secured promissory note for which we owe \$0.5 million and capital leases under which we owe \$0.2 million as of December 31, 2010. As of December 31, 2010, future payments under these debt obligations and minimum future payments under non-cancellable operating leases are as follows:

	Payments Due By Period				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
	(In thousands)				
Debt obligations					
Debt	\$ 547	\$ 243	\$ 304	\$ —	\$—
Capital lease obligations	181	181	—	—	—
Operating leases	4,267	949	2,977	341	—
Purchase obligations	<u>710</u>	<u>559</u>	<u>151</u>	<u>—</u>	<u>—</u>
Total contractual obligations	<u>\$5,705</u>	<u>\$1,932</u>	<u>\$3,432</u>	<u>\$341</u>	<u>\$—</u>

The above contractual obligations table does not include amounts for milestone payments related to development, regulatory, or commercialization events to licensors or collaboration partners, as the payments are contingent on the achievement of these milestones, which we have not achieved.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We invest our excess cash in high quality, interest-bearing securities. The primary objective of our investment activities is to preserve principal while at the same time achieving acceptable yields without any significant risk. To achieve this objective, 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. If a 10% change in interest rates were to have occurred on December 31, 2010, this change would not have had a material effect on future earnings, cash flows or the fair value of our investment portfolio as of that date.

Foreign Currency Exchange Rate Risk

We have entered into some contractual agreements denominated, wholly or partly, in foreign currencies, and, in the future, we may enter into additional, agreements denominated in foreign currencies. If the values of these currencies increase against the United States dollar, our costs would increase. To date, we have not entered into any contracts to reduce the risk of fluctuations in currency exchange rates. In the future, depending upon the amounts payable under any such agreements, we may enter into forward foreign exchange contracts to reduce the risk of unpredictable changes in these costs. However, due to the variability of timing and amount of payments under any such agreements, foreign exchange contracts may not mitigate the potential adverse impact on our financial results.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item is included in our Financial Statements and Supplementary Data listed in Item 15 of Part IV of this Annual Report on Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit pursuant to the Securities Exchange Act 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, 2010. 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, 2010, 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.

Ernst & Young LLP, the independent registered public accounting firm that audited our financial statements included elsewhere in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting. That report appears in Item 15 of Part IV of this Annual Report on Form 10-K and is incorporated by reference to this Item 9A.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2010 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

Incorporated by reference to the sections labeled "Proposal 1 Election of Directors," "Executive Officers," and "Corporate Governance" in our proxy statement to be filed in connection with our 2011 annual meeting of stockholders.

ITEM 11. EXECUTIVE COMPENSATION

Incorporated by reference to the sections labeled "Executive Compensation," "Compensation of Directors" and "Compensation Committee Report" in our proxy statement to be filed in connection with our 2011 annual meeting of stockholders.

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

Incorporated by reference to the sections labeled "Principal Stockholders," and "Executive Compensation" in our proxy statement to be filed in connection with our 2011 annual meeting of stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Incorporated by reference to the sections labeled "Certain Relationships and Related Transactions" and "Corporate Governance" in our proxy statement to be filed in connection with our 2011 annual meeting of stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Incorporated by reference to the section labeled "Independent Registered Public Accountants" in our proxy statement to be filed in connection with our 2011 annual meeting of stockholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The following documents are included on pages F-1 through F-29 attached hereto and are filed as part of this annual report on Form 10-K.

Reports of Independent Registered Public Accounting Firm	F-1, F-2
Consolidated Balance Sheets as of December 31, 2010 and 2009	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2010, 2009 and 2008 . . .	F-4
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2010, 2009 and 2008	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2010, 2009 and 2008 . . .	F-6
Notes to Consolidated Financial Statements	F-7

(a)(2) Financial Statement Schedules

Not applicable

(a)(3) List of Exhibits

The exhibits which are filed with this report or which are incorporated herein by reference are set forth in the Exhibit Index hereto.

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 16th day of March, 2011.

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Russell H. Plumb Russell H. Plumb	President, Chief Executive Officer, Chief Financial Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)	March 16 , 2011
/s/ Michael A. Henos Michael A. Henos	Chairman of the Board of Directors	March 16, 2011
/s/ M. James Barrett, Ph.D. M. James Barrett, Ph.D.	Director	March 16 , 2011
/s/ Chris McGuigan, M.Sc., Ph.D. Chris McGuigan	Director	March 16, 2011
/s/ A. Keith Willard. A. Keith Willard.	Director	March 16, 2011
/s/ Russell M. Medford, M.D., Ph.D. Russell M. Medford, M.D., Ph.D.	Director	March 16, 2011
/s/ Marc L. Preminger, FSA, MAAA Marc L. Preminger, FSA, MAAA	Director	March 16, 2011
/s/ Gabriele M. Cerrone. Gabriele M. Cerrone	Director	March 16, 2011

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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Inhibitex, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Atlanta, Georgia
March 16, 2011

INHIBITEX, INC.
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

We have audited Inhibitex, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Inhibitex, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, Inhibitex, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the accompanying consolidated balance sheets of Inhibitex, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010 and our report dated March 16, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Atlanta, Georgia
March 16, 2011

INHIBITEX, INC.
Consolidated Balance Sheets

	December 31,	
	2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,554,151	\$ 11,290,332
Short-term investments	11,014,747	26,625,496
Prepaid expenses and other current assets	599,042	831,196
Accounts receivable	178,654	61,062
Total current assets	20,346,594	38,808,086
Property and equipment, net	1,090,029	1,621,392
Other assets	52,514	40,290
Total assets	\$ 21,489,137	\$ 40,469,768
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,768,020	\$ 1,590,804
Accrued expenses	2,917,347	1,537,637
Current portion of notes payable	243,056	78,125
Current portion of capital lease obligations	180,792	207,100
Current portion of deferred revenue	129,167	191,667
Other current liabilities	238,703	202,531
Total current liabilities	6,477,085	3,807,864
Long-term liabilities:		
Notes payable, net of current portion	303,819	546,875
Capital lease obligations, net of current portion	—	180,792
Deferred revenue, net of current portion	—	87,500
Other liabilities, net of current portion	867,455	1,096,629
Total long-term liabilities	1,171,274	1,911,796
Total liabilities	7,648,359	5,719,660
Stockholders' equity:		
Preferred stock, \$.001 par value; 5,000,000 shares authorized at December 31, 2010 and 2009, none issued and outstanding at December 31, 2010 and 2009	—	—
Common stock, \$.001 par value; 150,000,000 shares authorized at December 31, 2010 and 2009, respectively; 62,423,358 and 61,559,782 shares issued and outstanding at December 31, 2010 and 2009, respectively	62,423	61,560
Additional paid-in capital	270,187,742	267,432,572
Accumulated other comprehensive income	542	8,977
Warrants	11,145,558	12,133,216
Accumulated deficit	(267,555,487)	(244,886,217)
Total stockholders' equity	13,840,778	34,750,108
Total liabilities and stockholders' equity	\$ 21,489,137	\$ 40,469,768

See accompany notes to the consolidated financial statements

INHIBITEX, INC.
Consolidated Statements of Operations

	<u>Year Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Revenue:			
License fees and milestones	\$ 861,667	\$ 150,000	\$ 1,650,000
Collaborative research and development	<u>1,000,000</u>	<u>1,000,000</u>	<u>1,500,000</u>
Total revenue	1,861,667	1,150,000	3,150,000
Operating expense:			
Research and development	21,040,727	15,393,066	12,548,430
General and administrative	<u>4,059,675</u>	<u>3,551,682</u>	<u>5,075,048</u>
Total operating expense	<u>25,100,402</u>	<u>18,944,748</u>	<u>17,623,478</u>
Loss from operations	(23,238,735)	(17,794,748)	(14,473,478)
Other income, net	504,073	36,535	87,651
Interest income, net	<u>65,392</u>	<u>168,212</u>	<u>1,224,584</u>
Net loss	<u>\$(22,669,270)</u>	<u>\$(17,590,001)</u>	<u>\$(13,161,243)</u>
Basic and diluted net loss per share	<u>\$ (0.37)</u>	<u>\$ (0.38)</u>	<u>\$ (0.31)</u>
Weighted average shares used to compute basic and diluted net loss per share	<u>62,001,757</u>	<u>46,664,811</u>	<u>43,090,432</u>

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
Exercise of stock options and warrants and issuances of employee stock purchase plan . .	—	—	—	—	863,576	863	1,571,901	—	(706,935)	—	865,829
Expiration of common stock warrants	—	—	—	—	—	—	280,723	—	(280,723)	—	—
Share-based compensation expense	—	—	—	—	—	—	902,546	—	—	—	902,546
Net loss	—	—	—	—	—	—	—	—	—	(22,669,270)	(22,669,270)
Other comprehensive loss	—	—	—	—	—	—	—	(8,435)	—	—	(8,435)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	(22,677,705)
Balance at December 31, 2010	—	\$—	—	\$—	62,423,358	\$62,423	\$270,187,742	\$ 542	\$11,145,558	\$(267,555,487)	\$ 13,840,778

See accompany notes to the consolidated financial statements

INHIBITEX, INC.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2010	2009	2008
Cash flows from operating activities:			
Net loss	\$(22,669,270)	\$(17,590,001)	\$(13,161,243)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	631,001	806,152	837,094
Share-based compensation expense	902,546	515,386	1,491,119
Gain on sale of property and equipment	(10,487)	(39,890)	(74,076)
Amortization of investment premium or discount	430,210	84,224	(647,417)
Changes in operating assets and liabilities, net of acquisition:			
Prepaid expenses and other assets	219,930	(217,813)	411,812
Accounts receivable	(117,592)	47,496	(63,570)
Accounts payable and other liabilities	984,214	108,833	335,098
Accrued expenses	1,379,710	536,590	(5,367,203)
Deferred revenue	(150,000)	(400,000)	(150,000)
Net cash used in operating activities	<u>(18,399,738)</u>	<u>(16,149,023)</u>	<u>(16,388,386)</u>
Cash flows from investing activities:			
Purchases of property and equipment	(99,638)	(98,837)	(468,507)
Purchases of investments	(20,903,896)	(34,367,313)	(45,913,947)
Proceeds from maturities and sales of investments	36,076,000	29,190,000	61,019,763
Proceeds from sale of property and equipment	10,487	39,890	81,730
Cash paid in connection with the acquisition	—	—	(179,222)
Net cash provided by (used in) investing activities	<u>15,082,953</u>	<u>(5,236,260)</u>	<u>14,539,817</u>
Cash flows from financing activities:			
Proceeds from capital lease financing	—	—	368,121
Payments on promissory note and capital leases	(285,225)	(332,416)	(1,075,153)
Repurchase of common stock	—	(3,213)	(130,583)
Proceeds from the issuance of common stock	865,829	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	<u>580,604</u>	<u>21,168,478</u>	<u>(822,437)</u>
Decrease in cash and cash equivalents	(2,736,181)	(216,805)	(2,671,006)
Cash and cash equivalents at beginning of year	<u>11,290,332</u>	<u>11,507,137</u>	<u>14,178,143</u>
Cash and cash equivalents at end of year	<u>\$ 8,554,151</u>	<u>\$ 11,290,332</u>	<u>\$ 11,507,137</u>
Supplemental cash flow information:			
Interest paid	<u>\$ 39,359</u>	<u>\$ 64,054</u>	<u>\$ 67,972</u>
Non-cash investing and financing activities:			
Fixed assets capitalized using capital lease	\$ —	\$ —	\$ 269,854
Warrants to purchase 347,924 shares of common stock were exercised in a cashless transaction at an exercise price of \$1.46 per share resulting in the issuance of 138,709 shares of common stock	\$ 507,969	\$ —	\$ —

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 oral, small molecule compounds to treat viral infections, and in particular, chronic infections caused by hepatitis C virus, or ("HCV"), and herpes zoster, also referred to as shingles, which is caused by the varicella zoster virus, or ("VZV"). Currently, available antiviral therapies that are used to treat these and other infections have a number of therapeutic limitations that include inadequate potency, significant adverse side effects, complex and inconvenient dosing schedules 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 medical 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 observable inputs based on 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, 2010 and 2009 consisted primarily of U.S. treasury securities, U.S. government agency securities, commercial paper, corporate debt and money market accounts.

INHIBITEX, INC. — (Continued)

Fair Value Measurements. The Company has adopted the guidance related to fair value measurements pertaining to financial and non-financial assets and 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.

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:

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

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 for indicators of impairment and related impairment testing.

Revenue Recognition. Revenue relates to fees 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 employee 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 that 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 which 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

INHIBITEX, INC. — (Continued)

future turnover and other qualitative and quantitative factors which may change over time. There may be adjustments to future periods if actual forfeitures differ from current estimates. The Company's time-based awards are issued with graded vesting. The compensation cost for time-based graded vesting awards is recognized on the straight-line method. The Company has issued performance based options, for which at the time of grant the achievement of the performance condition is not probable. When achievement of the performance condition becomes probable, the Company records a change in estimate in the period of change by recording a cumulative catch-up adjustment over the implicit service period using 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, and market research 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 valuation allowance may be 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 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

INHIBITEX, INC. — (Continued)

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 is classified in the balance sheet as other liabilities.

Recent Accounting Pronouncements.

In April 2010, the Financial Accounting Standards Board (“FASB”) amended the guidance for applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, the Company may recognize revenue contingent upon the achievement of a milestone in its entirety in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. This amendment is effective on a prospective basis for research and development milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. This amendment is effective for the Company beginning January 1, 2011. The adoption of this amendment is not expected to have a material 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. The adoption of this amendment is not expected to have a material impact on the Company’s consolidated financial position or results of operations.

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.

INHIBITEX, INC. — (Continued)

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

	Year Ended December 31,		
	2010	2009	2008
Historical			
Numerator:			
Net loss attributable to common stockholders	<u>\$(22,669,270)</u>	<u>\$(17,590,001)</u>	<u>\$(13,161,243)</u>
Denominator:			
Weighted average common shares outstanding	<u>62,001,757</u>	<u>46,664,811</u>	<u>43,090,432</u>
Basic and diluted net loss per share	<u>\$ (0.37)</u>	<u>\$ (0.38)</u>	<u>\$ (0.31)</u>

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

	December 31,		
	2010	2009	2008
Common stock options	6,967,567	5,740,908	4,820,459
Restricted common stock	—	—	140,000
Common stock warrants	<u>12,868,100</u>	<u>14,053,318</u>	<u>8,022,863</u>
Total	<u>19,835,667</u>	<u>19,794,226</u>	<u>12,983,322</u>

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, 2010, 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.

The Company's short-term investments have been classified as Level 2, which have been initially valued at the transaction price and subsequently revalued, at the end of each reporting period, utilizing a third party pricing service. The pricing service utilizes industry standard valuation models and observable market inputs to determine value that include surveying the bond dealer community, obtaining benchmark quotes, incorporating relevant trade data, and updating spreads daily.

There have been no transfers of assets or liabilities between the fair value measurement classifications.

INHIBITEX, INC. — (Continued)

<u>December 31, 2010</u>	<u>Total</u>	<u>Quoted Prices in Active Markets for Identical Assets (Level 1)</u>	<u>Significant Other Observable Inputs (Level 2)</u>	<u>Significant Unobservable Inputs (Level 3)</u>
Cash equivalents	\$ 7,932,606	\$7,932,606	\$ —	\$—
Short-term investments available-for-sale	<u>11,014,747</u>	<u>—</u>	<u>11,014,747</u>	<u>—</u>
Total	<u><u>\$18,947,353</u></u>	<u><u>\$7,932,606</u></u>	<u><u>\$11,014,747</u></u>	<u><u>\$—</u></u>

Cash equivalents consist primarily of money market funds and certificates of deposit with original maturity dates of three months or less. Short-term investments consist of commercial paper, corporate debt, U.S. agency securities and U.S. Treasury securities, classified as available-for-sale and have maturities greater than 90 days, but less than 365 days from the date of acquisition.

The Company has had no realized gains or losses from the sale of investments for the twelve months ended December 31, 2010. The following table shows the unrealized gains and losses and fair values for those investments as of December 31, 2010 and December 31, 2009 aggregated by major security type:

<u>December 31, 2010</u>	<u>At Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized (Losses)</u>	<u>At Fair Value</u>
Money market funds	\$ 7,932,606	\$ —	\$ —	\$ 7,932,606
Commercial paper	6,494,842	2,713	—	6,497,555
Corporate debt	<u>4,519,363</u>	<u>221</u>	<u>(2,392)</u>	<u>4,517,192</u>
Total	<u><u>\$18,946,811</u></u>	<u><u>\$2,934</u></u>	<u><u>\$(2,392)</u></u>	<u><u>\$18,947,353</u></u>

<u>December 31, 2009</u>	<u>At Cost</u>	<u>Unrealized Gains</u>	<u>Unrealized (Losses)</u>	<u>At Fair Value</u>
Certificates of deposit and money market funds	\$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	<u>503,986</u>	<u>103</u>	<u>(66)</u>	<u>504,023</u>
Total	<u><u>\$36,996,982</u></u>	<u><u>\$15,477</u></u>	<u><u>\$(6,500)</u></u>	<u><u>\$37,005,959</u></u>

As of December 31, 2010, the Company had investments in an unrealized loss position. The Company has determined that the unrealized losses on these investments at December 31, 2010 are temporary in nature and expects the security to mature at its stated maturity principal. All available-for-sale securities held at December 31, 2010 will mature within one year or less.

INHIBITEX, INC. — (Continued)

5. Prepaid Expenses

The components of prepaid expenses are as follows:

	December 31,	
	2010	2009
Interest receivable	\$102,250	\$166,967
Prepaid preclinical, clinical and manufacturing	285,294	392,797
Prepaid other	211,498	271,432
Total	\$599,042	\$831,196

6. Property and Equipment

The components of property and equipment are as follows:

	December 31,	
	2010	2009
Laboratory equipment	\$ 1,853,144	\$ 2,044,804
Leasehold improvements	2,455,321	2,455,321
Computer software and equipment	463,629	671,227
Office furniture and fixtures	115,002	115,002
Sub-total	4,887,096	5,286,354
Less accumulated depreciation and amortization	(3,797,067)	(3,664,962)
Total property and equipment, net	\$ 1,090,029	\$ 1,621,392

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 \$631,001, \$806,152 and \$966,345 for the years ended December 31, 2010, 2009 and 2008, respectively.

In 2010, the Company retired \$260,247 of laboratory equipment and \$215,991 in computer equipment with a net asset value of \$325. In 2009, the Company retired \$912,594 of laboratory equipment with a net asset value of \$71,664. 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 \$246,221 and \$431,521 as of December 31, 2010 and 2009.

INHIBITEX, INC. — (Continued)

7. Accrued Expenses

The components of accrued expenses are as follows:

	December 31,	
	2010	2009
Preclinical, clinical and manufacturing expense	\$1,325,360	\$ 410,207
Salaries and benefits expense	693,256	481,765
Professional fee expense	304,916	252,802
Other operating expense	593,815	392,863
Total	<u>\$2,917,347</u>	<u>\$1,537,637</u>

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 net present value 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 \$136,873 and \$181,012 as of December 31, 2010 and 2009, 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, 2010, 2009 and 2008, gross rent expense totaled approximately \$900,000, \$932,000 and \$920,000, respectively; these amounts were offset against sublease rental receipts of

INHIBITEX, INC. — (Continued)

\$140,000, \$119,000 and \$104,000, respectively. Future minimum payments and receipts under these operating leases at December 31, 2010 are as follows:

<u>Year Ending December 31,</u>	<u>Payments</u>	<u>Receipts</u>
2011	\$ 948,678	\$ 75,179
2012	967,940	128,036
2013	992,137	132,535
2014	1,016,939	—
2015 and after	<u>341,758</u>	<u>—</u>
Total minimum lease payments and receipts under operating leases	<u>\$4,267,452</u>	<u>\$335,750</u>

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 211,000 pounds sterling in annual cooperative research agreement funding as of December 31, 2010. 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, 2010 are as follows:

<u>Year Ending December 31,</u>	
2011	\$ 188,913
2012	<u>—</u>
Total future minimum lease payments	188,913
Less amount representing interest	<u>(8,121)</u>
Present value of future minimum lease payments	180,792
Less current portion of capital lease obligations	<u>(180,792)</u>
Long-term portion of capital lease obligations	<u>\$ —</u>

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 made one payment of \$78,125 on January 1, 2010 and then will 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, 2010 and December 31, 2009, \$546,875 and \$625,000 were outstanding under this note payable, respectively. The loan is secured by leasehold lab improvements of the Company's facility.

INHIBITEX, INC. — (Continued)

Future minimum payments due under notes payable as of December 31, 2010 are as follows:

<u>Year Ending December 31,</u>	
2011	\$243,056
2012	243,056
2013	<u>60,763</u>
Total future payments	<u>\$546,875</u>

10. Other Liabilities

The components of other liabilities are as follows:

	<u>December 31,</u>	
	<u>2010</u>	<u>2009</u>
Deferred amortization of leasehold improvements and deferred rent	\$ 950,510	\$1,106,873
Other	155,648	192,287
Less current portion of other liabilities	<u>(238,703)</u>	<u>(202,531)</u>
Long term portion of other liabilities	<u>\$ 867,455</u>	<u>\$1,096,629</u>

The Company entered into a lease for its office and laboratory facility (See Note 8-Commitments) pursuant to which leasehold improvements paid by the lessor pursuant to the lease agreement were capitalized. The leasehold improvement assets are being amortized over seven years and the liability is being amortized over 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, 2010, the Company had available federal net operating loss (“NOL”) carry forwards of approximately \$216,505,729 and state NOL carry forwards of \$207,314,225 which continue to expire over a period of 20 years. The Company had \$263,039 of federal and state NOL carry forwards expire in 2010. A portion of the Company’s existing NOL carry forwards relates to excess benefits on equity compensation and will be recorded as an increase to stockholders’ equity when realized in future periods. The Company also has approximately \$4,746,414 of research and development (“R&D”) tax credit carry forwards as of December 31, 2010 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.

INHIBITEX, INC. — (Continued)

The Company has no uncertain tax positions. As of December 31, 2010, 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, 2010. 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, 2010, 2009 and 2008. The primary factors causing income tax expense to be different than the federal statutory rates are as follows:

	December 31,		
	2010	2009	2008
Income tax benefit at statutory rate	\$(7,707,552)	\$(5,980,600)	\$(4,474,823)
State income tax benefit, net of federal tax benefit	(880,980)	(644,536)	(548,995)
IPR&D expense	—	—	(43,945)
General business credit	(696,264)	(456,792)	(425,273)
Other	155,988	446,713	(194,829)
Valuation allowance	<u>9,128,808</u>	<u>6,635,215</u>	<u>5,687,865</u>
Income tax expense	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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,	
	2010	2009
Deferred tax assets:		
Net operating loss carry forwards	\$ 81,798,194	\$ 73,770,008
Research and development tax credit carry forwards	4,746,414	4,062,559
Depreciation and amortization	1,908,944	1,826,603
Accruals and reserves	653,049	511,286
Compensation accruals	1,096,956	929,661
Other, net	<u>(7,613)</u>	<u>(32,981)</u>
Total deferred tax assets	90,195,944	81,067,136
Less valuation allowance	<u>(90,195,944)</u>	<u>(81,067,136)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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 \$9,128,808 and \$6,635,215 in 2010 and 2009, respectively, as follows:

	December 31,	
	2010	2009
Deferred tax valuation allowance at beginning of year	\$81,067,136	\$74,431,921
Change in cumulative tax differences	<u>9,128,808</u>	<u>6,635,215</u>
Deferred tax valuation allowance at end of year	<u>\$90,195,944</u>	<u>\$81,067,136</u>

INHIBITEX, INC. — (Continued)

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, 2010 and 2009, the Company was authorized to issue 150,000,000 shares of common stock. Each holder of common stock is entitled to one vote for each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

Private Placement. In October 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, 2010. 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, 2010, the Company had 624 shares committed to be released to employees and had granted 100,039 shares out of the plan. The Company recorded \$1,070 of share-based compensation expense on all discounts to the fair market value during the purchase period of 2010.

INHIBITEX, INC. — (Continued)

Common Stock Warrants. In 2010, a total of 448,628 warrants expired with a weighted average exercise price of \$2.64. The total Black-Scholes value of those warrants was \$280,723 and such amount was reclassified from warrants to additional paid-in capital. Additionally in 2010, a total of 736,590 warrants were exercised with a weighted average exercise price of \$1.19 and a total Black-Scholes value of \$706,935. 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, 2010 and 2009, there were 12,868,100 and 14,053,318 warrants outstanding, respectively. As of December 31, 2010, all of the outstanding warrants are exercisable and expire from May 12, 2011 to September 26, 2018. The weighted average strike price as of December 31, 2010 and 2009 was \$1.14 and \$1.19, respectively.

Share-Based Award Plan

For the twelve months ended December 31, 2010, 2009 and 2008, the Company recorded share-based compensation expense related to grants from these plans of \$902,546, \$515,386 and \$1,491,119, or \$0.01, \$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, 2010, 2009 and 2008.

2004 Stock Incentive Plan. In March 2010, the Board of Directors approved the 2004 amended and restated Stock Incentive Plan (“the 2004 Plan”). The 2004 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock units, restricted stock awards, stock appreciation rights, cash payments and other forms of stock-based compensation, which may be granted to employees, non-employee directors, contractors and consultants. The 2004 Plan will terminate upon the earlier of its termination by the Company’s Compensation Committee or on December 31, 2020.

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. Stock awards granted under the 2004 Plan to employees generally vest annually over one to four years. Initial and annual stock awards under the 2004 Plan to non-employee directors will vest over three years after the date of grant at the rate of 33% for each completed year of service. As of December 2010, an aggregate of 12,518,428 shares of common stock were reserved for issuance under the 2004 Plan. As of December 31, 2010, there were 6,967,567 outstanding option awards to purchase the Company’s common stock, with 1,934,048 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 2010, 2009 and 2008.

Stock Options. The fair value of each stock award was estimated at the date of grant using the Black-Scholes method in 2010, 2009 and 2008 with the following assumptions:

	December 31,		
	2010	2009	2008
Risk-free interest rate	1.27%	1.51%	2.72%
Expected life	3.9 years	3.1 years	4 years
Weighted average fair value of options granted	\$.96	\$.44	\$.43
Volatility71	.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

INHIBITEX, INC. — (Continued)

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.

	<u>Number of Options</u>	<u>Weighted-Average Exercise Price per Option</u>	<u>Weighted-Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value (\$000)</u>
Balance at December 31, 2009	5,740,908	\$1.95		
Granted	2,061,000(1)	1.75		
Exercised	(330,866)	1.49		
Forfeited or expired	<u>(503,475)</u>	<u>2.98</u>		
Balance at December 31, 2010	<u>6,967,567</u>	<u>\$1.84</u>	<u>5.86</u>	<u>\$7,605</u>
Vested or expect to vest at				
December 31, 2010	<u>6,759,523</u>	<u>\$1.84</u>	<u>5.75</u>	<u>\$7,411</u>
Exercisable at December 31, 2010	<u>3,413,417</u>	<u>\$2.21</u>	<u>4.54</u>	<u>\$3,516</u>

(1) Includes performance-based options of 923,000, subject to specific performance conditions.

Stock options granted during the twelve month period ended December 31, 2010 were 2,061,000 with a weighted-average exercise price of \$1.75. The weighted-average grant date fair value of the stock options granted during the twelve month period ended December 31, 2010 was \$0.96, using the assumptions in the above table. As of December 31, 2010, there was \$1,297,157 of total unrecognized share-based compensation expense related to unvested stock option awards (excluding unvested 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 1.8 years.

As of December 31, 2010, the Company has \$893,098 of total unrecognized share-based compensation expense related to 1,290,750 performance-based stock option awards that are contingent upon meeting specific performance goals with respect to the Company's programs FV-100 and INX-189.

The total intrinsic value of stock options exercised during the twelve month period ended December 31, 2010, 2009 and 2008 was \$786,751, \$32,121 and \$4,948, respectively, from which the Company received cash proceeds of \$491,734 for the twelve month period ended December 31, 2010. 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.

INHIBITEX, INC. — (Continued)

The following tables summarize information relating to outstanding and exercisable options as of December 31, 2010:

Exercise Prices	December 31, 2010				
	Outstanding			Exercisable	
	Number of Shares	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$0.31 — \$0.97	306,588	5.15	\$0.70	255,088	\$0.68
\$1.00	1,280,000	3.84	1.00	248,000	1.00
\$1.04 — \$1.36	755,500	4.34	1.29	588,750	1.36
\$1.45	1,581,875	6.72	1.45	1,163,225	1.45
\$1.46 — \$1.62	251,000	6.39	1.51	60,750	1.60
\$1.79	1,497,000	9.76	1.79	—	—
\$1.96 — \$2.62	897,234	3.98	2.12	699,234	2.04
\$2.91 — \$9.38	398,370	1.34	7.82	398,370	7.82
	<u>6,967,567</u>	<u>5.86</u>	<u>\$1.84</u>	<u>3,413,417</u>	<u>\$2.21</u>

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

	December 31,		
	2010	2009	2008
Common stock options	6,967,567	5,740,908	4,820,459
Restricted common stock	—	—	140,000
Common stock warrants	12,868,100	14,053,318	8,022,863
Total	<u>19,835,667</u>	<u>19,794,226</u>	<u>12,983,322</u>

13. Other Income

In October 2010, the Company was awarded \$488,948 in grants for two Qualifying Therapeutic Discovery Projects (“QTDP”) under the Patient Protection and Affordable Care Act. Each project was awarded \$244,474, based on qualifying expenses incurred by the Company in 2009.

14. Comprehensive Loss

The components of comprehensive loss for the twelve months ended December 31, 2010, 2009 and 2008 are as follows:

	Twelve Months Ended December 31,		
	2010	2009	2008
Net loss	\$(22,669,270)	\$(17,590,001)	\$(13,161,243)
Change in net unrealized gains (losses) on investments	(8,435)	(102,473)	4,970
Comprehensive loss	<u>\$(22,677,705)</u>	<u>\$(17,692,474)</u>	<u>\$(13,156,273)</u>

15. Research and License Agreements

In-licensing Agreements

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

INHIBITEX, INC. — (Continued)

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 C1fA 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

INHIBITEX, INC. — (Continued)

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 \$8,250,000 in an upfront license fee and annual research support payments and \$666,667 in milestone payments from Pfizer as of December 31, 2010. 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.

In 2010, the Company announced that Pfizer had initiated recruitment in a randomized, double-blind Phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of three ascending dose levels of a 3-antigen *Staphylococcus aureus* (“*S. aureus*”) vaccine (SA3Ag) in 408 healthy adults. The vaccine contains an antigen originating from the Company’s proprietary MSCRAMM protein platform. The Company earned a payment of \$667,000 upon the achievement of this milestone.

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.

16. 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 \$128,000, \$127,000 and \$124,000 in 2010, 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-employment benefits upon termination. These benefits cannot be reasonably estimated and no measurable event has occurred as of December 31, 2010.

INHIBITEX, INC. — (Continued)

17. Quarterly Financial Data (Unaudited)

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

	<u>Revenue</u>	<u>Loss from Operations</u>	<u>Net Loss</u>	<u>Net Loss Attributable To Common Stockholders per Share — Basic and Diluted</u>
Year Ended December 31, 2010				
First Quarter	\$999,167	\$(4,814,489)	\$(4,793,153)	\$(0.08)
Second Quarter	287,500	(5,587,233)	(5,558,790)	(0.09)
Third Quarter	287,500	(5,290,664)	(5,273,462)	(0.08)
Fourth Quarter	287,500	(7,546,349)	(7,043,865)	(0.11)
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)

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
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 July 1, 2010).
10.2.2	Non-Employee Directors Stock Option Agreement (incorporated by reference to Exhibit 4.2 of the Registration Statement filed on Form S-8 filed with the Securities and Exchange Commission on July 1, 2010).
10.2.3	Employee Stock Option Agreement (incorporated by reference to Exhibit 4.3 of the Registration Statement filed on Form S-8 filed with the Securities and Exchange Commission on July 1, 2010).
10.4	2004 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 of the March 2004 S-1).
10.10	Amended and Restated Master Rights Agreement, dated December 19, 2003, by and among the registrant and holders of the registrant's capital stock (incorporated by reference to Exhibit 10.10 of the March 2004 S-1).
10.11	Amendment No. 1 to Amended and Restated Master Rights Agreement dated February 20, 2004 (incorporated by reference to Exhibit 10.11 of the March 2004 S-1).
10.11.1	Amendment No. 2 to Amended and Restated Master Rights Agreement dated May 27, 2004 (incorporated by reference to Exhibit 10.1 of the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 16, 2004).
10.12	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.12 of the March 2004 S-1).
10.18†	License and Development Collaboration Agreement, dated August 2, 2001, by and between the registrant and American Home Products Corporation, acting through its Wyeth-Ayerst Laboratories Division (incorporated by reference to Exhibit 10.18 of Amendment No. 3 the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on May 25, 2004 ("Amendment No. 3").
10.19†	License Agreement, dated February 4, 2000, between the registrant and The Texas A&M University System (incorporated by reference to Exhibit 10.19 of Amendment No. 3).
10.20†	Amendment No. 1 to License Agreement, dated April 29, 2002, between the registrant and The Texas A&M University System (incorporated by reference to Exhibit 10.20 of Amendment No. 3).
10.21	Amendment No. 2 to License Agreement, dated April 29, 2002, between the registrant and The Texas A&M University System (incorporated by reference to Exhibit 10.21 of the March 2004 S-1).
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).

<u>Exhibit No.</u>	<u>Description</u>
10.39†	Agreement, dated November 5, 2004, between the registrant and Lonza Biologics PLC (incorporated by reference to Exhibit 10.39 of Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on January 19, 2005).
10.40	Loan agreement, dated December 28, 2004 between the registrant and Development Authority of Fulton County (incorporated by reference to Exhibit 10.40 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 28, 2005).
10.41	Form of Securities Purchase Agreement dated August 17, 2005 between the registrant and each of the investors signatory thereto (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 17, 2005).
10.48	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).
10.50	Employment Agreement, dated December 21, 2010, by and between registrant and Geoff Henson (incorporated by reference to Exhibit 10.50 of the Annual Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2007).
10.51	Employment Agreement, dated December 21, 2010, by and between registrant and Joseph M. Patti (incorporated by reference to Exhibit 10.51 of the Current Report on Form 8-K/A filed with the Securities and Exchange Commission on March 30, 2007).
10.52†	License Agreement, dated November 9, 2007, by and between registrant and University College Cardiff Consultants Limited and Katholieke Universiteit Leuven (incorporated by reference to Exhibit 10.52 of the Annual Report on Form 10-K filed the Securities and Exchange Commission on November on March 14, 2008).
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).
10.55†	License Agreement, dated October 1, 2009, by and between registrant and University College Cardiff Consultants Limited (incorporated by reference to Exhibit 10.55 of the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2010).
10.56	At Market Issuance Sales Agreement, dated November 23, 2010, by and between Inhibitex, Inc. and McNicoll, Lewis & Vlak LLC (incorporated by reference to Exhibit 10.56 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 24, 2010).
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.

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, FSA, MAAA

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 16, 2011, at 9:00 am EST at the Ritz Carlton-Buckhead, 3434 Peachtree Road, Northeast, Atlanta, GA 30326.

Investor Information Requests

Copies of the Inhibitex, Inc. 2010 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.



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