

INFINITY PHARMACEUTICALS, INC.

Form 10-K

March 13, 2012

Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended: December 31, 2011

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: 000-31141

**INFINITY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware** **33-0655706**  
(State or other jurisdiction of **(I.R.S. Employer**  
  
**incorporation or organization)** **Identification No.)**  
**780 Memorial Drive, Cambridge, Massachusetts 02139**  
  
(Address of principal executive offices) (zip code)

**Registrant's telephone number, including area code: (617) 453-1000**

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

**Common Stock, \$.001 par value** **NASDAQ Global Select Market**  
(Title of each class) **(Name of each exchange on which listed)**

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

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 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 (§232.405 of this chapter) 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 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 aggregate market value of voting Common Stock held by non-affiliates of the registrant as of June 30, 2011 was \$151,010,270 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

Number of shares outstanding of the registrant's Common Stock as of February 29, 2012: 26,760,058

### **Documents incorporated by reference:**

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2012 in connection with our 2012 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

**Table of Contents****TABLE OF CONTENTS**

	<b>Page No.</b>
Part I	
Item 1: <u>Business</u>	1
Item 1A: <u>Risk Factors</u>	21
Item 1B: <u>Unresolved Staff Comments</u>	40
Item 2: <u>Properties</u>	40
Item 3: <u>Legal Proceedings</u>	40
Item 4: <u>Mine Safety Disclosures</u>	40
Part II	
Item 5: <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	41
Item 6: <u>Selected Financial Data</u>	43
Item 7: <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	44
Item 7A: <u>Quantitative and Qualitative Disclosures about Market Risk</u>	59
Item 8: <u>Financial Statements and Supplementary Data</u>	60
Item 9: <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	88
Item 9A: <u>Controls and Procedures</u>	88
Item 9B: <u>Other Information</u>	90
Part III	
Item 10: <u>Directors, Executive Officers and Corporate Governance</u>	91
Item 11: <u>Executive Compensation</u>	91
Item 12: <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	91
Item 13: <u>Certain Relationships and Related Transactions, and Director Independence</u>	91
Item 14: <u>Principal Accountant Fees and Services</u>	91
Part IV	
Item 15: <u>Exhibits and Financial Statement Schedules</u>	92
<u>Signatures</u>	93

---

**Table of Contents****Forward-Looking Information**

*This Annual Report on Form 10-K contains forward-looking statements regarding our expectations with respect to the possible achievement of discovery and development milestones in 2012, our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy, and other objectives for future operations. We often use words such as anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, should, continue, and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify them by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause actual results or events to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our drug candidates, our ability to obtain, maintain and enforce intellectual property rights for our drug candidates, our dependence on our alliance partners, our ability to obtain any necessary financing to conduct our planned activities, and other risk factors. Please refer to the section entitled Risk Factors in Part I of this report for a description of these risks and uncertainties. Unless required by law, we do not undertake any obligation to publicly update any forward-looking statements.*

**PART I****Item 1. Business  
Overview**

We are an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines for difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. Our programs in the inhibition of the Hedgehog pathway, the heat shock protein 90 chaperone system, and phosphoinositide-3-kinase are evidence of our innovative approach to drug discovery and development.

**Hedgehog Pathway Inhibitor Program.** Our lead product candidate is saridegib, also known as IPI-926, a novel, potent, oral molecule that inhibits the Hedgehog pathway by binding to the Smoothed receptor, a protein that plays a critical role in the malignant activation of the Hedgehog pathway. We believe that Smoothed inhibition represents a significant opportunity for addressing a number of difficult-to-treat cancers by disrupting malignant activation of the Hedgehog pathway through multiple, distinct mechanisms. We are evaluating saridegib in a randomized, double-blind Phase 2 clinical trial to assess the safety and efficacy of saridegib compared to placebo in approximately 140 patients with metastatic or locally advanced, inoperable chondrosarcoma. We believe this trial is the first and only randomized clinical trial being conducted in this indication. We expect to complete enrollment in this trial in the second half of 2012 and to report data from this trial in the first half of 2013. In addition, we are actively enrolling patients in an exploratory Phase 2 clinical trial evaluating the safety and efficacy of saridegib in patients with myelofibrosis. We expect to report data from this trial in the second half of 2012. In January 2012, we discontinued our randomized Phase 2 clinical trial evaluating saridegib in combination with gemcitabine, a chemotherapy, in patients with previously untreated, metastatic, pancreatic cancer, following a preliminary analysis of data showing a difference in survival favoring the placebo plus gemcitabine treatment group. This difference in survival was due to a higher rate of progressive disease in the saridegib plus gemcitabine treatment group, and not a result of the safety profile of saridegib. We expect to present final data from this trial after our analyses are complete. Mundipharma International Corporation Limited, or Mundipharma, has commercialization rights outside of the United States for products arising out of our Hedgehog pathway inhibitor program.

---

**Table of Contents**

**Hsp90 Inhibitor Program.** Retaspimycin hydrochloride (HCl), also known as IPI-504, is a novel, potent and selective inhibitor of heat shock protein 90, or Hsp90. Cancer cells depend on Hsp90 to maintain many proteins critical for cancer growth, proliferation and survival in a functional state. Certain anticancer therapies may enhance the dependency of cancer cells on Hsp90. Therefore, combining an Hsp90 inhibitor with another anticancer therapy may enhance cancer cell killing. Retaspimycin HCl is currently being evaluated in a randomized, double-blind Phase 2 clinical trial in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in approximately 200 patients with second- or third-line non-small cell lung cancer, or NSCLC, who are naive to docetaxel treatment and have a history of heavy smoking. We expect to complete enrollment in this trial in the second half of 2012 and to report data from this trial in the second half of 2013. We are also enrolling patients in a Phase 1b/2 trial to explore the safety and efficacy of retaspimycin HCl in combination with everolimus, an mTOR inhibitor, in NSCLC patients with a KRAS mutation. The objective of this Phase 1b/2 trial is to determine the recommended dose for the combination treatment and to evaluate the safety and clinical activity of retaspimycin HCl in combination with everolimus. We expect to report top-line data from this trial in the second half of 2012. We have worldwide development and commercialization rights for our Hsp90 inhibitor program.

**PI3K Inhibitor Program.** The phosphoinositide-3-kinases, or PI3Ks, are a family of enzymes involved in key immune cell functions, including cell proliferation and survival, cell differentiation, and cellular trafficking. PI3K-delta and PI3K-gamma, two isoforms of PI3K, play key roles in inflammatory and autoimmune diseases. Additionally, in certain hematologic malignancies, PI3K-gamma and PI3K-delta contribute to the survival and proliferation of cancer cells. Therefore, inhibition of PI3K-delta and PI3K-gamma may have therapeutic potential across a broad range of inflammatory diseases and hematologic malignancies. Our lead compound in this program is IPI-145, a potent, orally-available inhibitor of PI3K-delta and PI3K-gamma. In the second half of 2011, we initiated two Phase 1 clinical trials of IPI-145. The first Phase 1 trial of IPI-145 is a double-blind, randomized, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple escalating doses of IPI-145 in healthy adult subjects. The second Phase 1 trial is an open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies. Following the determination of the maximum tolerated dose in the dose escalation phase of this study, we plan to conduct an expansion phase in patients with specific hematologic malignancies. We expect to report data from both Phase 1 trials in the second half of 2012 and to commence Phase 2 development of IPI-145 in inflammation in 2012. Mundipharma has commercialization rights outside of the United States for products arising from our PI3K inhibitor program.

**Other Programs.** In addition to our three clinical stage programs, we have several innovative projects in earlier stages of development, encompassing emerging targets in fields such as cancer metabolism, apoptosis and protein homeostasis. Through our internal discovery efforts, we also discovered IPI-940, a novel, orally available inhibitor of fatty acid amide hydrolase, or FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. We have licensed worldwide development and commercialization rights to our FAAH program to Mundipharma and its independent associated company, Purdue Pharmaceutical Products L.P., or Purdue.

**Corporate Information**

We were incorporated in California on March 22, 1995 under the name IRORI and, in 1998, we changed our name to Discovery Partners International, Inc., or DPI. In July 2000, we reincorporated in Delaware. On September 12, 2006, DPI completed a merger with Infinity Pharmaceuticals, Inc., or IPI, pursuant to which a wholly-owned subsidiary of DPI merged with and into IPI. IPI was the surviving corporation in the merger, changed its name to Infinity Discovery, Inc., or IDI, and became a wholly owned subsidiary of DPI. In addition, we changed our corporate name from Discovery Partners International, Inc. to Infinity Pharmaceuticals, Inc., and our ticker symbol on the NASDAQ Global Market to INFI. Our common stock currently trades on the NASDAQ Global Select Market.

## **Table of Contents**

Our principal executive offices are located at 780 Memorial Drive, Cambridge, Massachusetts 02139 and our telephone number at that address is (617) 453-1000.

The Infinity logo and all other Infinity product names are trademarks of Infinity or its subsidiary in the United States and in other select countries. We may indicate U.S. trademark registrations and U.S. trademarks with the symbols ® and ™, respectively. Other third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

## **Product Development Pipeline**

Our product development programs arise from a combination of internally developed programs and strategic licensing arrangements. Whether our programs are developed internally or obtained from a third party, we are drawn to targets that have the potential to represent fundamentally new approaches to how disease is treated, and where we believe we can use our scientific capabilities to identify differentiated drug candidates with well-defined development paths. We seek to take advantage of what we believe to be our innovative approaches to drug discovery and translational medicine, and our robust internal capabilities across all of the key scientific disciplines, including medicinal chemistry, cell biology, biochemistry, pharmacology and molecular pathology. Our goal is to successfully integrate these disciplines to rapidly identify drug candidates, and because discovery does not stop when a drug candidate is identified, we also deploy our discovery capabilities to better understand which populations, or subpopulations, of patients may benefit most from our product candidates. We view biomarkers as an integral part of our drug development strategy and are actively researching biomarkers in each of our clinical development programs.

Our first three clinical candidates, stemming from programs in the inhibition of the Hedgehog pathway, Hsp90, and FAAH, emerged from our internal research efforts. Our fourth clinical candidate, which is directed to the inhibition of PI3K, arose out of our strategic licensing arrangement with Intellikine, Inc., or Intellikine, which was acquired in January 2012 by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In addition to these programs, we have several innovative projects in earlier stages of development, encompassing emerging targets in fields such as cancer metabolism, apoptosis and protein homeostasis.

In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us several product opportunities in oncology and inflammatory disease areas with broad commercial potential. This strategy also ensures that our success is not dependent on any single product or indication, allowing us to optimize our portfolio on several dimensions in response to new data.

We also believe that the ability to deliver innovative new medicines to patients is an essential component of our mission. To this end, we have retained U.S. commercialization rights to all product candidates in our portfolio that are primarily directed to cancer and inflammatory diseases and we have a substantial royalty interest in the U.S. commercialization of IPI-940, which is primarily directed to pain.

**Table of Contents**

Our product development programs as of February 29, 2012 are illustrated in the following chart:

During 2012, we expect to advance our product development pipeline by achieving the following program milestones:

*Hedgehog Pathway Inhibitor Program*

Completing enrollment in the Phase 2 trial in patients with metastatic or locally advanced, unresectable chondrosarcoma

Reporting data from the Phase 2 trial in patients with myelofibrosis

*Hsp90 Inhibitor Program*

Completing enrollment in the Phase 2 trial in combination with docetaxel in patients with NSCLC

Reporting top-line data from the dose-escalation portion of the Phase 1b/2 trial in combination with everolimus in NSCLC patients with a KRAS mutation

*PI3K Inhibitor Program*

Reporting data from the Phase 1 trial in healthy subjects

Reporting data from the Phase 1 trial in patients with hematologic malignancies

Commencing Phase 2 development in inflammation



## **Table of Contents**

### ***Hedgehog Pathway Inhibitor Program***

The Hedgehog pathway represents a new way of understanding and potentially attacking the progression and reoccurrence of a broad range of cancers. The Hedgehog pathway is normally active during embryonic development and regulates tissue and organ formation. Malignant activation of the Hedgehog pathway is believed to be responsible for a broad range of cancers through three distinct and independent mechanisms:

**Targeting the tumor cell:** In some tumors, such as chondrosarcoma, tumor cells signal to themselves through the Hedgehog pathway in a manner that promotes tumor growth. Inhibition of the Hedgehog pathway in these tumors may delay or stop tumor growth. In other cancers, such as basal cell carcinoma and some medulloblastomas, a genetic mutation is responsible for malignant activation of the Hedgehog pathway in tumor cells. In these cancers, inhibition of the Hedgehog pathway may result in tumor cell death and tumor regression.

**Targeting the tumor microenvironment:** In some cancers, the tumor cells signal through the Hedgehog pathway to stromal cells in the tumor's microenvironment, which provides support for tumor growth and survival. In some malignancies, such as myelofibrosis, the fibrosis itself is responsible for the morbidity and mortality of the disease. Inhibition of the Hedgehog pathway may result in a decrease in fibrosis, resulting in decreased morbidity and mortality.

**Targeting residual disease:** In some cancers, such as lung cancer, acute lymphocytic leukemia, and ovarian cancer, the Hedgehog pathway may signal to tumor progenitor cells. These tumor progenitor cells may be responsible for tumor regrowth following tumor regression or tumor debulking with chemotherapy or targeted agents. Inhibition of the Hedgehog pathway in these cancers may delay tumor regrowth and prolong survival.

We are developing saridegib, a novel, potent, oral molecule that inhibits the Hedgehog pathway by binding to the Smoothened receptor, a protein that plays a critical role in the malignant activation of the Hedgehog pathway. We believe that Smoothened inhibition represents a significant opportunity for addressing a number of difficult-to-treat cancers by disrupting malignant activation of the Hedgehog pathway through these distinct and independent mechanisms. When systemically administered in multiple preclinical animal models representing a wide variety of cancers, saridegib has demonstrated significant anti-tumor activity and attractive pharmacologic properties such as oral bioavailability, long plasma half-life and duration of action, and dose-dependent inhibition of tumor growth.

We are evaluating saridegib in a Phase 2 clinical trial as a single agent in patients with metastatic or locally advanced, inoperable chondrosarcoma, which we believe is the first and only randomized clinical trial being conducted in this indication. Chondrosarcoma is a rare, life-threatening cancer of the cartilage. In the United States, chondrosarcoma accounts for approximately one-third of the 2,000 cases of primary bone cancer diagnosed each year. The most common locations for chondrosarcoma tumors are the bones of the extremities and the pelvis. Chondrosarcoma predominantly affects middle-aged and older adults, usually occurring in patients over 40 years old, with the incidence gradually increasing up to age 75. As chondrosarcomas are largely resistant to chemotherapy and radiotherapy, the standard therapeutic strategy is surgery. For patients with metastatic disease or with locally advanced tumors who are not candidates for surgery, no treatment has been shown to be effective and there is no established standard of care.

Our randomized, double-blind Phase 2 clinical trial is designed to compare the safety and efficacy of saridegib to matching placebo in approximately 140 patients with metastatic or locally advanced, inoperable chondrosarcoma. Patients in the placebo treatment arm who experience disease progression have the option to cross over and receive saridegib in an open-label arm of the trial. The primary endpoint of the trial is progression-free survival. Secondary endpoints include time to progression, overall survival, overall response rate and response duration. We expect to complete enrollment in this trial in the second half of 2012 and to report data from this trial in the first half of 2013. We have received orphan drug designation from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, for saridegib for the treatment of chondrosarcoma.

## **Table of Contents**

In addition, we are actively enrolling patients in an exploratory Phase 2 clinical trial evaluating saridegib in patients with myelofibrosis. Myelofibrosis is a blood cancer that affects up to an estimated 18,500 patients in the United States and is marked by the replacement of normal bone marrow by a dense, fibrous stroma. This leads to relocation of blood cell production, or hematopoiesis, from the bone marrow to organs such as the spleen and liver, causing the characteristic debilitating symptoms of abdominal pain and fatigue due to an enlarged spleen, also known as splenomegaly, and pancytopenia, which is the reduction of red and white blood cells and platelets. Inhibition of the Hedgehog pathway may deplete the stroma, potentially resulting in restoration of normal hematopoiesis and resolution of symptoms.

The single-arm Phase 2 trial in myelofibrosis is designed to evaluate the safety and efficacy of saridegib in this population. The primary endpoint of the trial is response rate according to the International Working Group Criteria, which includes a variety of measures such as improvement in bone marrow fibrosis, restoration of normal blood counts, and improvement in splenomegaly. The trial is designed to initially enroll 12 patients and may be expanded to up to 45 patients based on the response rate observed in the first cohort of patients. We expect to report data from this trial in the second half of 2012.

In January 2012, we discontinued our randomized Phase 2 clinical trial evaluating saridegib in combination with gemcitabine in patients with previously untreated, metastatic, pancreatic cancer. A preliminary analysis of data from the study showed a difference in survival favoring the placebo plus gemcitabine arm treatment group. This difference in survival was due to a higher rate of progressive disease in the saridegib plus gemcitabine treatment group. Specifically, the median survival for patients receiving saridegib plus gemcitabine was less than the historical median survival for single-agent gemcitabine of approximately six months, as compared to a median survival for the placebo plus gemcitabine arm of greater than six months. The adverse events observed in both arms of the trial were consistent with the known safety profile of each agent, with no unexpected toxicities. We expect to present final data from this trial after our analyses of the data are complete.

Also in 2011, we initiated an investigator sponsored trial program for saridegib to explore a range of potential indications as well as to study saridegib in combination with both commonly used and emerging treatments.

Mundipharma has commercialization rights outside of the United States for products arising out of our Hedgehog pathway inhibitor program.

### ***Hsp90 Inhibitor Program***

Hsp90 is emerging as a major therapeutic target of interest for the treatment of a broad range of cancers. Proteins are responsible for carrying out vital functions of every cell in the human body, and in order for proteins to function properly they must be stable and properly folded. Hsp90 is a member of the chaperone system of proteins which serves to maintain the structure and activity of specific proteins within the cell. The proteins chaperoned by Hsp90 are known as its client proteins, and include cancer-causing forms of ALK, BCR-ABL, mutant EGFR, mutant FLT3 and HER2. Inhibiting the function of Hsp90 knocks out a critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. In addition, certain anticancer therapies, such as chemotherapies, may enhance the dependency of cancer cells on Hsp90. Therefore, Hsp90 inhibition in combination with another proven anticancer agent may represent an important approach to treating certain cancers.

Retaspimycin HCl, also known as IPI-504, is a novel, potent and selective inhibitor of Hsp90. Retaspimycin HCl has been shown in preclinical studies to inhibit Hsp90 potently and selectively, thereby inhibiting cancer cell growth. In addition, preclinical studies suggest that retaspimycin HCl preferentially targets and accumulates in tumor tissues. For these reasons, we believe that retaspimycin HCl has broad potential for the treatment of patients with a wide variety of solid and hematologic tumors, including cancers that are resistant to other drugs.

---

**Table of Contents**

We have two ongoing clinical trials evaluating retaspimycin HCl, both of which are focused on patients with NSCLC. According to the National Cancer Institute, lung cancer is the second most common form of cancer in the United States, with over 220,000 new cases estimated in 2011. There are two main types of lung cancer: NSCLC and small cell lung cancer. According to the American Cancer Society, approximately 90 percent of all lung cancers are classified as non-small cell. While NSCLC is notoriously difficult to treat, there have been some treatment advances in recent years, largely due to the rapidly evolving understanding of the underlying molecular mechanisms that are responsible for the development of the disease. Despite recent advancements, there are large NSCLC subpopulations who continue to have especially poor prognoses and limited treatment options. These patient subpopulations include patients who have squamous cell carcinoma, a history of heavy smoking, or a KRAS gene mutation, representing up to an estimated 35%, 70% and 30%, respectively, of all NSCLC patients. As our knowledge of genetic mutations and environmental factors that impact the disease progression of NSCLC expands, research is underway to understand how various patient subpopulations respond differently to therapies. Ultimately, our goal is to develop and deliver more effective, targeted (or personalized ) treatment approaches that are based on each patient's particular disease characteristics.

Retaspimycin HCl is the only Hsp90 inhibitor for which clinical responses have been observed when combined with chemotherapy in NSCLC patients who do not have a mutation in ALK. For this reason, we are evaluating retaspimycin HCl dosed once weekly in a randomized, double-blind Phase 2 clinical trial in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in approximately 200 patients with second- or third-line NSCLC, who are naive to docetaxel treatment and have a history of heavy smoking. The primary endpoint of the study is overall survival. We also plan to evaluate the relationship between survival and certain patient characteristics, including histology, tobacco exposure, and a variety of biomarkers. This trial was based, in part, on results from our Phase 1b trial of retaspimycin HCl in combination with docetaxel which showed that retaspimycin HCl, dosed once weekly in combination with docetaxel dosed once every three weeks, was well-tolerated and clinically active in heavily pretreated patients with NSCLC. Partial responses were seen in six of 23, or 26 percent, of patients, with higher response rates observed among heavily pretreated patients with squamous cell carcinoma (n=3/7, or 43%) or a history of heavy smoking (n=6/18, or 33%). In this trial, there were no dose reductions or discontinuations in response to liver function tests, gastrointestinal toxicities were low grade, and no significant ocular toxicities were observed. We expect to complete enrollment in this trial in the second half of 2012 and to report data from this trial in the second half of 2013.

In addition, we are enrolling patients in a Phase 1b/2 trial to explore the safety and efficacy of retaspimycin HCl in combination with everolimus, an mTOR inhibitor, in NSCLC patients with a KRAS mutation. The objective of this Phase 1b/2 trial is to determine the recommended dose for the combination treatment and to evaluate the safety and clinical activity of retaspimycin HCl in combination with everolimus. The endpoint of the Phase 2 trial is overall response rate. In preclinical models, treatment with retaspimycin HCl in combination with an mTOR inhibitor resulted in synergistic activity and tumor regression. We expect to report top-line data from this trial in the second half of 2012.

We have worldwide development and commercialization rights for our Hsp90 inhibitor program.

***PI3K Inhibitor Program***

PI3Ks are a family of enzymes involved in key immune cell functions, including cell proliferation and survival, cell differentiation, and cellular trafficking. PI3K-delta and PI3K-gamma, two isoforms of PI3K, play key roles in inflammatory and autoimmune diseases. Additionally, in certain hematologic malignancies, PI3K-gamma and PI3K-delta contribute to the survival and proliferation of cancer cells. Therefore, inhibition of PI3K-delta and PI3K-gamma may have therapeutic potential across a broad range of inflammatory diseases and hematologic malignancies. In July 2010, we entered into a development and license agreement with a predecessor company to Millennium under which we obtained global development and commercialization rights to a portfolio of compounds targeting the delta and/or gamma isoforms of PI3K, including our lead compound in this program, IPI-145.

## **Table of Contents**

IPI-145 is a potent, orally-available inhibitor of PI3K-delta and PI3K-gamma. In the second half of 2011, we initiated two Phase 1 clinical trials of IPI-145. The first Phase 1 trial of IPI-145 is a double-blind, randomized, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple escalating doses of IPI-145 in healthy adult subjects. The second Phase 1 trial is an open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies. Following the determination of the maximum tolerated dose in the dose escalation phase of this study, we plan to conduct an expansion phase in patients with specific hematologic malignancies. We expect to report data from both Phase 1 trials in the second half of 2012 and commence Phase 2 development of IPI-145 in inflammation in 2012.

Mundipharma has commercialization rights outside of the United States for products arising from our PI3K inhibitor program.

### ***Other Programs***

In addition to our three clinical stage programs, we have several innovative projects in earlier stages of development, encompassing emerging targets in fields such as cancer metabolism, apoptosis and protein homeostasis. Through our internal discovery efforts, we also discovered IPI-940, a novel, orally available inhibitor of FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. We have licensed worldwide development and commercialization rights to our FAAH program to Mundipharma and Purdue, who are responsible for performing all subsequent research, development and commercialization activities at their own expense. We retain a royalty interest in any worldwide sales of products arising out of the FAAH program.

### **Strategic Alliances**

Since our inception, strategic alliances have been integral to our growth. These alliances have provided access to breakthrough science, significant research support and funding, and innovative drug development programs, all intended to help us realize the full potential of our product pipeline while at the same time allowing us to retaining significant downstream value in our programs through commercialization rights and royalties. Since our inception, all of our revenue has been derived from our strategic alliances, and all of our revenue during 2011, 2010 and 2009 was derived from our alliance with Mundipharma and Purdue.

### ***Mundipharma and Purdue***

#### *Scope*

In November 2008, we entered into a strategic alliance with Mundipharma and Purdue to develop and commercialize pharmaceutical products. The alliance is governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue. The agreement with Purdue is focused on the development and U.S. commercialization of products targeting FAAH. The agreement with Mundipharma is focused on the development and commercialization outside of the United States of all products and product candidates covered by the alliance, including those targeting FAAH. The alliance currently includes product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of our early discovery projects in all disease fields that are conducted during a prescribed discovery period that runs through December 31, 2013. Our Hsp90 program is expressly excluded from the alliance.

Mundipharma also has the option to include in the alliance certain products or product candidates that we may in-license during the discovery period by paying us a prescribed percentage of the up-front license fee or other acquisition cost, which percentage could be up to 60% of such fee or cost, and by funding research and development costs in the same manner as products or product candidates arising out of our internal discovery

## **Table of Contents**

programs, as described below. If we in-license any product or product candidate during the discovery period for which GLP (Good Laboratory Practice) toxicology studies have not been initiated, as we did with our PI3K inhibitor program in 2010, such products are automatically included in the alliance just as if they arose out of our internal discovery projects.

We have responsibility and decision-making authority for the development of all of our product candidates and performance of early discovery projects on a worldwide basis. There are no joint steering or similar committees for the alliance. Except with respect to products targeting FAAH, for which Mundipharma and Purdue currently have global commercialization rights, and products for which Mundipharma has opted out of development as described below, we will have the right and responsibility to market and sell products arising from the alliance in the United States, and Mundipharma will have the right and responsibility to market and sell products arising from the alliance outside of the United States. Other than pursuant to the strategic alliance agreements, neither we, Purdue nor Mundipharma may develop, manufacture or commercialize products that are directed to the same target or pathway as a product included in the strategic alliance, unless and until a party terminates its rights with respect to such products.

Following entry into the strategic alliance agreements, we consider Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes because of their equity ownership in our company.

### *Research and Development Funding*

For each alliance program other than FAAH, Mundipharma is obligated to reimburse us for all research and development expenses we incur, up to an annual aggregate cap, until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of a product candidate, which we refer to as the transition date. The funding caps for the years ending December 31, 2012 and December 31, 2013 are \$110 million and \$147.5 million, respectively. The funding caps for the years ended December 31, 2011 and December 31, 2010 were \$85 million and \$65 million, respectively. We are obligated to fund any activities in excess of the annual funding cap ourselves, which we did in 2010 primarily as the result of costs associated with the licensing of our PI3K inhibitor program, and in 2011 primarily due to expanded clinical trial activities for saridegib and the commencement of clinical development of IPI-145. After the transition date for each product candidate, we are obligated to share equally with Mundipharma all research and development costs for such product candidate.

In October 2010, following completion of the first Phase 1 clinical trial of IPI-940, Mundipharma and Purdue exercised their rights to assume all worldwide development and commercialization activities and to fund all subsequent research, development and commercialization expenses for products arising out of our FAAH program. All expenses associated with activities we conduct related to the transition of the FAAH program to Purdue and Mundipharma are reimbursed by Purdue and Mundipharma, with such amounts not counting towards the annual funding cap.

### *Opt-out and Termination Rights*

Mundipharma has the right to opt out of any alliance program, except the Hedgehog program, on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma would continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for all programs included in the alliance for the calendar year following the date of such opt out, up to an annual cap. This funding commitment for the year ending December 31, 2013 is \$51.3 million for our PI3K and early discovery programs.

Mundipharma may next exercise its right to opt out of the Hedgehog program in November 2013. Mundipharma is obligated to fund the Hedgehog program until it is required to make the decision to opt out or continue funding the program. If Mundipharma elects to opt out of participation in the Hedgehog program in

## **Table of Contents**

November 2013, then Mundipharma would be obligated to make an immediate payment of \$23.65 million to us, which we can use on any program in the alliance. In addition, Mundipharma would be obligated to reimburse us for up to \$23.65 million of additional expenses incurred during 2013 that are associated with the completion of Phase 2 clinical trials of saridegib that are ongoing at that time. If Mundipharma elects to continue participation in the Hedgehog program in November 2013, it would thereafter have the same annual opt-out right, and one-year residual funding obligation, that applies to the other alliance programs.

In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for 50% of post-transition date research and development expenses for the product candidate. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

Each of the strategic alliance agreements expire when the parties thereto have no further obligations to each other thereunder. Either party may terminate the strategic alliance agreement to which it is a party on 60 days prior written notice if the other party materially breaches the agreement and fails to cure such breach within the 60-day notice period. The agreements may also be terminated by Mundipharma or Purdue in the event of a change in control of Infinity or in the event that, during the discovery period, either Adelene Perkins or Julian Adams is no longer a full-time executive of Infinity. Upon termination of either strategic alliance agreement by us or either Mundipharma or Purdue, either party to the other strategic alliance agreement may terminate that agreement.

### *Royalties*

Except with respect to products that have been in-licensed by us following initiation of GLP toxicology studies, for which no royalties will be payable between the parties, we are obligated to pay Mundipharma a 5% royalty on net sales of the commercialized products until such time as Mundipharma has recovered all research and development expenses paid to us under the research program prior to the applicable transition date. After such cost recovery, we are obligated to pay a tiered, 1% to 3% royalty on U.S. net sales of those products. For products in which Mundipharma has opted-out of development prior to the transition date, we are obligated to pay royalties of 1% to 5% of worldwide net sales as a function of the stage of development of the applicable product candidate at the time of opt out. For products in which either party has opted-out of development following the transition date, the commercializing party is obligated to pay the other party a 5% royalty on net sales.

Mundipharma is obligated to pay us a tiered, 10% to 20% royalty on annual net sales outside of the United States of each product arising out of the alliance, and Purdue is obligated to pay us a tiered, 10% to 20% royalty on annual net sales of FAAH products in the United States. Royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the rates above is reduced by one-half. In addition, all royalties payable under the strategic alliance agreements, whether by us, Mundipharma or Purdue, are subject to reduction on account of third party royalty payments or patent litigation damages or settlements, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

### *Securities Purchase and Line of Credit Agreements*

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and a line of credit agreement in November 2008 with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP.

## Table of Contents

Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of six million shares of our common stock and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$75 million. An equal number of securities were sold to each purchaser.

The line of credit agreement provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. In November 2011, we borrowed the full \$50 million available to us under the line of credit. The loan matures and is payable in full, including principal and any accrued interest, on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. The loan bears interest at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and is reset on the last business day of each month ending thereafter. Interest is compounded on each successive three-month anniversary of the funding of the loan. The loan may be prepaid without penalty or premium prior to the maturity date. Even if we prepay the loan, we do not have the ability to borrow under the line of credit agreement again. We have certain rights to repay the loan in shares of our common stock.

**Millennium.** In July 2010, we entered a development and license agreement with a predecessor company to Millennium under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. We paid a \$13.5 million up-front license fee to obtain rights to this program. In addition to developing IPI-145, we are seeking to identify additional novel delta, gamma and dual delta/gamma-specific inhibitors of PI3K for future development. We are obligated to pay up to \$25 million in success-based milestones for the development of two distinct product candidates, and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. In addition, we are obligated to pay Millennium tiered royalties on net sales ranging from single digits to low teens upon successful commercialization of products licensed to us, which are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction in certain circumstances.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. For a product in which the first Phase 2 clinical trial conducted is in an oncology indication, which we refer to as an oncology product, Millennium will have the option, at the end of Phase 2 clinical development and upon payment of an option fee, to convert its royalty interest in U.S. sales into the right to share in 50% of profits and losses on U.S. development and commercialization, and to participate in up to 30% of the detailing effort for these products in the United States. Mundipharma, pursuant to its strategic alliance agreement with us, has commercialization rights outside the United States for products arising out of our PI3K inhibitor program.

Millennium may terminate its participation rights in any oncology product with 12 months' prior written notice to us, after which Millennium's participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Millennium would not be entitled to receive royalty payments for net sales occurring prior to the termination date and certain specified milestone payments.

Other than pursuant to the agreement, neither we nor Millennium may research, develop or commercialize products directed to the delta and/or gamma isoforms of PI3K which meet certain selectivity criteria, except that Millennium may research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

The agreement expires when the parties have no further obligations to each other thereunder, unless earlier terminated. Either party may terminate the agreement on 75 days' prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Additionally, Millennium may terminate the agreement upon 30 days' prior written notice if we or a related party bring an action challenging

## **Table of Contents**

the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days' prior written notice provided after the end of the research term that is currently set to expire in July 2013.

### **Intellectual Property**

Our intellectual property consists of patents, trademarks, trade secrets and know-how. Our ability to compete effectively depends in large part on our ability to obtain patents and trademarks for our technologies and products, maintain trade secrets, operate without infringing the rights of others and prevent others from infringing our proprietary rights. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, or are effectively maintained as trade secrets. As a result, patents or other proprietary rights are an essential element of our business.

In the United States, we have 20 issued or allowed patents related to our clinical-stage programs expiring on various dates between 2024 and 2029 as well as numerous pending patent applications and foreign counterpart patent filings which relate to our proprietary technologies. These patents and patent applications include claims directed to compositions of matter, pharmaceutical compositions, methods of treatment, and methods of making these compositions for multiple applications.

We have eight issued or allowed U.S. patent applications covering saridegib and related molecules, which expire on various dates between 2025 and 2029, excluding any patent term extension. These patents include composition of matter, pharmaceutical composition, method of treatment, and synthetic method claims.

We have 11 issued U.S. patents covering retaspimycin HCl and related molecules, which expire on various dates between 2024 and 2025, excluding any patent term extension. These patents and allowed patent applications include composition of matter, pharmaceutical composition, method of treatment, and synthetic method claims.

In addition, as of February 29, 2012, we had several hundred additional patents and patent applications filed worldwide, substantially all of which pertain to our product development programs. Any patents that may issue from our pending patent applications would expire between 2024 and 2032, excluding any patent term extension. These patents and patent applications disclose composition of matter, pharmaceutical composition, methods of use and synthetic methods.

Our policy is to obtain and enforce the patents and proprietary technology rights that are commercially important to our business. We intend to continue to file patent applications to protect technology and compounds that are commercially important to our business, and to do so in countries where we believe it is commercially reasonable and advantageous to do so. We also rely on trade secrets to protect our technology where patent protection is deemed inappropriate or unobtainable. We protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, collaborators and contractors.

### **Competition**

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in research and development of drugs for the treatment of the same diseases and conditions as our current and potential future product candidates. Many of these companies have substantially greater financial and other resources, larger research and development staffs and more extensive marketing and manufacturing organizations than we do. In addition, some of them have considerably more experience than us in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also develop products that may be competitive with our product candidates, either on their own or through collaborative efforts.



**Table of Contents**

We and our alliance partners expect to encounter significant competition for any drugs we develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. We are aware that many other companies or institutions are pursuing the development of drugs in the areas in which we are currently seeking to develop our own drug candidates, and there may be other companies working on competitive projects of which we are not aware. For example, we believe that the following companies, among others, are seeking to develop compounds targeting the Hedgehog pathway:

Genentech, a member of the Roche Group, which recently received FDA approval of vismodegib for the treatment of certain patients with advanced basal cell carcinoma, and which we believe has an active investigator-sponsored trial program exploring other applications for vismodegib;

Pfizer, Inc., which we believe is conducting two Phase 2 clinical trials of PF-04449913;

Novartis AG, which we believe is conducting a two Phase 2 trials and multiple Phase 1 trials of erismodegib and a Phase 1 trial of LEQ-506

Bristol Myers Squibb Company, through its collaboration with Exelixis, Inc., which we believe is conducting multiple Phase 1 clinical trials of BMS-833923;

Millennium, which we believe is conducting a Phase 1 clinical trial of TAK-441; and

In addition, we believe that the following companies, among others, are seeking to develop compounds targeting Hsp90:

Synta Pharmaceuticals Corp., which we believe is conducting Phase 2 clinical trials of ganetespib;

Novartis AG, which we believe is conducting multiple Phase 1 and 2 clinical trials of AUY-922 and a Phase 1 clinical trial of HSP990;

Astex Pharmaceuticals, Inc., which we believe is conducting multiple Phase 1 clinical trials of AT-13387;

Celgene Corporation, which we believe is conducting a Phase 1 clinical trial of ABI-010;

Daiichi Sankyo, Inc., which we believe is conducting a Phase 1 clinical trial of DS-2248;

Debiopharm Group, which we believe is conducting a Phase 1 clinical trial of Debio 0932;

Exelixis, Inc., which we believe is conducting a Phase 1 clinical trial of XL888;

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

Kyowa Hakko Kirin Co. Ltd., which we believe is conducting a Phase 1 clinical trial of KW-2478; and

Myrexis, Inc., which we believe is conducting a Phase 1 clinical trial of MPC-3100.

We believe that the following companies, among others, are seeking to develop compounds targeting the delta and/or gamma isoforms of PI3K:

Gilead Sciences, Inc., which we believe is conducting multiple Phase 1 and Phase 2 clinical trials of GS-1101 and has completed a Phase 1 clinical trial of CAL-263; and

Amgen, Inc., which we believe is conducting a Phase 1 clinical trial of AMG-319.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals, and begin commercialization of their products sooner than we and/or our collaborative partners may for our own drug candidates. These competitive products may have superior safety or efficacy, or be manufactured less expensively, than our drug candidates. If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize our drug candidates or achieve a competitive position in the market. This would adversely affect our business.

## **Table of Contents**

### **Research and Development**

As of February 29, 2012, our research and development group consisted of 145 individuals, of whom over 37 percent hold Ph.D. or M.D. degrees and over an additional 33 percent hold other advanced degrees. Our research and development group is focusing on drug discovery, preclinical research, clinical trials and manufacturing technologies. Our research and development expense for the years ended December 31, 2011, 2010 and 2009 was approximately \$108.6 million, \$99.2 million and \$77.9 million, respectively. Reimbursement for our strategic collaborator-sponsored research and development expenses totaled approximately \$88.5 million, \$67.0 million and \$46.5 million, for the years ended December 31, 2011, 2010 and 2009, respectively. In calculating strategic collaborator-sponsored research and development expenses, we have included all reimbursement for our research and development efforts and excluded license fees. Our remaining research and development expense is company-sponsored.

### **Manufacturing and Supply**

We rely primarily on third parties, and in some instances we rely on only one third party, to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of any products we successfully develop.

A natural product is utilized in the production of saridegib. This product is currently supplied from naturally available plant material. If saridegib is successfully developed we will need to acquire and process sufficient amounts of plant material to satisfy commercial demand for the product. We are currently seeking to identify alternative sources of this natural product, including identifying additional locations where this plant naturally occurs and establishing sustainable methods for growing this plant or producing this natural product in a controlled environment.

### **Sales and Marketing**

We currently have limited marketing, and no commercial sales or distribution, capabilities. We do, however, currently have commercialization rights in the United States for products arising out of all of our programs, except the FAAH program, and worldwide commercialization rights for our Hsp90 inhibitor program, including retaspimycin HCl. In order to commercialize any of these drugs if and when they are approved for sale in the United States, we will need to, and we intend to, develop the necessary marketing, sales and distribution capabilities.

### **Government Regulation**

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, storage, recordkeeping, approval, promotion, labeling, advertising, distribution, marketing, post-approval monitoring and reporting, sampling, and export and import of pharmaceutical products such as those we are developing. We cannot provide assurance that any of our drug candidates will prove to be safe or effective, will receive regulatory approvals or will be successfully commercialized.

#### ***New Drug Approval in the United States***

In the United States, drugs and drug testing are regulated by the FDA and other federal agencies, as well as by state and local government authorities. Before any of our products may be marketed in the United States, we must comply with the Federal Food, Drug and Cosmetic Act, which generally involves the following:

preclinical laboratory and animal tests performed under the FDA's GLP regulations;

## **Table of Contents**

development of manufacturing processes which conform to FDA-mandated current Good Manufacturing Practices, or cGMPs;

submission and acceptance of an investigational new drug application, or IND, which must become effective before clinical trials may begin in the United States;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for its intended use; and

the submission to and review and approval by the FDA of a New Drug Application, or NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

***Preclinical testing.*** Preclinical tests include laboratory evaluation of a drug candidate, its chemistry, formulation, safety and stability, as well as animal studies to assess the potential safety and efficacy of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. We must submit the results of the preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol to the FDA as part of an IND. An IND is a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application. Preclinical tests and studies can take several years to complete, and despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

***The IND process.*** The FDA requires a 30-day waiting period after the filing of each IND application before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue. The IND application process may become extremely costly and substantially delay development of our products. Moreover, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Prior to initiation of clinical studies, an independent Institutional Review Board, or IRB, at each medical site proposing to conduct the clinical trial must review and approve each study protocol and study subjects must provide informed consent.

***Clinical trials.*** Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1: The drug candidate is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, bioavailability, absorption, distribution, excretion and metabolism. For cancer drugs such as those we are developing, this phase of study is generally conducted in patients.

Phase 2: The drug candidate is introduced into a limited patient population to: (1) assess the efficacy of the candidate in specific, targeted indications; (2) assess dosage tolerance and optimal dosage; and (3) identify possible adverse effects and safety risks.

Phase 3: These are commonly referred to as pivotal studies. If a drug candidate is found to have an acceptable safety profile and to be potentially effective in Phase 1 and 2 trials, Phase 3 clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse patient population at geographically dispersed clinical study sites.

We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our drug candidates within any specific time period, if at all. Clinical testing must meet requirements for IRB oversight,



## **Table of Contents**

informed consent and good clinical practices. The FDA and the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

***The NDA process.*** If clinical trials are successful, the next step in the drug regulatory approval process is the preparation and submission to the FDA of an NDA. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for marketing and sale in the United States. The NDA must contain a description of the manufacturing process and quality control methods, as well as results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the NDA, unless an exemption applies. Every new drug must be the subject of an approved NDA before commercialization in the United States.

Upon submission of the NDA, the FDA will make a threshold determination of whether the application is sufficiently complete to permit review, and, if not, will issue a refuse-to-file letter. If the application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the user fee law. Current timing commitments under the user fee law vary depending on whether an NDA is for a priority drug or not, and in any event are not a guarantee that an application will be approved or even acted upon by any specific deadline. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. In addition, the FDA may approve a drug candidate subject to the completion of post-marketing studies, commonly referred to as Phase 4 trials, to monitor the effect of the approved product. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a special risk management plan. The FDA has broad post-market regulatory and enforcement powers, including the ability to issue warning letters, levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

***Manufacturing and post-marketing requirements.*** If approved, a drug may only be marketed in the dosage forms and for the indications approved in the NDA. Special requirements also apply to any drug samples that are distributed in accordance with the Prescription Drug Marketing Act. The manufacturers of approved products and their manufacturing facilities are subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA's cGMP requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA, and make certain other required reports. Product and labeling changes, as well as certain changes in a manufacturing process or facility or other post-approval changes, may necessitate additional FDA review and approval. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as untitled letters, warning letters, suspension of manufacturing, seizure of product, voluntary recall of a product, injunctive action or possible criminal or civil penalties. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. Failure of third party manufacturers to comply with cGMP or other FDA requirements applicable to our products may result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for

## **Table of Contents**

direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as off-label use), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

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

### ***New Drug Approval Outside of the United States***

Approval of a drug in the United States does not guarantee approval in any other country and vice versa. Thus, we will have to complete approval processes that are similar to those in the United States in virtually every foreign market in order to conduct clinical or preclinical research and to commercialize our drug candidates in those countries. The approval procedures and the time required for approvals vary from country to country, may involve additional testing, and may take longer than in the United States. Foreign approvals may not be granted on a timely basis, or at all. In addition, regulatory approval of drug prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

In common with the United States, the various phases of preclinical and clinical research are subject to significant regulatory controls within the European Union. Variations in the national regimes exist. Most jurisdictions, however, require regulatory and IRB approval of interventional clinical trials. Most European regulators also require the submission of adverse event reports during a study and a copy of the final study report. Under European Union regulatory systems, for products that have an Orphan Drug designation or which target cancer, such as the drug candidates we are currently developing, marketing authorizations must be submitted under a centralized procedure that provides for the grant of a single marketing authorization that is valid for all European Union member states.

### ***Orphan Drug Designation***

Under the Orphan Drug Act and corresponding European Union regulations, the FDA and European Union regulatory authorities may grant Orphan Drug designation to drugs intended to treat a rare disease or condition. In the United States, a rare disease or condition is one that affects fewer than 200,000 individuals, or more than 200,000 individuals but for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States of that drug. In the European Union, a rare disease or condition is one that affects fewer than five in 10,000 individuals. In the United States, Orphan Drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, nor does it assure approval.

In the United States, if a product that has Orphan Drug designation receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. In the European Union, the period of product exclusivity is ten years. Orphan Drug exclusivity, however, also could block the approval of one of our products in the United States for

## **Table of Contents**

seven years for an Orphan Drug indication if a competitor obtains approval of the same drug, as defined by the FDA, for such Orphan Drug indication or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. The FDA and EMA have granted Orphan Drug designation to saridegib for the treatment of chondrosarcoma, and we intend to continue seeking Orphan Drug status for our product candidates as appropriate. Orphan Drug designation may not, however, provide us with a material commercial advantage.

### ***Other Regulatory Matters***

In the United States, manufacturing, sales, promotion and other activities following the approval of a new drug are subject to regulation by regulatory authorities in addition to the FDA, including the Federal Trade Commission, the Department of Justice, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, and state and local governments. Among other laws and requirements, our sales, marketing and scientific/educational programs would need to comply with the anti-kickback provisions of the Social Security Act, the False Claims Act and similar state laws. Our pricing and rebate programs would need to comply with pricing and reimbursement rules. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Finally, certain jurisdictions have other trade regulations from time to time to which our business is subject such as technology or environmental export controls and political trade embargoes. Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into supply contracts, including government contracts.

In addition to regulations enforced by the FDA, we also are subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other present and potential future foreign, federal, state, and local laws and regulations. Our research and development involves the controlled use of hazardous materials, including corrosive, explosive and flammable chemicals, various radioactive compounds, and compounds known to cause birth defects. Although we believe that our safety procedures for storing, handling, using, and disposing of such materials comply with the standards prescribed by applicable regulations, the risk of contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any such liability could materially affect our ongoing business.

### **Employees**

We refer to our employees as citizen-owners. As of February 29, 2012, we had 190 full-time citizen-owners, 145 of whom were engaged in research and development and 45 of whom were engaged in management, administration and finance. Over 63 percent of our citizen-owners hold advanced degrees. Our success depends, in part, on our ability to recruit and retain talented and trained scientific and business personnel and senior leadership. We believe that we have been successful to date in obtaining and retaining these individuals, but we do not know whether we will be successful doing so in the future. None of our citizen-owners are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced work stoppages. We believe that relations with our citizen-owners are good.



**Table of Contents****Executive Officers**

The following table lists the positions, names and ages of our executive officers as of February 29, 2012:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Adelene Q. Perkins	52	President and Chief Executive Officer
Julian Adams, Ph.D.	57	President of Research & Development
Joshua Hamermesh	40	Vice President, Business & Corporate Development
Vito J. Palombella, Ph.D.	49	Chief Scientific Officer
Gerald E. Quirk, Esq.	44	Vice President, Corporate Affairs and General Counsel
Pedro Santabarbara, M.D., Ph.D.	59	Chief Medical Officer
Winselaw S. Tucker, Jr.	44	Vice President, Marketing

*Adelene Q. Perkins* has served as our President and Chief Executive Officer since January 2010, President and Chief Business Officer from October 2008 through December 2009 and as our Executive Vice President and Chief Business Officer between September 2006 and October 2008. Ms. Perkins served as Executive Vice President of IPI from February 2006 until its merger with DPI in September 2006 and Chief Business Officer of IPI from June 2002 until the DPI merger. Prior to joining IPI, Ms. Perkins served as Vice President of Business and Corporate Development of TransForm Pharmaceuticals, Inc., a private pharmaceutical company, from 2000 to 2002. From 1992 to 1999, Ms. Perkins held various positions at Genetics Institute, most recently serving as Vice President of Emerging Business and General Manager of the DiscoverEase® business unit. From 1985 to 1992, Ms. Perkins held a variety of positions at Bain & Company, a strategy consulting firm. Ms. Perkins received a B.S. in Chemical Engineering from Villanova University and an M.B.A. from Harvard Business School.

*Julian Adams, Ph.D.*, has served as our President of Research & Development since October 2007, our Chief Scientific Officer between September 2006 and May 2010, as Chief Scientific Officer of IPI from October 2003 until the merger with DPI in September 2006, as our President between September 2006 and October 2007 and as President of IPI from February 2006 until September 2006. Prior to joining Infinity, Dr. Adams served as Senior Vice President, Drug Discovery and Development with Millennium Pharmaceuticals, Inc. from 1999 to 2001. Dr. Adams served as Senior Vice President, Research and Development with LeukoSite Inc., a private biopharmaceutical company, from July 1999 until its acquisition by Millennium in December 1999. Dr. Adams served as a director and Executive Vice President of Research and Development with ProScript, Inc., a private biopharmaceutical company, from 1994 until its acquisition by LeukoSite in 1999. Prior to joining ProScript, Dr. Adams held a variety of positions with Boehringer Ingelheim, a private pharmaceutical company, and Merck & Co., Inc., a publicly traded pharmaceutical company. Dr. Adams has served as a director of Aileron Therapeutics, Inc., a privately held biopharmaceutical company, since May 2011. Dr. Adams received a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology in the field of synthetic organic chemistry.

*Joshua D. Hamermesh* has served as our Vice President, Business and Corporate Development since April 2011. Prior to joining Infinity, Mr. Hamermesh held the position of senior vice president, strategy and corporate development at Pervasis Therapeutics, Inc. from October 2009 to April 2011 where he led strategic partnering initiatives for the company's product development portfolio. Between October 2008 and October 2009, Mr. Hamermesh served as an independent business development and strategy consultant. Prior to that, he served as vice president, commercial and business development at Molecular Insight Pharmaceuticals, Inc. from April 2005 to October 2008 where he completed numerous in-licensing transactions and supported the company's initial public offering. Mr. Hamermesh began his biotechnology career at Genzyme Corporation, where he served as chief operating officer of MG Biotherapeutics, a joint venture with Medtronic, Inc., after holding positions of increasing responsibility in the marketing and business development groups from September 1999 to April 2005. He also served as a business strategy consultant to the industry at the Monitor Company. Mr. Hamermesh received his M.B.A. from Harvard Business School and his B.A. in Economics from Amherst College.

**Table of Contents**

*Vito J. Palombella, Ph.D.*, has served as our Chief Scientific Officer since May 2010. He is responsible for our drug discovery and preclinical development activities and alliance management responsibility for our strategic alliance with Mundipharma and Purdue. Prior to his role as Chief Scientific Officer, Dr. Palombella was Vice President, Drug Discovery from September 2006 to May 2010 and Vice President, Biology of IPI from January 2004 to September 2006. Prior to joining Infinity, Dr. Palombella was Director of Molecular Biology and Protein Chemistry at Syntonix Pharmaceuticals where he was responsible for improving and expanding its core Fc receptor-mediated drug delivery technology. Before joining Syntonix, Dr. Palombella was Senior Director of Cell and Molecular Biology at Millennium Pharmaceuticals, which he joined through its acquisition of LeukoSite (where he held the same title) in 1999. Prior to its acquisition by LeukoSite, Dr. Palombella held a number of positions at ProScript, Inc. (between 1994 and 1999). While at ProScript, LeukoSite and Millennium, Dr. Palombella was involved in the discovery and development of Velcade® (bortezomib), a proteasome inhibitor for cancer therapy. He also managed a number of additional projects, including research into NF-kB regulation. Dr. Palombella received a B.S. in Microbiology from Rutgers University and his M.S. and Ph.D. in Viral Oncology and Immunology from the New York University Medical Center. He was also a post-doctoral fellow at Harvard University in the laboratory of Dr. Tom Maniatis.

*Gerald E. Quirk, Esq.*, has served as our Vice President, Corporate Affairs and General Counsel since September 2009 and as Vice President and General Counsel from September 2006 until September 2009. He is responsible for investor and public relations, corporate governance, finance and accounting, intellectual property and legal affairs. Prior to joining Infinity, Mr. Quirk served in a number of legal and business development positions of increasing responsibility from 1998 to September 2006 at Genzyme Corporation, a publicly traded biopharmaceutical company, where he led licensing and corporate partnering, M&A, merger integration and financing activities for several business units, and served on the launch team for Clolar® (clofarabine). From 1994 to 1998, Mr. Quirk served as an associate in the biotechnology practice group at Palmer & Dodge LLP, a Boston law firm. Mr. Quirk earned his J.D. from Northeastern University School of Law, an Ed.M. in Educational Administration from Harvard University and a B.A. in Political Science from Swarthmore College.

*Pedro Santabarbara, M.D., Ph.D.*, has served as our Chief Medical Officer since November 2010. Prior to joining Infinity in November 2010, Dr. Santabarbara spent five years with PharmaMar, a publicly traded biopharmaceutical company, where he most recently led the development and approval of Yondelis® (trabectedin). Prior to joining PharmaMar, he served as vice president of clinical research oncology at OSI Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, from 2001 to 2005 where he led the successful approval of Tarceva® (erlotinib). Before joining OSI, Dr. Santabarbara led development activities for Campath® (alemtuzumab) at ILEX Oncology, Inc., a private biopharmaceutical company, from 1996 to 2001. He was also employed at Rhone Poulenc Rorer, a publicly traded biopharmaceutical company, from 1994 to 1996 where he led the North American clinical development of Taxotere® (docetaxel), which he drove to approval in breast cancer and designed the strategy for non-small cell lung cancer. Prior to Rhone Poulenc Rorer, Dr. Santabarbara was at Bristol-Myers Squibb, a publicly traded biopharmaceutical company, where he contributed to the development of Taxol® (paclitaxel). Dr. Santabarbara's experience also includes 14 years in research and clinical practice. Dr. Santabarbara holds a M.D. and Ph.D. from University of Barcelona, School of Medicine.

*Winslow S. Tucker, Jr.*, has served as our Vice President, Marketing since May 2010. Mr. Tucker has 15 years of comprehensive commercial pharmaceutical experience in sales, new product marketing and brand leadership in both global and country level positions across a number of therapeutic areas. Prior to joining Infinity, Mr. Tucker held roles of increasing responsibility at Novartis Pharmaceuticals, a publicly traded biopharmaceutical company, in the US and Global operations from 2003 to May 2010, most recently at Novartis Oncology where he was the global brand leader for the company's Gleevec® (imatinib) and Tassigna® (nilotinib) franchise. Prior to that, he spent several years in commercial roles at GlaxoSmithKline Pharmaceuticals, a publicly traded biopharmaceutical company, from 1996 to 2003. Mr. Tucker holds a Bachelor's degree in Business Administration from Howard University and an M.B.A. in Marketing from Indiana University.

---

## **Table of Contents**

### **Available Information**

Our Internet website is <http://www.infi.com>. 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 amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the U.S. Securities and Exchange Commission. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled Investors/Media, as a source of information about us.

Our Code of Conduct and Ethics and the charters of the Audit, Compensation, Nominating & Corporate Governance and Research & Development Committees of our board of directors are all available on our website at <http://www.infi.com> at the Investors/Media section under Corporate Governance. Stockholders may request a free copy of any of these documents by writing to Investor Relations, Infinity Pharmaceuticals, Inc., 780 Memorial Drive, Cambridge, Massachusetts 02139, U.S.A.

The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this report by reference.

### **Item 1A. Risk Factors**

This Annual Report on Form 10-K contains forward-looking statements, regarding our expectations with respect to the possible achievement of discovery and development milestones in 2012, our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy, intellectual property and other objectives for future operations. We often use words such as anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify them by the fact that they do not relate strictly to historical or current facts. Such statements are subject to numerous factors, risks and uncertainties that may cause actual events or results to differ materially from our current expectations. For example, there can be no guarantee that our strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products, L.P., or Purdue, will continue for its expected term or that they will fund our programs as agreed, or that any product candidate we are developing will successfully complete necessary preclinical and clinical development phases. Further, there can be no guarantee that any positive developments in our product development pipeline will result in stock price appreciation. Among the important factors that may cause actual events or results to differ materially from those indicated or implied by forward-looking statements are those discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

### **Risks Related to Our Stage of Development as a Company**

*Our results to date do not guarantee that any of our product candidates will be safe or effective, or receive regulatory approval.*

The risk of failure of our current drug candidates is high. To date, the data supporting our clinical development strategy for our drug candidates are derived solely from laboratory and preclinical studies and limited early-to-mid-stage clinical trials. Later clinical trials may not yield data consistent with earlier clinical trials, as was the case with our randomized Phase 2 clinical trial of saridegib in patients with pancreatic cancer, which we elected to discontinue in January 2012 following a preliminary analysis of data that did not confirm what was observed in the single-arm, Phase 1b portion of the study. In the event that later clinical trials do not yield data consistent with earlier clinical trials, it may be necessary for us to change our development strategy or

---

**Table of Contents**

abandon development of that drug candidate, either of which would result in delays, additional costs and a decrease in our stock price. It is impossible to predict when or if any of our drug candidates will prove safe or effective in humans or receive regulatory approval. These drug candidates may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies or early-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. If we are unable to discover or successfully develop drugs that are safe and effective in humans, we will not have a viable business.

***If our global strategic alliance with Mundipharma and Purdue, or any future alliance we may enter into, is unsuccessful, our operations may be negatively impacted.***

We have a global strategic alliance with Mundipharma to research, develop and jointly commercialize saridegib, IPI-145 and product candidates arising out of our early discovery programs, and with Mundipharma and Purdue to develop and commercialize IPI-940 throughout the world. Under the strategic alliance agreements, Mundipharma and Purdue have committed to provide substantial funding, significant capabilities in the field of pain and, in the case of Mundipharma, significant capabilities in marketing and sales outside of the United States. The success of this alliance is largely dependent on the resources, efforts, technology and skills brought to such alliance by our alliance partners. Disputes and difficulties in these types of relationships are common, often due to conflicting priorities or conflicts of interest. Merger and acquisition activity may exacerbate these conflicts. The benefits of our alliances will be reduced or eliminated if any of our alliance partners:

terminates the applicable strategic alliance agreement;

fails to devote financial or other resources to the applicable alliance, thereby hindering or delaying development, manufacturing or commercialization activities;

in the case of Mundipharma and Purdue, fails to successfully develop or manufacture any products arising out of our fatty acid amide hydrolase, or FAAH, program or to commercialize any drug candidate under the applicable alliance; or

fails to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs, if any, or its own operations.

Under our agreements with Mundipharma and Purdue, each agreement may be terminated on 60 days prior written notice if we were to materially breach such agreement and fail to cure such breach within the 60-day notice period. In addition, each of these strategic alliance agreements may be terminated in the event we experience a change in control or in the event that, during the period ending on December 31, 2013, either Adelene Perkins or Julian Adams is no longer a full-time executive of Infinity. Mundipharma also has the right to opt out of participation in the phosphoinositide-3-kinase, or PI3K, inhibitor program and/or any early discovery program in November of each calendar year, subject to 12 months of continued funding. In addition, Mundipharma has the right to opt out of continued development funding of our Hedgehog pathway program in November 2013, subject to prescribed residual funding obligations. If Mundipharma elects to continue participation in the Hedgehog program when it makes its next decision, it would thereafter have the annual November opt-out right, and one-year residual funding obligation, that applies to other programs in the alliance. If Mundipharma and/or Purdue were to exercise its right to opt out of a program or to terminate its respective agreement, we may not have sufficient financial resources or capabilities to continue development and commercialization of products from the affected program, and our ability to attract a new alliance partner would be made more difficult.

Much of the potential revenue from our alliance with Mundipharma and Purdue, and any alliances we may enter into in the future, will consist of contingent payments, such as royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our alliance partners', ability to

---

**Table of Contents**

successfully develop, introduce, market and sell new products. In some cases, we will not be involved in these processes and we will depend entirely on our alliance partners. For example, Mundipharma will be responsible for all of the commercialization efforts outside of the United States for any products that are successfully developed from our Hedgehog pathway and PI3K inhibitor programs and our early stage development programs, and Purdue and Mundipharma are jointly responsible for all development and commercialization activities for products arising out of our FAAH program. Any of our current or future alliance partners may fail to develop or effectively commercialize these products because it:

decides not to devote the necessary resources because of internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other drug development programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;

does not have sufficient resources necessary to carry the drug candidate through clinical development, regulatory approval and commercialization; or

cannot obtain the necessary regulatory approvals.

In addition, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, in 2010 under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. While our agreement with Millennium precludes Millennium from developing or commercializing products directed to the PI3K delta and/or gamma isoforms that meet certain selectivity criteria, Millennium may research, develop and commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine, and Millennium or other potential competitors may develop products directed to other isoforms of PI3K.

If any current or future alliance partner fails to develop or effectively commercialize our drug candidates, we may not be able to develop and commercialize that drug independently, and our financial condition and operations would be negatively impacted.

***We have a history of operating losses, expect to incur significant and increasing operating losses in the future, and may never be consistently profitable.***

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue from sales. We have primarily incurred operating losses. As of December 31, 2011, we had an accumulated deficit of \$269.1 million. We expect to continue to spend significant resources to fund the research and development of saridegib, retaspimycin HCl, IPI-145 and our other drug candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

Our drug candidates are in varying stages of preclinical and clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until one of our drug candidates successfully completes clinical trials and receives regulatory approval. Since even our most advanced drug candidate requires substantial additional clinical development, we do not expect to receive revenue from our drug candidates for several years, if at all. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

***We may be unable to raise the substantial additional capital that we will need to sustain our operations.***

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current

## Table of Contents

cash and investments, together with research and development funding from Mundipharma, are sufficient to fund our planned operations into 2014. In the absence of changes to our current operating plans, we will need to raise additional funds by that date. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectations, if we do not receive the payments we expect to receive from Mundipharma, if we acquire a third party or if we acquire or license rights to additional drug candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including if:

our drug candidates require more extensive clinical or preclinical testing than we currently expect;

we advance more of our drug candidates than expected into costly later stage clinical trials;

we advance more preclinical drug candidates than expected into early stage clinical trials;

the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;

we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties;

Mundipharma or Purdue elects to discontinue its participation in a partnered program; or

we experience a loss in our investments due to general market conditions or other reasons.

We may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, or at all, particularly in light of current market conditions. In addition, the terms of such financings may result in, among other things, dilution for stockholders or the incurrence of indebtedness that may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our product development programs.

***If we are not able to attract and retain key personnel and advisors, we may not be able to operate our business successfully.***

We are highly dependent on our management team, particularly Adelene Perkins and Julian Adams, and the other members of our executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice, and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. In addition, Mundipharma and Purdue each have the right to terminate its strategic alliance with us if, prior to December 31, 2013, either Adelene Perkins or Julian Adams is no longer a full-time executive of Infinity. We do not maintain key person insurance on any of our employees.

Recruiting and retaining qualified scientific and business personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. This competition is particularly intense near our headquarters in Cambridge, Massachusetts. We also experience competition for the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by other entities, have commitments under consulting or advisory contracts with third parties that limit their availability to us, or both.



## **Table of Contents**

### ***We may encounter difficulties in managing our growth, which could adversely affect our operations.***

Our ability to manage our growth effectively depends upon the continual improvement of our processes and procedures, and the preservation of our corporate culture. We may not be able to implement improvements in an efficient or timely manner, or maintain our corporate culture through organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may slow our growth or give rise to inefficiencies that would increase our losses or delay our programs.

### ***We may undertake strategic acquisitions in the future and any difficulties from integrating acquired businesses, technologies, products and product candidates could adversely affect our business and our stock price.***

We may acquire additional businesses, technologies, products or product candidates that complement or augment our existing business. We may not be able to integrate any acquired business, technology, product or product candidate successfully or operate any acquired business profitably. Integrating any newly acquired business, technology, product or product candidate could be expensive and time-consuming. Integration efforts often place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we expect. The diversion of the attention of our management to, and any delay or difficulties encountered in connection with, any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards, controls, procedures and policies that could adversely affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. We may need to raise additional funds through public or private debt or equity financings to acquire any businesses, technologies, products or product candidates, which may result in, among other things, dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire businesses, technologies, products and product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence in an effort to identify and evaluate material risks involved in the transaction. We will also need to make certain assumptions regarding acquired product candidates, including, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. If we are unsuccessful in identifying or evaluating all such risks or our assumptions prove to be incorrect, we might not realize some or all of the intended benefits of the transaction. If we fail to realize intended benefits from acquisitions we may consummate in the future, our business, and financial statements could be adversely affected.

In addition, we will likely incur significant expenses in connection with our efforts, if any, to consummate acquisitions. These expenses may include fees and expenses for investment bankers, attorneys, accountants and other advisers in connection with our efforts, and could be incurred whether or not an acquisition is consummated. Even if we consummate a particular acquisition, we may incur as part of such acquisition substantial closure costs associated with, among other things, elimination of duplicate operations and facilities. In such case, the incurrence of these costs could adversely affect our financial statements for particular quarterly or annual periods.

### ***Our investments are subject to risks that may cause losses and affect the liquidity of these investments.***

As of December 31, 2011, we had approximately \$115.9 million in cash, cash equivalents and available-for-sale securities. We historically have invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, U.S. Treasury securities and mortgage-backed securities meeting the criteria of our investment policy, which is focused on the preservation of our capital. Corporate obligations may include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. Our investments are subject to general credit, liquidity, market and interest rate risks and instability in the global financial markets. We may realize losses in the fair value of these investments or a complete loss of these investments. In



---

## **Table of Contents**

addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have a material adverse effect on our financial statements.

*The estimates and judgments we make, or the assumptions on which we rely, in preparing our consolidated financial statements could prove inaccurate.*

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include those related to revenue recognition, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates and judgments on historical experience, facts and circumstances known to us and on various assumptions that we believe to be reasonable under the circumstances. These estimates and judgments, or the assumptions underlying them, may change over time or prove inaccurate. If this is the case, we may be required to restate our financial statements as we did in 2011, which could in turn subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial statements and cause our stock price to decline.

*If we are not able to maintain effective internal controls under Section 404 of the Sarbanes-Oxley Act, our business and stock price could be adversely affected.*

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls, and requires our independent auditors to attest to the effectiveness of our internal controls. Any failure by us to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

### **Risks Related to the Development and Commercialization of Our Drug Candidates**

*All of our drug candidates remain subject to clinical testing and regulatory approval. This process is highly uncertain and we may never be able to obtain marketing approval for any of our drug candidates.*

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our drug candidates. Our drug candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our drug candidates. For example, our latest stage drug candidates, saridegib and retaspimycin HCl, are being evaluated in Phase 2 clinical trials, which are intended to evaluate the safety and effectiveness of the drug candidate in a particular disease indication. In addition, we are conducting Phase 1 clinical trials to evaluate the safety and tolerability of IPI-145, the lead compound in our PI3K inhibitor program. If any of these trials are successful, we will need to conduct further clinical trials and apply for regulatory approval before we may market or sell any of our drug products. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing, or may in the future develop, either alone or in collaboration with strategic alliance partners, will obtain marketing approval. In connection with the clinical trials of our current and future drug candidates, we face, among other risks, risks that:

the drug candidate may not prove to be safe or effective;

the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials, as was the case with our Phase 2 clinical trial of saridegib in patients with pancreatic cancer; and

the results may not meet the level of statistical significance required by the FDA or other regulatory authorities.



## **Table of Contents**

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and comparable foreign regulatory agencies. The time required to complete clinical trials and for regulatory review by the FDA and other countries' regulatory agencies is uncertain and typically takes many years. Some of our drug candidates may be eligible for the FDA's programs that are designed to facilitate the development and expedite the review of certain drugs, but we cannot provide any assurance that any of our drug candidates will qualify for one or more of these programs. Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification.

Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to changes in government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenues from the particular drug candidate. Furthermore, the uses for which any regulatory authority may grant approval to market a product may be limited, thus placing limitations on the manner in which we may market the product and limiting its market potential.

***Our drug candidates must undergo rigorous clinical trials prior to receipt of regulatory approval. Any problems in these clinical trials could delay or prevent commercialization of our drug candidates.***

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials, as was the case with our decision to discontinue our Phase 2 clinical trial of saridegib in patients with pancreatic cancer, or to delay the analysis of data from ongoing clinical trials. Any of the following could delay the clinical development of our drug candidates:

unexpected or unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

delays in enrolling patients into clinical trials;

a lower than anticipated retention rate of patients in clinical trials;

the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;

inadequate supply, delays in distribution or deficient quality of, or inability to purchase drug product or other materials necessary to conduct our clinical trials;

unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious and unexpected drug-related side effects experienced by participants in our clinical trials;

a finding that the trial participants are being exposed to unacceptable health risks;

the placement by the FDA of a clinical hold on a trial; or

any restrictions on, or post-approval commitments with regard to, any regulatory approval we ultimately obtain that render the drug candidate not commercially viable.

## **Table of Contents**

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a drug candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for our drug candidates, for any of the foregoing reasons, could adversely affect our efforts to obtain regulatory approval for and to commercialize our drug candidates, increase our operating expenses, and have a material adverse effect on our financial statements.

***Our inability to enroll sufficient numbers of patients in our clinical trials, or any delays in patient enrollment, can result in increased costs and longer development periods for our drug candidates.***

Clinical trials require sufficient patient enrollment, which is a function of many factors, including:

the size of the patient population;

the nature of the trial protocol;

the number of clinical trial sites and the proximity of patients to those sites;

the availability of effective treatments for the relevant disease;

the eligibility criteria for the trial;

the commitment of clinical investigators to identify eligible patients; and

competing studies or trials.

Our failure to enroll patients in a clinical trial could delay the completion of the clinical trial beyond current expectations. In addition, the FDA could require us to conduct clinical trials with a larger number of subjects than has been projected for any of our drug candidates. As a result of these factors, we may not be able to enroll a sufficient number of patients in a timely or cost-effective manner.

Furthermore, enrolled patients may drop out of a clinical trial, which could impair the validity or statistical significance of the clinical trial. A number of factors can influence the patient discontinuation rate, including, but not limited to:

the inclusion of a placebo arm in a trial;

possible inactivity or low activity of the drug candidate being tested at one or more of the dose levels being tested;

the occurrence of adverse side effects, whether or not related to the drug candidate; and

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

the availability of numerous alternative treatment options that may induce patients to discontinue their participation in the trial. A delay in our clinical trial activities could adversely affect our efforts to obtain regulatory approval for and to commercialize our drug candidates, increase our operating expenses, and have a material adverse effect on our financial statements.

***If we are unable to successfully develop companion diagnostics for our drug candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our drug candidates.***

An important component of our business strategy is to develop companion diagnostics for each of our drug candidates. There has been limited success to date industry wide in developing companion diagnostics. To be

**Table of Contents**

successful, we will need to address a number of scientific, technical and logistical challenges. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our drug candidates that receive marketing approval. Given our limited experience in developing diagnostics, we expect to rely, in part, on third parties for their design and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our drug candidates, or experience delays in doing so, the development of our drug candidates may be adversely affected, our drug candidates may not receive marketing approval and we may not realize the full commercial potential of any drug candidates that receive marketing approval.

***We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily.***

We rely on third parties such as contract research organizations, medical institutions and external investigators to enroll qualified patients, conduct our clinical trials and provide services in connection with such clinical trials, and we intend to rely on these and other similar entities in the future. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or the trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Replacing a third party contractor may result in a delay of the affected trial and unplanned costs. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our drug candidates may be delayed.

In addition, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocol for the trial. The FDA requires us to comply with certain standards, referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of our trial investigators or third party contractors does not comply with good clinical practices, we may not be able to use the data and reported results from the trial. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our drug candidates may be delayed.

***Manufacturing difficulties could delay or preclude commercialization of our drug candidates and substantially increase our expenses.***

Our drug candidates require precise, high quality manufacturing. The third party manufacturers on which we rely may not be able to comply with the FDA's current good manufacturing practices, or cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of our drug candidates to be released for use in one or more countries. In addition, such a failure could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our drug candidates and seriously hurt our business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third party manufacturers' performance and compliance with these applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be

---

## **Table of Contents**

unable to replace such third party manufacturers in a timely manner and the production of our drug candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and, depending on the type of material manufactured at the contract facility, the change in contract manufacturer must be submitted to and/or approved by the FDA and comparable regulatory authorities outside of the United States. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drug candidates after receipt of regulatory approval. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all.

To date, our drug candidates have been manufactured for preclinical testing and clinical trials primarily by third party manufacturers. If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, we expect that we would continue to rely, at least initially, on third party manufacturers to produce commercial quantities of our approved drug candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved drug candidates in a timely or economical manner, or at all. Significant scale-up of manufacturing might entail changes in the manufacturing process that have to be submitted to or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by us are unable to successfully increase the manufacturing capacity for a drug candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

A natural product is utilized in the production of saridegib. This product is currently supplied from naturally available plant material. Our ability to acquire and process sufficient amounts of plant material to meet our manufacturing requirements is subject to a number of risks, including the receipt of permits from federal and state authorities, adverse weather conditions or natural disasters that may impact plant availability or our ability to harvest it. In addition, we may be unsuccessful in identifying other locations where this plant naturally occurs, establishing a sustainable method for growing this plant in a controlled environment or identifying an alternative source for this natural product. A material shortage of this natural product could adversely impact or disrupt the manufacture of saridegib, thus impacting our clinical trial activities and, if saridegib is successfully developed, our ability to satisfy commercial demand for the product, thus adversely affecting our financial statements.

***We have certain commercialization rights to our product portfolio, but we currently have limited marketing, sales and distribution experience and capabilities.***

We currently have commercialization rights in the United States for products arising out of our all of our programs, other than our FAAH inhibitor program, and commercialization rights outside the United States for retaspimycin HCl. In order to successfully commercialize our drug candidates, we will need to, and we intend to, establish adequate marketing, sales and distribution capabilities. We may not successfully establish these capabilities or have sufficient resources to do so. If we do not establish adequate marketing, sales and distribution capabilities, our ability to successfully commercialize any drug candidates that we successfully develop will be adversely affected, as will our financial statements. Even if we do develop such capabilities, we will compete with other companies that have more experienced and well-funded marketing, sales and distribution operations, and we will incur additional expenses.

***If physicians and patients do not accept our future drugs, we may not be able to generate significant revenues from product sales.***

Even if any of our drug candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

timing of our receipt of any marketing approvals, the terms of any such approvals and the countries in which any such approvals are obtained;

timing of market introduction of competitive drugs;



## Table of Contents

lower demonstrated clinical safety and efficacy compared to other drugs;

lack of cost-effectiveness;

lack of reimbursement from managed care plans and other third-party payors;

inconvenient or difficult administration;

prevalence and severity of side effects;

potential advantages of alternative treatment methods;

safety concerns with similar drugs marketed by others;

the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;

the success of our physician education programs; and

ineffective sales, marketing and distribution support.

If any of our approved drugs fails to achieve market acceptance, we would not be able to generate significant revenue from those drugs or achieve profitability.

***Even if we receive regulatory approvals for marketing our drug candidates, we could lose our regulatory approvals and our business would be adversely affected if we, our strategic alliance partners, or our contract manufacturers fail to comply with continuing regulatory requirements.***

The FDA continues to review products even after they receive initial approval. If we receive approval to commercialize any of our drug candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, GMPs, adverse event requirements, and prohibitions on promoting a product for unapproved uses. Enforcement actions resulting from our failure to comply with government and regulatory requirements could result in fines, suspension of approvals, withdrawal of approvals, product recalls, product seizures, mandatory operating restrictions, criminal prosecution, civil penalties and other actions that could impair the manufacturing, marketing and sale of our drug candidates and our ability to conduct our business.

***If our drug candidates exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could become subject to costly and damaging product liability claims.***

Even if we receive regulatory approval for any of our drug candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our products, new risks and side effects associated with our products may be discovered. In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities. We also might have to withdraw or recall our products from the marketplace. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in us becoming subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and

marketing our product.

***We are subject to uncertainty relating to reimbursement policies that could hinder or prevent the commercial success of our drug candidates.***

Our ability to commercialize our product candidates successfully will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a

## **Table of Contents**

threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for our drug candidates or we may be required to sell our drug candidates at prices that are below our expectations.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of our drug candidates in determining whether to approve reimbursement for our drug candidates and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of our drug candidates from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which our drug candidates will be reimbursed to a smaller set than we believe our drug candidates are effective in treating.

In some foreign countries, particularly Canada and the countries of Europe, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidates to other available therapies. If reimbursement for our products is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We expect to experience pricing pressures in connection with the sale of our drug candidates and our future products due to the potential healthcare reforms discussed below, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

### ***Healthcare reform measures could hinder or prevent our product candidates' commercial success.***

The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Healthcare Act and the Health Care and Education Reconciliation Act. This healthcare reform law increases the number of individuals who receive health insurance coverage and closes a gap in drug coverage under Medicare Part D as established under the Medicare Prescription Drug Improvement Act of 2003; each of these reforms could potentially increase our future revenue from any of our drug candidates that are approved for sale. The law, however, also implements cost containment measures that could adversely affect our future revenue. These measures include increased drug rebates under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care. The legislation also extends 340B discounted pricing on outpatient drugs to children's hospitals, critical access hospitals, and rural health centers; this expansion reduces the amount of reimbursement received for drugs purchased by these new 340B-covered entities.

Additional provisions of the health care reform law may negatively affect our future revenue and prospects for profitability. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we would be assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid. As part of the health care reform law's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will also be required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within the donut hole.

---

## **Table of Contents**

In the aftermath of the healthcare reform law, private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services. These cost-control initiatives could decrease the price we might establish for any of our drug candidates, which would result in lower product revenue or royalties payable to us.

In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. These proposed reforms could result in reduced reimbursement rates for any of our drug candidates, which would adversely affect our business strategy, operations and financial results.

***Our business could be harmed if we are unable to comply with applicable fraud and abuse and other laws and regulations where our drug candidates may ultimately be sold.***

As our pipeline of drug candidates matures, we are becoming increasingly subject to extensive and complex laws and regulations, including but not limited to healthcare fraud and abuse and patient privacy laws and regulations by both the federal government and the states in which we conduct our business. These laws and regulations include:

the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any drug candidates that we successfully develop in compliance with all applicable U.S. laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

**Table of Contents****Risks Related to Our Field*****Our competitors and potential competitors may develop products that make ours less attractive or obsolete.***

In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us several product opportunities in oncology, inflammatory disease and pain, which are highly competitive and rapidly changing segments of the pharmaceutical industry. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various diseases in these segments. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products in these segments including Bristol-Myers Squibb Company, the Roche Group and its subsidiary Genentech, Novartis AG and Pfizer, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer, inflammatory diseases and pain. We are also aware of a number of companies seeking to develop drug candidates directed to the same biological targets that our own drug candidates are designed to inhibit. Specifically, we are aware of numerous companies that have clinical development programs or have received FDA approval for compounds targeting the Hedgehog pathway, which is the target of saridegib. These companies include, without limitation, Genentech, Pfizer, Inc., Bristol Myers Squibb Company (through its collaboration with Exelixis, Inc.), Millennium, and Novartis AG. In addition, we believe the following companies are developing compounds that target Hsp90, which is the target of retaspimycin HCl: Synta Pharmaceuticals Corp., Novartis AG, Astex Pharmaceuticals, Inc., Celgene Corporation, Daiichi Sankyo, Inc., Debiopharm Group, Exelixis, Inc., Kyowa Hakko Kirin Co. Ltd. and Myrexis, Inc. Also, we believe that Gilead Sciences, Inc. and Amgen Inc. are developing drugs that target the delta and/or gamma isoforms of PI3K.

Many of our competitors have:

significantly greater financial, technical and human resources than us, and may be better equipped to discover, develop, manufacture and commercialize drug candidates;

more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products; and/or

drug candidates that have been approved or are in later-stage clinical development than our own drug candidates.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals, and begin commercialization of their products sooner than we and/or our strategic alliance partners may for our own drug candidates. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than our drug candidates. If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize our drug candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

***We may have significant product liability exposure that may harm our business and our reputation.***

We face exposure to significant product liability or other claims if any of our drug candidates is alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the commercial launch of any of our drug candidates. Our insurance may not, however, provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of

## **Table of Contents**

insurance coverage or obtain additional or sufficient insurance at a reasonable cost. If we are sued for any injury caused by our products or product candidates, our liability could exceed our insurance coverage and our total assets, and we would need to divert management attention to our defense. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to recruit investigators and patients to our clinical trials, obtain physician acceptance of our products, or expand our business.

### ***We work with hazardous materials that may expose us to liability.***

Our activities involve the controlled storage, use and disposal of hazardous materials, including infectious agents, corrosive, explosive and flammable chemicals, various radioactive compounds, and compounds known to cause birth defects. We are subject to certain federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We incur significant costs to comply with these laws and regulations. In addition, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, regulatory authorities may curtail our use of these materials, and we could be liable for any civil damages that result. These damages may exceed our financial resources or insurance coverage, and may seriously harm our business. Additionally, an accident could damage, or force us to shut down, our operations.

### ***Security breaches may disrupt our operations and harm our operating results.***

Our network security and data recovery measures may not be adequate to protect against computer viruses, break-ins, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including research or clinical data, could have a material adverse impact on our business, operating results and financial condition. Additionally, any break-in or trespass of our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets, could have a material adverse impact on our business, operating results and financial condition.

## **Risks Related to Intellectual Property**

### ***Our success depends substantially upon our ability to obtain and maintain intellectual property protection for our drug candidates.***

We own or hold exclusive licenses to a number of U.S. and foreign patents and patent applications directed to our drug candidates. Our success depends on our ability to obtain patent protection both in the United States and in other countries for our drug candidates, their methods of manufacture and methods of their use. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends substantially on our ability to obtain and enforce our patents.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical or molecular diagnostics patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us, including the patent applications claiming the compositions of, and methods of using, IPI-145 and IPI-940. Even if patents do issue, we cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products, or will afford us a commercial advantage over competitive products.

## **Table of Contents**

The U.S. Congress recently passed the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in September 2011 and will become effective in March 2013. The America Invents Act reforms United States patent law in part by changing the standard for patent approval for certain patents from a first to invent standard to a first to file standard and developing a post-grant review system. This new law changes United States patent law in a way that may severely weaken our ability to obtain patent protection in the United States. Additionally, recent judicial decisions establishing new case law and a reinterpretation of past case law, as well as regulatory initiatives, may make it more difficult for us to protect our intellectual property.

If we do not obtain adequate intellectual property protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we had been required to undertake to obtain approval of the products by the FDA. Regardless of any patent protection, under the current statutory framework the FDA is prohibited by law from approving any generic version of any of our products for up to five years after it has approved our product. Upon the expiration of that period, or if that time period is altered, the FDA could approve a generic version of our product unless we have patent protection sufficient for us to block that generic version. Without sufficient patent protection, the applicant for a generic version of our product would only be required to conduct a relatively inexpensive study to show that its product is bioequivalent to our product, and would not have to repeat the studies that we conducted to demonstrate that the product is safe and effective. In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries of products that duplicate our products.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of our development efforts are performed in China, India, and other countries outside of the United States through third party contractors. We may not be able to monitor and assess intellectual property developed by these contractors effectively; therefore, we may not appropriately protect this intellectual property and could thus lose valuable intellectual property rights. In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective of intellectual property rights as in the United States, and we may, therefore, be unable to acquire and protect intellectual property developed by these contractors to the same extent as if these development activities were being conducted in the United States. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

In addition, we rely on intellectual property assignment agreements with our strategic alliance partners, vendors, employees, consultants, scientific advisors and other collaborators to grant us ownership of new intellectual property that is developed by them. These agreements may not result in the effective assignment to us of that intellectual property. As a result, our ownership of key intellectual property could be compromised.

***Patent interference, opposition or similar proceedings relating to our intellectual property portfolio are costly, and an unfavorable outcome could prevent us from commercializing our drug candidates.***

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the PTO for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or their therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our drug candidates or a similar invention, we may have to participate in interference proceedings declared by the PTO or the third party to determine priority of invention in the United States. For example, we are aware of third parties who are actively researching ansamycin analogs that are similar to retaspimycin HCl. These third parties have pending applications related to these analogs, but we have the first published application covering retaspimycin HCl. Notwithstanding the fact that we filed the first patent application related to these analogs, it is possible that an interference proceeding could be declared between our application covering retaspimycin HCl and one or more of these third party applications, even those applications for which we have secured a license. An adverse decision in an interference proceeding may result in the loss of rights under a patent or patent application. In addition, the cost of interference proceedings could be substantial.

---

## **Table of Contents**

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to comply with these requirements, competitors might be able to enter the market earlier than would otherwise have been the case.

***Claims by third parties of intellectual property infringement are costly and distracting, and could deprive us of valuable rights we need to develop or commercialize our drug candidates.***

Our commercial success will depend on whether there are third party patents or other intellectual property relevant to our potential products that may block or hinder our ability to develop and commercialize our drug candidates. We may not have identified all U.S. and foreign patents or published applications that may adversely affect our business either by blocking our ability to manufacture or commercialize our drugs or by covering similar technologies that adversely affect the applicable market. In addition, we may undertake research and development with respect to potential products, even when we are aware of third party patents that may be relevant to such potential products, on the basis that we may challenge or license such patents. For example, in our Hsp90 inhibitor program, we are conducting clinical trials evaluating the administration of retaspimycin HCl in combination with docetaxel and everolimus. We are aware of issued patents and published applications directed to combinations of Hsp90 inhibitors with a variety of therapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 inhibitors. We are in the process of evaluating the scope and validity of these patents and applications to determine whether we need to obtain one or more licenses.

While we are not currently aware of any litigation or third party claims of intellectual property infringement related to our drug candidates, the biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents and claim that the use of our technologies infringes these patents or that we are employing their proprietary technology without authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

pay substantial damages;

stop developing, manufacturing and/or commercializing the infringing drug candidates or approved products;

develop non-infringing products, technologies and methods; and

obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

If any of the foregoing were to occur, we may be unable to commercialize the affected products, or we may elect to cease certain of our business operations, either of which could severely harm our business.

***We may undertake infringement or other legal proceedings against third parties, causing us to spend substantial resources on litigation and exposing our own intellectual property portfolio to challenge.***

Competitors may infringe our patents. To prevent infringement or unauthorized use, we may need to file infringement suits, which are expensive and time-consuming. In an infringement proceeding, a court may decide





---

## **Table of Contents**

that one or more of our patents is invalid, unenforceable, or both. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the ground that the other party's activities are not covered by our patents. In this case, third parties may be able to use our patented technology without paying licensing fees or royalties. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. In addition, third parties may affirmatively challenge our rights to, or the scope or validity of, our patent rights.

### ***Confidentiality agreements may not adequately prevent disclosure of trade secrets and other proprietary information.***

In order to protect our proprietary technology, we rely in part on confidentiality agreements with our vendors, strategic alliance partners, employees, consultants, scientific advisors, clinical investigators and other collaborators. We generally require each of these individuals and entities to execute a confidentiality agreement at the commencement of a relationship with us. These agreements may not effectively prevent disclosure of confidential information, and may not provide an adequate remedy in the event of unauthorized disclosure or misuse of confidential information or other breaches of the agreements.

In addition, we may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets are, however, difficult to protect. Others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside of the United States 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 could result in a diversion of management's attention, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

### ***If we fail to obtain necessary or useful licenses to intellectual property, we could encounter substantial delays in the research, development and commercialization of our drug candidates.***

We may decide to license third party technology that we deem necessary or useful for our business. We may not be able to obtain these licenses at a reasonable cost, or at all. If we do not obtain necessary licenses, we could encounter substantial delays in developing and commercializing our drug candidates while we attempt to develop alternative technologies, methods and drug candidates, which we may not be able to accomplish. Furthermore, if we fail to comply with our obligations under our third party license agreements, we could lose license rights that are important to our business. For example, if we fail to use diligent efforts to develop and commercialize compounds and products licensed under our development and license agreement with Millennium, we could lose our license rights under that agreement, including rights to IPI-145.

## **Risks Associated with Our Common Stock**

### ***Our common stock may have a volatile trading price and low trading volume.***

The market price of our common stock has been and could continue to be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

the results of our current and any future clinical trials of our drug candidates;

the results of preclinical studies and planned clinical trials of our discovery-stage programs;

product portfolio decisions resulting in the delay or termination of our product development programs;

future sales of, and the trading volume in, our common stock;

**Table of Contents**

our entry into key agreements, including those related to the acquisition or in-licensing of new programs, or the termination of key agreements, including our strategic alliance agreements with Mundipharma and Purdue and our development and license agreement with Millennium;

the results and timing of regulatory reviews relating to the approval of our drug candidates;

the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights;

the initiation of, material developments in, or conclusion of litigation to defend product liability claims;

the failure of any of our drug candidates, if approved, to achieve commercial success;

the results of clinical trials conducted by others on drugs that would compete with our drug candidates;

issues in manufacturing our drug candidates or any approved products;

the loss of key employees;

changes in estimates or recommendations, or publication of inaccurate or unfavorable research about our business, by securities analysts who cover our common stock;

future financings through the issuance of equity or debt securities or otherwise;

changes in the structure of healthcare payment systems;

our cash position and period-to-period fluctuations in our financial results; and

general and industry-specific economic conditions.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, when the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, negative publicity could be generated and we could incur substantial costs defending the lawsuit. A stockholder lawsuit could also divert the time and attention of our management.

***We do not anticipate paying cash dividends, so you must rely on stock price appreciation for any return on your investment.***

We anticipate retaining any future earnings for reinvestment in our research and development programs. Therefore, we do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. Investors

seeking cash dividends should not invest in our common stock.

***Our stockholder rights plan, anti-takeover provisions in our organizational documents, and Delaware law may make an acquisition of us difficult.***

We are a party to a stockholder rights plan, also referred to as a poison pill, which is intended to deter a hostile takeover by making any unsolicited proposed acquisition of us more expensive and less desirable to the potential acquirer.

In addition, we are incorporated in Delaware. Anti-takeover provisions of Delaware law and our organizational documents may make a change in control more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. For example, our charter authorizes our board of directors

## **Table of Contents**

to issue up to 901,000 shares of currently undesignated preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If our board of directors exercises this power, it could be more difficult for a third party to acquire a majority of our outstanding voting stock. Our charter and by-laws also contain provisions limiting the ability of stockholders to call special meetings of stockholders.

Our stock incentive plan generally permits our board of directors to provide for acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control. If our board of directors uses its authority to accelerate vesting of options, this action could make an acquisition more costly, and it could prevent an acquisition from going forward.

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors could use this provision to vote against any such transaction. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

*Our executive officers, directors and major shareholders may be able to exert significant control over the company, which may make an acquisition of us difficult.*

Our executive officers, directors, certain affiliates and other major shareholders control approximately 31% of our outstanding common stock and have the ability to influence the company through this ownership position. For example, as a result of this concentration of ownership, these stockholders, if acting together, may have the ability to affect the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger or similar transaction. This concentration of ownership may, therefore, harm the market price of our common stock by:

delaying, deferring or preventing a change in control of Infinity;

impeding a merger, consolidation, takeover or other business combination involving Infinity; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of Infinity.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

We currently lease under two lease agreements an aggregate of approximately 73,900 square feet of laboratory and office space among three buildings located at 780, 784, and 790 Memorial Drive in Cambridge, Massachusetts. One lease covering approximately 67,000 square feet of laboratory and office space expires in January 2016. We currently sublease approximately 13,000 square feet of this space under a sublease agreement that expires in December 2012. The second lease covers approximately 6,900 square feet of office space and expires in October 2014. Should we require additional space, we believe that a suitable facility would be available to accommodate expansion of our operations on commercially reasonable terms.

### **Item 3. Legal Proceedings**

We are not a party to any material legal proceedings.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**  
**Market Information**

Our common stock is traded on the NASDAQ Global Select Market under the symbol INFI. Prior to January 3, 2011, our common stock was traded on the NASDAQ Global Market. The following table sets forth the range of high and low sales prices for our common stock for the quarterly periods indicated, as reported by NASDAQ. Such quotations represent inter-dealer prices without retail mark up, mark down or commission and may not necessarily represent actual transactions.

	2011		2010	
	High	Low	High	Low
First quarter	\$ 6.10	\$ 5.23	\$ 6.68	\$ 5.75
Second quarter	8.30	5.58	7.96	5.85
Third quarter	10.42	5.81	6.33	4.42
Fourth quarter	10.00	6.50	6.99	5.09

 **Holders**

As of February 29, 2012, there were 102 holders of record of our common stock.

 **Dividends**

We have never paid cash dividends on our common stock, and we do not expect to pay any cash dividends in the foreseeable future.

 **Comparative Stock Performance Graph**

The information included under the heading Comparative Stock Performance Graph included in this Item 5 of Part II of this Annual Report on Form 10-K shall not be deemed to be soliciting material or subject to Regulation 14A or 14C, shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

The graph below shows a comparison of cumulative total stockholder returns from December 31, 2006 through December 31, 2011 for our common stock, the NASDAQ Stock Market (U.S.) Index and the NASDAQ Biotechnology Index. The graph assumes that \$100 was invested in our common stock and in each index on December 31, 2006, and that all dividends were reinvested. No cash dividends have been declared or paid on our common stock.

The stockholder returns shown on the graph below are not necessarily indicative of future performance, and we will not make or endorse any predictions as to future stockholder returns.

**Table of Contents**

**Comparison of 5-Year Cumulative Total Return  
among Infinity Pharmaceuticals, Inc.,  
the NASDAQ Stock Market (U.S.) Index,  
and the NASDAQ Biotechnology Index**

42



**Table of Contents****Item 6. Selected Financial Data**

The following financial data should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this report. Amounts below are in thousands, except for shares and per share amounts.

	Year Ended December 31,				
	2011	2010	2009	2008	2007
<b>Statement of Operations Data:</b>					
Collaborative research and development revenue:					
From Purdue entities	\$ 92,773	\$ 71,331	\$ 50,765	\$ 3,027	\$
Other(1)				80,558	24,536
<b>Total revenue</b>	<b>92,773</b>	<b>71,331</b>	<b>50,765</b>	<b>83,585</b>	<b>24,536</b>
Operating expenses:					
Research and development	108,582	99,231	77,857	47,466	33,793
General and administrative	22,719	21,070	19,456	16,837	14,034
<b>Total operating expenses</b>	<b>131,301</b>	<b>120,302</b>	<b>97,313</b>	<b>64,303</b>	<b>47,827</b>
Income (loss) from operations	(38,528)	(48,971)	(46,548)	19,282	(23,291)
Interest income (expense), net	(1,514)	(1,447)	744	3,321	6,393
Income from NIH reimbursement			1,745		
Income from residual funding after reacquisition of Hsp90 program			12,450	1,195	
Income from Therapeutic Discovery Grants		733			
Income (loss) before income taxes	(40,042)	(49,684)	(31,609)	23,798	(16,898)
Income tax benefit		700	330		
<b>Net income (loss)</b>	<b>\$ (40,042)</b>	<b>\$ (48,984)</b>	<b>\$ (31,279)</b>	<b>\$ 23,798</b>	<b>\$ (16,898)</b>
Earnings (loss) per common share:					
Basic	\$ (1.50)	\$ (1.86)	\$ (1.20)	\$ 1.18	\$ (0.87)
Diluted	\$ (1.50)	\$ (1.86)	\$ (1.20)	\$ 1.15	\$ (0.87)
Weighted average number of common shares outstanding:					
Basic	26,620,278	26,321,398	26,096,515	20,236,743	19,511,485
Diluted	26,620,278	26,321,398	26,096,515	20,765,536	19,511,485

- (1) Revenue for the year ended December 31, 2008 was impacted by the acceleration of revenue recognition for up-front license fees received under arrangements with Novartis Institutes for BioMedical Research and MedImmune, a division of AstraZeneca plc.

	As of December 31,				
	2011	2010	2009	2008	2007
<b>Selected Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities, including long-term	\$ 115,937	\$ 100,959	\$ 130,737	\$ 126,772	\$ 114,189
Working capital	88,995	75,378	119,408	119,360	97,097
Total assets	124,490	124,566	157,318	160,618	129,725
Long-term debt due to Purdue entities, net of debt discount(1)	37,553				
Accumulated deficit	(269,052)	(229,010)	(180,026)	(148,747)	(172,546)
Total stockholders' equity	15,433	49,484	90,312	103,121	51,143

- (1) In November 2011, we borrowed \$50 million under the line of credit agreement with Purdue and its independent associated entity, Purdue Pharma L.P., or PPLP. We reduced the long-term debt on our balance sheet with a debt discount. See note 7 of the financial statements.



## Table of Contents

### **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in Part I Item 1A of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

#### **Business Overview**

##### *Overview*

We are an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines for difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. Our programs in the inhibition of the Hedgehog pathway, the heat shock protein 90 chaperone system, and phosphoinositide-3-kinase are evidence of our innovative approach to drug discovery and development.

**Hedgehog Pathway Inhibitor Program.** Our lead product candidate is saridegib, also known as IPI-926, a novel, potent, oral molecule that inhibits the Hedgehog pathway by binding to the Smoothed receptor, a protein that plays a critical role in the malignant activation of the Hedgehog pathway. We believe that Smoothed inhibition represents a significant opportunity for addressing a number of difficult-to-treat cancers by disrupting malignant activation of the Hedgehog pathway through multiple, distinct mechanisms. We are evaluating saridegib in a randomized, double-blind Phase 2 clinical trial to assess the safety and efficacy of saridegib compared to placebo in approximately 140 patients with metastatic or locally advanced, inoperable chondrosarcoma. We believe this trial is the first and only randomized clinical trial being conducted in this indication. We expect to complete enrollment in this trial in the second half of 2012 and to report data from this trial in the first half of 2013. In addition, we are actively enrolling patients in an exploratory Phase 2 clinical trial evaluating the safety and efficacy of saridegib in patients with myelofibrosis. We expect to report data from this trial in the second half of 2012. In January 2012, we discontinued our randomized Phase 2 clinical trial evaluating saridegib in combination with gemcitabine, a chemotherapy, in patients with previously untreated, metastatic, pancreatic cancer, following a preliminary analysis of data showing a difference in survival favoring the placebo plus gemcitabine treatment group. This difference in survival was due to a higher rate of progressive disease in the saridegib plus gemcitabine treatment group, and not a result of the safety profile of saridegib. We expect to present final data from this trial after our analyses are complete. Mundipharma International Corporation Limited, or Mundipharma, has commercialization rights outside of the United States for products arising out of our Hedgehog pathway inhibitor program.

**Hsp90 Inhibitor Program.** Retaspimycin hydrochloride (HCl), also known as IPI-504, is a novel, potent and selective inhibitor of heat shock protein 90, or Hsp90. Cancer cells depend on Hsp90 to maintain many proteins critical for cancer growth, proliferation and survival in a functional state. Certain anticancer therapies may enhance the dependency of cancer cells on Hsp90. Therefore, combining an Hsp90 inhibitor with another anticancer therapy may enhance cancer cell killing. Retaspimycin HCl is currently being evaluated in a randomized, double-blind Phase 2 clinical trial in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in approximately 200 patients with second- or third-line non-small cell lung cancer, or NSCLC, who are naive to docetaxel treatment and have a history of heavy smoking. We expect to complete enrollment in this trial in the second half of 2012 and to report data from this trial in the second half of 2013. We are also enrolling patients in a Phase 1b/2 trial to explore the safety and efficacy of retaspimycin HCl in combination with everolimus, an mTOR inhibitor, in NSCLC patients with a KRAS mutation. The objective of this Phase 1b/2 trial is to determine the recommended dose for the combination treatment and to evaluate the safety and clinical activity of retaspimycin HCl in combination with everolimus. We expect to report top-line data from this trial in the second half of 2012. We have worldwide development and commercialization rights for our Hsp90 inhibitor program.

---

## **Table of Contents**

***PI3K Inhibitor Program.*** The phosphoinositide-3-kinases, or PI3Ks, are a family of enzymes involved in key immune cell functions, including cell proliferation and survival, cell differentiation, and cellular trafficking. PI3K-delta and PI3K-gamma, two isoforms of PI3K, play key roles in inflammatory and autoimmune diseases. Additionally, in certain hematologic malignancies, PI3K-gamma and PI3K-delta contribute to the survival and proliferation of cancer cells. Therefore, inhibition of PI3K-delta and PI3K-gamma may have therapeutic potential across a broad range of inflammatory diseases and hematologic malignancies. Our lead compound in this program is IPI-145, a potent, orally-available inhibitor of PI3K-delta and PI3K-gamma. In the second half of 2011, we initiated two Phase 1 clinical trials of IPI-145. The first Phase 1 trial of IPI-145 is a double-blind, randomized, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple escalating doses of IPI-145 in healthy adult subjects. The second Phase 1 trial is an open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies. Following the determination of the maximum tolerated dose in the dose escalation phase of this study, we plan to conduct an expansion phase in patients with specific hematologic malignancies. We expect to report data from both Phase 1 trials in the second half of 2012 and to commence Phase 2 development of IPI-145 in inflammation in 2012. Mundipharma has commercialization rights outside of the United States for products arising from our PI3K inhibitor program.

***Other Programs.*** In addition to our three clinical stage programs, we have several innovative projects in earlier stages of development, encompassing emerging targets in fields such as cancer metabolism, apoptosis and protein homeostasis. Through our internal discovery efforts, we also discovered IPI-940, a novel, orally available inhibitor of fatty acid amide hydrolase, or FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. We have licensed worldwide development and commercialization rights to our FAAH program to Mundipharma and its independent associated company, Purdue Pharmaceutical Products L.P., or Purdue.

## **Strategic Alliances**

### ***Mundipharma and Purdue***

#### *Scope*

In November 2008, we entered into a strategic alliance with Mundipharma and Purdue to develop and commercialize pharmaceutical products. The alliance is governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue. The agreement with Purdue is focused on the development and U.S. commercialization of products targeting FAAH. The agreement with Mundipharma is focused on the development and commercialization outside of the United States of all products and product candidates covered by the alliance, including those targeting FAAH. The alliance currently includes product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of our early discovery projects in all disease fields that are conducted during a prescribed discovery period that runs through December 31, 2013. Our Hsp90 program is expressly excluded from the alliance.

Mundipharma also has the option to include in the alliance certain products or product candidates that we may in-license during the discovery period by paying us a prescribed percentage of the up-front license fee or other acquisition cost, which percentage could be up to 60% of such fee or cost, and by funding research and development costs in the same manner as products or product candidates arising out of our internal discovery programs, as described below. If we in-license any product or product candidate during the discovery period for which GLP (Good Laboratory Practice) toxicology studies have not been initiated, as we did with our PI3K inhibitor program in 2010, such products are automatically included in the alliance just as if they arose out of our internal discovery projects.

We have responsibility and decision-making authority for the development of all of our product candidates and performance of early discovery projects on a worldwide basis. There are no joint steering or similar

---

## Table of Contents

committees for the alliance. Except with respect to products targeting FAAH, for which Mundipharma and Purdue currently have global commercialization rights, and products for which Mundipharma has opted out of development as described below, we will have the right and responsibility to market and sell products arising from the alliance in the United States and Mundipharma will have the right and responsibility to market and sell products arising from the alliance outside of the United States. Other than pursuant to the strategic alliance agreements, neither we, Purdue nor Mundipharma may develop, manufacture or commercialize products that are directed to the same target or pathway as a product included in the strategic alliance, unless and until a party terminates its rights with respect to such products.

Following entry into the strategic alliance agreements, we consider Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes because of their equity ownership in our company.

### *Research and Development Funding*

For each alliance program other than FAAH, Mundipharma is obligated to reimburse us for all research and development expenses we incur, up to an annual aggregate cap, until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of a product candidate, which we refer to as the transition date. The funding caps for the years ending December 31, 2012 and December 31, 2013 are \$110 million and \$147.5 million, respectively. The funding caps for the years ended December 31, 2011 and 2010 were \$85 million and \$65 million, respectively. The funding cap for the period between November 19, 2008 and December 31, 2009 was \$50 million. We are obligated to fund any activities in excess of the annual funding cap ourselves, which we did in 2010 primarily as the result of costs associated with the licensing of our PI3K inhibitor program, and in 2011 primarily due to expanded clinical trial activities for saridegib and the commencement of clinical development of IPI-145. After the transition date for each product candidate, we are obligated to share equally with Mundipharma all research and development costs for such product candidate. We are recognizing revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recognized \$85.0 million, \$65.0 million and \$46.5 million in such revenue in the years ended December 31, 2011, 2010 and 2009, respectively.

In October 2010, following the completion of the first Phase 1 clinical trial of IPI-940, Mundipharma and Purdue exercised their rights to assume all worldwide development and commercialization activities and to fund all subsequent research, development and commercialization expenses for products arising out of our FAAH program. All expenses associated with activities we conduct related to the transition of the FAAH program to Purdue and Mundipharma are reimbursed by Purdue and Mundipharma, with such amounts not counting towards the annual funding cap. We recognized \$3.5 million and \$2.0 million in revenue related to reimbursed research and development services for the transition of the FAAH program in the years ended December 31, 2011 and 2010, respectively.

### *Opt-out and Termination Rights*

Mundipharma has the right to opt out of any alliance program, except the Hedgehog program, on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma would continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for all programs included in the alliance for the calendar year following the date of such opt out, up to an annual cap. This funding commitment for the year ending December 31, 2013 is \$51.3 million for our PI3K and early discovery programs.

Mundipharma may next exercise its right to opt out of the Hedgehog program in November 2013. Mundipharma is obligated to fund the Hedgehog program until it is required to make the decision to opt out or continue funding the program. If Mundipharma elects to opt out of participation in the Hedgehog program in November 2013, then Mundipharma would be obligated to make an immediate payment of \$23.65 million to us, which we can use on any program in the alliance. In addition, Mundipharma would be obligated to reimburse us

---

## **Table of Contents**

for up to \$23.65 million of additional expenses incurred during 2013 that are associated with the completion of Phase 2 clinical trials of saridegib that are ongoing at that time. If Mundipharma elects to continue participation in the Hedgehog program in November 2013, it would thereafter have the same annual opt-out right, and one-year residual funding obligation, that applies to the other alliance programs.

In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for 50% of post-transition date research and development expenses for the product candidate. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

Each of the strategic alliance agreements expire when the parties thereto have no further obligations to each other thereunder. Either party may terminate the strategic alliance agreement to which it is a party on 60 days' prior written notice if the other party materially breaches the agreement and fails to cure such breach within the 60-day notice period. The agreements may also be terminated by Mundipharma or Purdue in the event of a change in control of Infinity or in the event that, during the discovery period, either Adelene Perkins or Julian Adams is no longer a full-time executive of Infinity. Upon termination of either strategic alliance agreement by us or either Mundipharma or Purdue, either party to the other strategic alliance agreement may terminate that agreement.

### *Royalties*

Except with respect to products that have been in-licensed by us following initiation of GLP toxicology studies, for which no royalties will be payable between the parties, we are obligated to pay Mundipharma a 5% royalty on net sales of the commercialized products until such time as Mundipharma has recovered all research and development expenses paid to us under the research program prior to the applicable transition date. After such cost recovery, we are obligated to pay a tiered, 1% to 3% royalty on U.S. net sales of those products. For products in which Mundipharma has opted-out of development prior to the transition date, we are obligated to pay royalties of 1% to 5% of worldwide net sales as a function of the stage of development of the applicable product candidate at the time of opt out. For products in which either party has opted-out of development following the transition date, the commercializing party is obligated to pay the other party a 5% royalty on net sales. Mundipharma is obligated to pay us a tiered, 10% to 20% royalty on annual net sales outside of the United States of each product arising out of the alliance, and Purdue is obligated to pay us a tiered, 10% to 20% royalty on annual net sales of FAAH products in the United States. Royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the rates above is reduced by one-half. In addition, all royalties payable under the strategic alliance agreements, whether by us, Mundipharma or Purdue, are subject to reduction on account of third party royalty payments or patent litigation damages or settlements, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

### *Securities Purchase and Line of Credit Agreements*

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and a line of credit agreement in November 2008 with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP.

Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of six million shares of our common stock and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$75 million. An equal number of securities were sold to each purchaser.

---

**Table of Contents**

The line of credit agreement provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. In November 2011, we borrowed the full \$50 million available to us under the line of credit. The loan matures and is payable in full, including principal and any accrued interest, on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. The loan bears interest at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and is reset on the last business day of each month ending thereafter. Interest is compounded on each successive three-month anniversary of the funding of the loan. The loan may be prepaid without penalty or premium prior to the maturity date. Even if we prepay the loan, we do not have the ability to borrow under the line of credit agreement again. We have certain rights to repay the loan in shares of our common stock.

The extension of the line of credit at an interest rate below our incremental borrowing rate represented the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset, with the offset to deferred revenue, on our balance sheet in 2008. We began amortizing this asset to interest expense over the life of the loan arrangement, or 10 years, on April 1, 2009. We recorded approximately \$1.6 million, \$1.7 million and \$1.3 million of related amortization expense in the years ended December 31, 2011, 2010 and 2009, respectively. Upon drawing down the \$50 million under the line of credit agreement, we reclassified the loan commitment asset as a debt discount which reduced the debt on our balance sheet. We are recording interest on the net amount borrowed using the effective interest method. We recorded \$0.3 million of related interest expense in the year ended December 31, 2011 subsequent to the borrowing in November 2011 using an effective interest rate of 7.29%. We will owe approximately \$63.4 million in interest and principal at the maturity date, assuming the prime rate of interest remains at 3.25%.

We recorded an aggregate of \$59.3 million in deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue, which consisted of the excess of the amount paid for the purchased shares over the closing market price on the day before the equity closings and the value of the loan commitment asset. We determined that the rights and licenses did not have stand-alone value, and we considered all of the obligations under the arrangement to be a single unit of accounting. There is no obligation for us to repay the \$59.3 million, and we are recognizing this deferred revenue ratably over 14 years, which is our estimated period of performance under the arrangement. We periodically review this estimate and may make adjustments as facts and circumstances dictate. We recognized \$4.3 million in such revenue in each of the years ended December 31, 2011, 2010 and 2009.

**Millennium.** In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. We paid Millennium a \$13.5 million up-front license fee. The entirety of this fee was included as research and development expense in the year ended December 31, 2010, although \$8.5 million of this fee was paid in January 2011. In addition to developing IPI-145, we are seeking to identify additional novel delta, gamma and dual delta/gamma-specific inhibitors of PI3K for future development. We are obligated to pay up to \$25 million in success-based milestones for the development of two distinct product candidates, and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. In addition, we are obligated to pay Millennium tiered royalties on net sales ranging from single digits to low teens upon successful commercialization of products licensed to us, which are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction in certain circumstances. During 2011, we paid Millennium \$4.0 million in milestone payments associated with the initiation of two Phase 1 studies of IPI-145, which we recorded as research and development expense during the year.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. For a product in which the first

---

## **Table of Contents**

Phase 2 clinical trial conducted is in an oncology indication, which we refer to as an oncology product., Millennium will have the option, at the end of Phase 2 clinical development and upon payment of an option fee, to convert its royalty interest in U.S. sales into the right to share in 50% of profits and losses on U.S. development and commercialization, and to participate in up to 30% of the detailing effort for these products in the United States. Mundipharma, pursuant to its strategic alliance agreement with us, has commercialization rights outside the United States for products arising out of our PI3K inhibitor program.

Millennium may terminate its participation rights in any oncology product with 12 months' prior written notice to us, after which Millennium's participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Millennium would not be entitled to receive royalty payments for net sales occurring prior to the termination date and certain specified milestone payments.

Other than pursuant to the agreement, neither we nor Millennium may research, develop or commercialize products directed to the delta and/or gamma isoforms of PI3K which meet certain selectivity criteria, except that Millennium may research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

The agreement expires when the parties have no further obligations to each other thereunder, unless earlier terminated. Either party may terminate the agreement on 75 days' prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Additionally, Millennium may terminate the agreement upon 30 days' prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days' prior written notice provided after the end of the research term that is currently set to expire in July 2013.

## **Financial Overview**

### ***Revenue***

All of our revenue to date has been derived from license fees, the reimbursement of research and development costs, contract service revenue and milestones payments received from our collaboration partners. License fees are recognized as revenue ratably over the expected research and development period under our arrangement with Mundipharma and Purdue. Because our agreements with Mundipharma and Purdue also provide for funding for our research and development efforts, we recognize this cost reimbursement as revenue in the period earned in proportion to our forecasted total expenses as compared to the total research funding budget for the year. In the future, we may generate revenue from a combination of product sales, research and development support services and milestone payments in connection with strategic relationships, and royalties resulting from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from year to year as a result of the timing and amount of license fees, research and development reimbursement, milestone and other payments earned under our collaborative or strategic relationships, and the amount and timing of payments that we earn upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our financial statements, would be materially adversely affected.

### ***Research and Development Expense***

We are a drug discovery and development company. Our research and development expense primarily consists of the following:

compensation of personnel associated with research activities;

clinical testing costs, including payments made to contract research organizations;



## **Table of Contents**

costs of purchasing laboratory supplies and materials;

costs of manufacturing drug candidates for preclinical testing and clinical studies;

costs associated with the licensing of research and development programs;

preclinical testing costs, including costs of toxicology studies;

fees paid to external consultants;

fees paid to professional service providers for independent monitoring and analysis of our clinical trials;

costs for collaboration partners to perform research activities, including development milestones for which a payment is due when achieved;

depreciation of equipment; and

allocated costs of facilities.

### ***General and Administrative Expense***

General and administrative expense primarily consists of compensation of personnel in executive, finance, accounting, legal, information technology infrastructure, corporate communications, corporate development, human resources and commercial functions. Other costs include facilities costs not otherwise included in research and development expense, and professional fees for legal and accounting services. General and administrative expense also consists of the costs of maintaining our intellectual property portfolio.

### ***Other Income and Expense***

Interest expense and other interest and investment income typically consists of interest earned on cash, cash equivalents and available-for-sale securities, net of interest expense, and amortization of warrants. Interest expense includes amortization of the loan commitment asset from Purdue entities, net, from April 2009 through November 2011 when we drew down the full \$50 million loan available under the line of credit agreement. Interest expense also includes accrued interest on the loan, including amortization of the debt discount.

### **Critical Accounting Policies and Significant Judgments and Estimates**

The following discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates. Differences between actual and estimated results have not been material and are adjusted in the period they become known. We believe that the following accounting policies and estimates are most critical to aid you in understanding and evaluating our reported financial results. Please refer to note 2 to our consolidated financial statements for a description of our significant accounting policies.

### ***Revenue Recognition***

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. On January 1, 2011, we adopted on a prospective basis a newly issued accounting standard related to multiple-deliverable revenue arrangements. We will apply this standard to new

## **Table of Contents**

revenue arrangements or material modifications of existing revenue arrangements. This standard eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon our best estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item was the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item was sold separately by the vendor.

Under our strategic alliance with Mundipharma and Purdue, we recognize revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is the research or development term. We regularly consider whether events warrant a change in the estimated period of performance under an agreement. Such a change would cause us to modify the period of time over which we recognize revenue from the up-front license fee on a prospective basis and would, in turn, result in changes in our quarterly and annual results. We recognize research and development funding as earned over the period of effort as related research costs are incurred in proportion to our forecasted total expenses as compared to the total research funding budget for the year. We recognize the impact of any change in forecasted total expenses as a change in accounting estimate.

On January 1, 2011, we adopted on a prospective basis a newly issued accounting standard related to the milestone method of revenue recognition. We will apply this standard to new revenue arrangements or material modifications to existing revenue arrangements. At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether;

the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone,

the consideration relates solely to past performance, and

the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

We evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. We recognize revenues related to substantive milestones in full in the period in which the substantive milestone is achieved. If a milestone payment is not considered substantive, we recognize the applicable milestone over the remaining period of performance. Our strategic alliance with Mundipharma and Purdue does not include potential milestone payments.

We will recognize royalty revenue, if any, based upon actual and estimated net sales by the licensee of licensed products in licensed territories, and in the period the sales occur. We have not recognized any royalty revenue to date.

### ***Research and Development Expense***

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, facilities expenses, overhead expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. We also include as research and development expense up-front license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. We are party to collaboration agreements in which we are reimbursed for work performed on behalf of

---

**Table of Contents**

the collaborator, as well as one in which we reimburse the collaborator for work it has performed. We record all appropriate expenses under our collaborations as research and development expense. If the arrangement provides for reimbursement of research and development expenses, as is the case with our alliance with Mundipharma and Purdue, we record the reimbursement as revenue. If the arrangement provides for us to reimburse the collaborator for research and development expenses or achieving a development milestone for which a payment is due, as is the case with our agreement with Millennium, we record the reimbursement or the achievement of the development milestone as research and development expense.

***Accrued Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date. Examples of services for which we must estimate accrued expenses include contract service fees paid to contract manufacturers in conjunction with pharmaceutical development work and to contract research organizations in connection with clinical trials and preclinical studies. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided. The majority of our service providers invoice us in arrears for services performed. In the event that we do not identify certain costs that have been incurred by our service providers, or if we over- or under-estimate the level of services performed or the costs of such services in any given period, our reported expenses for such period would be too low or too high. We often rely on subjective judgments to determine the date on which certain services commence, the level of services performed on or before a given date, and the cost of such services. We make these judgments based upon the facts and circumstances known to us. Our estimates of expenses in future periods may be over- or under-accrued.

***Stock-Based Compensation***

We expense the fair value of employee stock options and other equity compensation. We use our judgment in determining the fair value of our equity instruments, including in selecting the inputs we use for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any significant changes in any of our judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted and the associated compensation charge we record in our financial statements.

***Fair Value Measurements***

We define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions. We value our available-for-sale securities utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including benchmark yields, reportable trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, reference data, new issue data, monthly payment information and collateral performance. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and confirming those securities trade in active markets.

***New Accounting Pronouncements***

In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2011-05, *Comprehensive Income*, or ASU No. 2011-05, which will require companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The update does not change the items which

**Table of Contents**

must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. ASU No. 2011-05 is effective for interim and annual periods beginning after December 15, 2011. In December 2011, the FASB issued Accounting Standard Update No. 2011-12, *Comprehensive Income* ( ASU No. 2011-12 ), which deferred the adoption of changes related to the presentation of reclassification adjustments. Because this update only requires enhanced disclosure, the adoption of ASU No. 2011-05 and ASU No. 2011-12 will not impact our financial position or results of operations.

**Results of Operations**

The following table summarizes our results of operations for the years ended December 31, 2011, 2010 and 2009, in thousands, together with the change in each item as a percentage.

	2011	% Change	2010	% Change	2009
Revenue	\$ 92,773	30%	\$ 71,331	41%	\$ 50,765
Research and development expense	(108,582)	9%	(99,231)	27%	(77,857)
General and administrative expense	(22,719)	8%	(21,070)	8%	(19,456)
Interest expense	(1,841)	(4)%	(1,910)	47%	(1,300)
Interest and investment income	327	(29)%	463	(77)%	2,044
Income from Therapeutic Discovery Grants		(100)%	733		
Income from NIH reimbursement				(100)%	1,745
Income from residual funding after reacquisition of Hsp90 program				(100)%	12,450
Income tax benefit		(100)%	700	112%	330
<i>Revenue</i>					

Our revenue during the year ended December 31, 2011 consisted of approximately:

\$88.5 million related to reimbursed research and development services we performed under our strategic alliance entered into with Mundipharma and Purdue in November 2008, which includes \$3.5 million related to the transition of our FAAH program to Mundipharma and Purdue; and

\$4.3 million related to the amortization of the deferred revenue associated with the grant of rights and licenses under our strategic alliance with Mundipharma and Purdue.

Our revenue during the year ended December 31, 2010 consisted of approximately:

\$67.0 million related to reimbursed research and development services we performed under our strategic alliance with Mundipharma and Purdue, which includes \$2.0 million related to the transition of our FAAH program to Mundipharma and Purdue; and

\$4.3 million related to the amortization of the deferred revenue associated with the grant of rights and licenses under our strategic alliance with Mundipharma and Purdue.

Our revenue during the year ended December 31, 2009 consisted of approximately:

\$46.5 million related to reimbursed research and development services we performed under our strategic alliance with Mundipharma and Purdue; and

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

\$4.3 million related to the amortization of the deferred revenue associated with the grant of rights and licenses under our strategic alliance with Mundipharma and Purdue.

In the absence of any business development activities that generate revenue, we currently expect that all of our revenue in 2012 will be derived from reimbursed research and development services and amortization of deferred revenue under our alliance with Purdue and Mundipharma.

**Table of Contents**

*Research and Development Expense*

Research and development expenses represented approximately 83% of our total operating expenses for the year ended December 31, 2011, 82% of our total operating expenses for the year ended December 31, 2010, and 80% of our total operating expenses for the year ended December 31, 2009.

The increase in research and development expense for the year ended December 31, 2011 compared to the year ended December 31, 2010 was primarily attributable to:

an increase of \$10.3 million in clinical expenses, an increase of \$4.6 million in pharmaceutical development expenses and an increase in \$2.9 million in consulting expenses as our Hedgehog and PI3K programs have advanced; and

\$4.0 million associated with the achievement of milestones for the initiation of two Phase 1 clinical trials in our PI3K program. These increases were partially offset by an upfront fee of \$13.5 million to license- our PI3K program, which was recorded as research and development expense during the year ended December 31, 2010.

The increase in research and development expense for the year ended December 31, 2010 compared to the year ended December 31, 2009 was primarily attributable to:

the \$13.5 million upfront fee to license our PI3K program and \$1.2 million of related reimbursement for research and development services performed by Millennium;

an increase of \$2.8 million in compensation and benefits, which was primarily driven by annual base salary increases and an increase in our contingent cash compensation program;

an increase of \$2.7 million in clinical expenses associated with advancement of our Hedgehog and FAAH programs; and

an increase of \$1.2 million in consulting expenses primarily related to our Hedgehog and FAAH programs.

We began to track and accumulate costs by major program starting on January 1, 2006. The following table sets forth our estimates of research and development expenses, by program, over the last three years and cumulatively from January 1, 2006 to December 31, 2011. These expenses primarily relate to payroll and related expenses for personnel working on the programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. From August 2006 through December 2008, our Hsp90 inhibitor program was conducted in collaboration with MedImmune, a division of AstraZeneca plc, or MedImmune, and from August 2006 through November 2007, our Hedgehog pathway inhibitor program was conducted in collaboration with MedImmune. Under this collaboration, we shared research and development expenses equally with MedImmune. Pursuant to our cost-sharing arrangement, reimbursable amounts from MedImmune were credited to research and development expense, and the expenses for the Hsp90 inhibitor and Hedgehog pathway inhibitor programs below include credits of approximately \$34.4 million in years prior to 2009.

(Dollars in Millions)

Program	Year Ended December 31, 2011	Year Ended December 31, 2010	Year Ended December 31, 2009	January 1, 2006 to December 31, 2011
Hedgehog pathway inhibitor	\$ 48.4	\$ 33.4	\$ 22.8	\$ 128.7
Hsp90 chaperone inhibitor	15.2	13.9	32.7	102.7
FAAH inhibitor	2.9	18.7	9.4	31.0

Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

PI3K Inhibitor(1)	23.5	18.0	41.5
-------------------	------	------	------

(1) Includes an upfront license fee of \$13.5 million in 2010 and \$4.0 million in development milestones in 2011.



**Table of Contents**

We expect expenses for our clinical development to increase if our programs successfully advance. We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these programs nor represent what any other future drug development program we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a drug candidate and uncertainties related to cost estimates and our ability to obtain marketing approval for our drug candidates, accurate and meaningful estimates of the total costs required to bring our product candidates to market are not available.

Because of the risks inherent in drug discovery and development, we cannot reasonably estimate or know:

the nature, timing and estimated costs of the efforts necessary to complete the development of our programs;

the anticipated completion dates of these programs; or

the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future product candidates.

There is significant uncertainty regarding our ability to successfully develop any drug candidates. These risks include the uncertainty of:

the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future;

the scope and rate of progress of our preclinical studies and other research and development activities;

clinical trial results;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;

the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our programs under development;

the cost and timing of regulatory approvals;

the cost of establishing clinical supplies of any product candidates; and

the effect of competing technological and market developments.

*General and Administrative Expense*

The increase in general and administrative expense for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was primarily attributable to:

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

an increase of \$1.8 million in consulting expenses, principally related to early commercial development and corporate development activities; and

an increase of \$1.0 million in patent expenses.

These increases were partially offset by a decrease of \$1.5 million in compensation and benefits, including stock-based compensation expense for general and administrative employees, which is primarily related to the transition of our executive chair to a non-employee position during 2010.

The increase in general and administrative expense for the year ended December 31, 2010 as compared to the year ended December 31, 2009 was primarily attributable to:

an increase of \$2.0 million in compensation and benefits, including stock-based compensation expense for general and administrative employees, which was primarily driven by an increase in accrued amounts under our contingent cash compensation program as well as stock-based compensation expense related to the transition of our executive chair to a non-employee position; and

## **Table of Contents**

an increase of \$0.6 million in patent expenses, principally related to the addition of our PI3K program. These increases were partially offset by a decrease of \$1.2 million in consulting expenses, principally related to a decrease in early commercial development activities.

### *Interest Expense*

Interest expense increased for the years ended December 31, 2011 and 2010 compared to the year ended December 31, 2009 primarily as a result of amortizing the loan commitment asset from Purdue. We expect interest expense in 2012 to be higher than in 2011 primarily due to our draw down of all available amounts under the \$50.0 million line of credit from Purdue during November 2011.

### *Interest and Investment Income*

Interest and investment income decreased in the years ended December 31, 2011 and 2010 as compared to the year ended December 31, 2009 primarily as a result of lower yields on our cash equivalents and available-for-sale securities. We expect interest and investment income in 2012 to be comparable to 2011.

### *Income from Therapeutic Discovery Grants*

During the year ended December 31, 2010, we received tax grants aggregating \$0.7 million under the U.S. Government's Qualifying Therapeutic Discovery Project program for qualified expenses related to our Hedgehog, Hsp90 and FAAH programs.

### *Income from NIH Reimbursement*

During the year ended December 31, 2009, we received \$1.7 million from the National Institutes of Health, or NIH, relating to contract work performed by Discovery Partners International, Inc. from August 2004 through June 2006. We do not expect any such income in future periods.

### *Income from Residual Funding of Hsp90 Program*

In December 2008, we regained from MedImmune worldwide development and commercialization rights under our Hsp90 inhibitor program. Following reacquisition of the Hsp90 program, MedImmune remained obligated to fund an amount equivalent to its share of the Hsp90 program costs for the ensuing six-month period. In January 2009, we agreed with MedImmune to settle the residual funding obligations through lump sum payments totaling \$12.5 million, which we recorded as income from residual funding after reacquisition of Hsp90 program in the year ended December 31, 2009.

### *Income Tax Benefit*

During the year ended December 31, 2010, we recorded an income tax benefit of \$0.7 million because an uncertain tax position we took in a prior year was no longer subject to examination due to the expiration of the statute of limitations. We realized an income tax benefit of approximately \$0.3 million for the year ended December 31, 2009 primarily due to the Worker, Homeownership, and Business Assistance Act of 2009. This law contains a provision that permits companies to carry back certain 2009 or 2008 net operating losses for a period of up to five years and receive a benefit for prior tax expense.

## **Liquidity and Capital Resources**

We have not generated any revenue from the sale of drugs to date, and we do not expect to generate any such revenue for the next several years, if at all. We have instead relied on the proceeds from sales of equity securities, interest on investments, license fees, expense reimbursement under our collaborations, milestone

**Table of Contents**

payments, contract service payments and debt to fund our operations. Our available-for-sale debt securities primarily trade in liquid markets, and the average days to maturity of our portfolio, as of December 31, 2011, is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our significant capital resources are as follows (in thousands):

	December 31, 2011	December 31, 2010
Cash, cash equivalents and available-for-sale securities including long term	\$ 115,937	\$ 100,959
Working capital	88,995	75,378

	Years ended December 31,		
	2011	2010	2009
Cash (used in) provided by:			
Operating activities	\$ (33,109)	\$ (26,585)	\$ (4,757)
Investing activities	(13,688)	30,480	(7,496)
Capital expenditures (included in investing activities above)	(1,542)	(1,949)	(2,528)
Financing activities	50,577	235	11,966

**Cash Flows**

The principal use of cash in operating activities in all periods presented was our net spending on our research and development programs: that is, investments in research and development that are not reimbursed by our strategic alliance partners. Currently, spending on all of our research and development programs other than our Hsp90 program is reimbursed by Purdue and Mundipharma up to contractually specified annual caps, which were \$85 million in 2011 and \$65 million in 2010. We exceeded the contractually budgeted amount for both 2011 and 2010 due primarily to advancement in our Hedgehog and PI3K programs. Other than the income from residual funding of \$12.5 million in 2009, we have not been reimbursed for any of our investments in the Hsp90 program since we reacquired the program from MedImmune in December 2008. During the year ended December 31, 2010, we recorded \$13.5 million in research and development expense related to the up-front license fee for our PI3K program. During the year ended December 31, 2010, we paid \$5 million of this \$13.5 million fee and recorded the remaining \$8.5 million in accrued liabilities. We paid the remaining \$8.5 million license fee during the year ended December 31, 2011. Our cash used in operating activities for the year ended December 31, 2011 included a decrease in deferred revenue primarily due to the amortization of \$4.3 million to license revenue. Cash flows from operations in future periods can vary significantly due to the level of research and development reimbursement or future collaboration arrangements.

In November 2008, we entered into a strategic alliance with Mundipharma and Purdue and issued four million shares of our common stock to Purdue and one of its independent associated companies for cash proceeds of \$45.0 million. Of this amount, the shares were recorded at \$21.2 million, which represents the fair market value of our issued common stock and recorded in our cash flows from financing activities, and \$23.8 million was accounted for as an up-front license fee in deferred revenue and recorded in our cash flows from operating activities. During January 2009, we issued to Purdue and one of its independent associated companies an aggregate of two million shares of our common stock and warrants to purchase up to six million shares of our common stock for cash proceeds of \$30.0 million. These securities were recorded at their fair value of \$11.8 million and reflected as cash flows from financing activities. The balance of \$18.2 million was accounted for as an up-front license fee in deferred revenue and recorded in our cash flows from operating activities. During the year ended December 31, 2009, we collected all of our unbilled receivables from Mundipharma, Purdue and MedImmune.

---

**Table of Contents**

Our investing activities for the years ended December 31, 2011, 2010 and 2009 included the purchase of and proceeds from maturities and sales of available-for-sale securities and purchases of property and equipment. Our investing activities for the year ended December 31, 2011 included \$150.6 million in purchases of available-for-sale securities, proceeds of \$137.2 million from maturities of available-for-sale securities and proceeds of \$1.3 million from sales of available-for-sale securities. Capital expenditures for the year ended December 31, 2011 of \$1.5 million primarily consisted of laboratory equipment and software.

Our financing activities for the year ended December 31, 2011 includes borrowings of \$50.0 million on the line of credit made available to us by PPLP on attractive terms. The loan matures on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. The loan bears interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and is on the last business day of each month ending thereafter. Interest is compounded on each successive three-month anniversary of the funding of the loan. The loan may be prepaid without penalty or premium prior to the maturity date; however, any prepayments made cannot be re-borrowed. We have certain rights to repay borrowed amounts in shares of our common stock as a share-settled obligation.

We will need substantial additional funds to support our planned operations. We are entitled to receive up to \$110.0 million and \$147.5 million in research and development funding under our strategic alliance with Mundipharma for the years ended December 31, 2012 and 2013, respectively. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments, together with research and development funding from Mundipharma are sufficient to fund our planned operations into 2014. We may, however, need to raise additional funds before that date if our research and development expenses exceed our current expectations, if we do not receive the payments we expect to receive from Mundipharma and Purdue, if we acquire a third party or if we acquire or license rights to additional drug candidates or new technologies from one or more third parties. We may need to raise additional funds for other reasons, including if:

our drug candidates require more extensive clinical or preclinical testing than we currently expect;

we advance more of our drug candidates than expected into costly later stage clinical trials;

we advance more preclinical drug candidates than expected into early stage clinical trials;

the cost of acquiring raw materials for, and of manufacturing, our drug candidates is higher than anticipated;

we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties;

Mundipharma or Purdue elects to discontinue its participation in a partnered program; or

we experience a loss in our investments due to general market conditions or other reasons.

We may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, or at all, particularly in light of current market conditions. In addition, the terms of our financings may be dilutive to, or otherwise adversely affect, holders of our common stock, and such terms may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or drug candidates, and we may not be able to enter into such agreements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our product development programs.



**Table of Contents****Contractual Obligations**

As of December 31, 2011, we had the following contractual obligations, excluding contingent milestone payments:

Contractual Obligations	Total	Payments Due by Period (in thousands)					2017 and beyond
		2012	2013	2014	2015	2016	
Long-term debt, including interest(1)	\$ 63,409	\$	\$	\$	\$	\$	\$ 63,409
Software contract obligation	60	30	30				
Operating lease obligations	19,500	5,214	4,585	4,671	4,632	398	
Total contractual cash obligations	\$ 82,969	\$ 5,244	\$ 4,615	\$ 4,671	\$ 4,632	\$ 398	\$ 63,409

(1) As of December 31, 2011, the prime rate was 3.25%. The principal amount is \$50 million.

The above table does not include contracts with contract research organizations as they are generally cancellable, with notice, at our option. In addition, we have obligations to make milestone payments under our license agreement with Millennium. For a description of these obligations, please see our description of our license agreement with Millennium under the heading Strategic Alliances Millennium above.

**Off-Balance Sheet Arrangements**

Since inception, we have not engaged in any off-balance sheet financing activities, including the use of structured finance, special purpose entities or variable interest entities.

**Inflation**

We do not believe that inflation has had a significant impact on our revenues or results of operations since inception.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since a significant portion of our investments are in money market funds, corporate obligations, and U.S. government-sponsored enterprise obligations. We do not enter into investments for trading or speculative purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase.

A hypothetical 100 basis point increase in interest rates would result in an approximate \$762,000 decrease in the fair value of our investments as of December 31, 2011, as compared to an approximate \$467,000 decrease as of December 31, 2010. We have the ability to hold our fixed income investments until maturity and, therefore, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Our long-term debt bears interest at a fluctuating rate equal to the prime rate, reset each month. At the time of the borrowing, prime rate was 3.25%. A hypothetical 1% increase in the prime rate on the outstanding debt amount as of December 31, 2011 would result in an increase in interest expense of approximately \$400,000 over the next twelve month period.

**Table of Contents**

**Item 8. Financial Statements and Supplementary Data**  
**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Infinity Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Infinity Pharmaceuticals, Inc. as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. 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 evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Infinity Pharmaceuticals, Inc. at December 31, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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), the effectiveness of Infinity Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011, 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 13, 2012 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 13, 2012



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Balance Sheets**

	December 31,	
	2011	2010
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 24,196,974	\$ 20,416,997
Available-for-sale securities	91,080,819	79,804,921
Unbilled accounts receivable from Purdue entities	218,193	
Prepaid expenses and other current assets	2,484,309	2,907,057
<b>Total current assets</b>	<b>117,980,295</b>	<b>103,128,975</b>
Property and equipment, net	4,581,928	5,147,545
Loan commitment asset from Purdue entities, net		14,288,175
Long-term available-for-sale securities	659,179	736,739
Restricted cash	1,125,388	1,122,633
Other assets	143,279	141,855
<b>Total assets</b>	<b>\$ 124,490,069</b>	<b>\$ 124,565,922</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 5,951,759	\$ 2,606,303
Accrued expenses	18,819,167	20,363,884
Deferred revenue from Purdue entities	4,214,703	4,780,418
<b>Total current liabilities</b>	<b>28,985,629</b>	<b>27,750,605</b>
Long-term debt due to Purdue entities, net of debt discount	37,552,795	
Deferred revenue from Purdue entities, less current portion	42,147,045	46,361,745
Other liabilities	371,144	970,057
<b>Total liabilities</b>	<b>109,056,613</b>	<b>75,082,407</b>
Commitments and contingencies (note 10)		
<b>Stockholders equity:</b>		
Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2011 and 2010		
Common Stock, \$.001 par value; 100,000,000 shares authorized, and 26,721,739 and 26,519,217 shares issued and outstanding, at December 31, 2011 and December 31, 2010, respectively	26,722	26,519
Additional paid-in capital	284,435,973	278,412,580
Accumulated deficit	(269,051,664)	(229,009,563)
Accumulated other comprehensive income	22,425	53,979
<b>Total stockholders equity</b>	<b>15,433,456</b>	<b>49,483,515</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 124,490,069</b>	<b>\$ 124,565,922</b>

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Operations**

	Years Ended December 31,		
	2011	2010	2009
Collaborative research and development revenue from Purdue entities	\$ 92,773,162	\$ 71,330,987	\$ 50,765,462
Operating expenses:			
Research and development	108,582,411	99,231,414	77,856,836
General and administrative	22,718,634	21,070,279	19,456,341
Total operating expenses	131,301,045	120,301,693	97,313,177
Loss from operations	(38,527,883)	(48,970,706)	(46,547,715)
Other income (expense):			
Interest expense	(1,840,970)	(1,909,726)	(1,300,184)
Income from NIH reimbursement			1,745,386
Income from residual funding after reacquisition of Hsp90 program			12,450,000
Income from Therapeutic Discovery Grants		733,438	
Interest and investment income	326,752	463,014	2,044,430
Total other income (expense)	(1,514,218)	(713,274)	14,939,632
Loss before income taxes	(40,042,101)	(49,683,980)	(31,608,083)
Income tax benefit		700,321	329,566
Net loss	\$ (40,042,101)	\$ (48,983,659)	\$ (31,278,517)
Basic and diluted loss per common share	\$ (1.50)	\$ (1.86)	\$ (1.20)
Basic and diluted weighted average number of common shares outstanding	26,620,278	26,321,398	26,096,515

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2011	2010	2009
<b>Operating activities</b>			
Net loss	\$ (40,042,101)	\$ (48,983,659)	\$ (31,278,517)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	2,099,116	2,183,997	2,153,916
Stock-based compensation including 401(k) match	5,441,593	7,883,519	7,037,253
Gain on sale and disposals of property and equipment			(79,256)
Gain on sale of available-for-sale securities			(28,051)
Amortization of debt discount from long-term debt due to Purdue entities	102,062		
Amortization of loan commitment asset from Purdue entities	1,587,575	1,731,900	1,298,925
Net amortization of available-for-sale securities	915,197	1,496,004	129,973
Impairment of available-for-sale securities			15,666
Impairment of property and equipment		311,200	
Other, net	71,731	79,653	60,196
Changes in operating assets and liabilities:			
Unbilled accounts receivable	(218,193)		7,414,570
Prepaid expenses and other assets	355,832	599,134	(1,075,479)
Accounts payable, accrued expenses and other liabilities	1,358,648	11,761,744	(4,380,234)
Deferred revenue	(4,780,415)	(3,648,542)	13,974,116
Net cash used in operating activities	(33,108,955)	(26,585,050)	(4,756,922)
<b>Investing activities</b>			
Purchases of property and equipment	(1,542,113)	(1,948,592)	(2,527,627)
Proceeds from sale of property and equipment			79,256
Purchases of available-for-sale securities	(150,587,364)	(201,094,734)	(166,565,338)
Proceeds from maturities of available-for-sale securities	137,152,907	226,283,903	125,375,803
Proceeds from sales of available-for-sale securities	1,288,988	7,239,262	36,141,736
Net cash provided by (used in) investing activities	(13,687,582)	30,479,839	(7,496,170)

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Cash Flows (Continued)**

	Years Ended December 31,		
	2011	2010	2009
<b>Financing activities</b>			
Borrowings of long-term debt from Purdue entities	\$ 50,000,000	\$	\$
Proceeds from issuance of common stock to Purdue entities			11,830,000
Proceeds from issuances of common stock related to stock incentive plans	582,003	224,796	201,726
Release of restricted cash		26,642	
Capital lease payments	(5,489)	(6,459)	(5,954)
New employee loans		(10,000)	(60,000)
Net cash provided by financing activities	50,576,514	234,979	11,965,772
Net increase (decrease) in cash and cash equivalents	3,779,977	4,129,768	(287,320)
Cash and cash equivalents at beginning of period	20,416,997	16,287,229	16,574,549
Cash and cash equivalents at end of period	\$ 24,196,974	\$ 20,416,997	\$ 16,287,229
<b>Supplemental cash flow disclosure</b>			
Income taxes paid	\$	\$	\$ 75,000

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Stockholders Equity**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount				
Balance at December 31, 2008	24,064,857	\$ 24,065	\$ 251,128,955	\$ (148,747,387)	\$ 715,356	\$ 103,120,989
Exercise of stock options	101,384	101	201,625			201,726
Issuance of common stock to Purdue entities	2,000,000	2,000	10,578,000			10,580,000
Restricted stock issued that vested in the year			78,416			78,416
Stock-based compensation expense			6,506,680			6,506,680
401(k) plan match issued in common stock	72,713	73	530,500			530,573
Issuance of warrants to Purdue entities			1,250,000			1,250,000
Comprehensive loss:						
Unrealized loss on marketable securities					(678,065)	(678,065)
Net loss				(31,278,517)		(31,278,517)
Comprehensive loss						(31,956,582)
Balance at December 31, 2009	26,238,954	\$ 26,239	\$ 270,274,176	\$ (180,025,904)	\$ 37,291	\$ 90,311,802
Exercise of stock options	85,406	85	224,711			224,796
Issuance of common stock to executive chair	100,000	100	587,900			588,000
Repurchase and retirement of common stock	(966)	(1)				(1)
Restricted stock issued that vested in the year			30,370			30,370
Stock-based compensation expense			6,731,142			6,731,142
401(k) plan match issued in common stock	95,823	96	564,281			564,377
Comprehensive loss:						
Unrealized gain on marketable securities					16,688	16,688
Net loss				(48,983,659)		(48,983,659)
Comprehensive loss						(48,966,971)
Balance at December 31, 2010	26,519,217	\$ 26,519	\$ 278,412,580	\$ (229,009,563)	\$ 53,979	\$ 49,483,515

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Consolidated Statements of Stockholders Equity (Continued)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount				
Balance at December 31, 2010	26,519,217	\$ 26,519	\$ 278,412,580	\$ (229,009,563)	\$ 53,979	\$ 49,483,515
Exercise of stock options	114,815	115	581,888			582,003
Stock-based compensation expense			4,846,955			4,846,955
401(k) plan match issued in common stock	87,707	88	594,550			594,638
Comprehensive loss:						
Unrealized loss on marketable securities					(31,554)	(31,554)
Net loss				(40,042,101)		(40,042,101)
Comprehensive loss						(40,073,655)
Balance at December 31, 2011	26,721,739	\$ 26,722	\$ 284,435,973	\$ (269,051,664)	\$ 22,425	\$ 15,433,456

*The accompanying notes are an integral part of these consolidated financial statements.*

## **Table of Contents**

### **INFINITY PHARMACEUTICALS, INC.**

#### **Notes to Consolidated Financial Statements**

##### **1. Organization**

Infinity Pharmaceuticals, Inc. is an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines for difficult to treat diseases. As used throughout these consolidated financial statements, the terms Infinity, we, us, and our refer to the business of Infinity Pharmaceuticals, Inc. and its wholly owned subsidiary.

##### **2. Summary of Significant Accounting Policies**

###### **Basis of Presentation**

These consolidated financial statements include the accounts of Infinity and its wholly owned subsidiary. We have eliminated all significant intercompany accounts and transactions in consolidation.

The preparation of consolidated financial statements in accordance with generally accepted accounting principles requires our management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

###### **Reclassifications**

Certain amounts in the prior years' financial statements have been reclassified to conform with the current-year presentation. These reclassifications have no impact on previously reported net income, net loss or cash flows.

###### **Cash Equivalents and Available-For-Sale Securities**

Cash equivalents and available-for-sale securities primarily consist of money market funds, U.S. government-sponsored enterprise obligations, corporate obligations and mortgage-backed securities. Corporate obligations include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist of money market funds, are stated at fair value. They are also readily convertible to known amounts of cash and close enough to maturity that each presents insignificant risk of change in value due to changes in interest rates. Our classification of cash equivalents is consistent with prior periods.

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities at December 31, 2011 and 2010 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders' equity.

We adjust the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. We include such amortization and accretion in interest and investment income. The cost of securities sold is based on the specific identification method. We include interest and dividends on securities classified as available-for-sale in interest and investment income.

## **Table of Contents**

We conduct periodic reviews to identify and evaluate each investment that is in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income (loss).

For available-for-sale debt securities in an unrealized loss position, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss.

Regardless of our intent to sell a security, we perform additional analysis on all securities in an unrealized loss position to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security and are recorded within earnings as an impairment loss.

## **Concentration of Risk**

We have no significant off-balance sheet risk.

Cash and cash equivalents are primarily maintained with two major financial institutions in the United States. Deposits at banks may exceed the insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Financial instruments that potentially subject us to concentration of credit risk primarily consist of available-for-sale securities. Available-for-sale securities consist of U.S. government-sponsored enterprise obligations, investment grade corporate obligations and mortgage-backed securities. Our investment policy, which has been approved by our board of directors, limits the amount that we may invest in one issuer of investments, thereby reducing credit risk concentrations.

## **Segment Information**

We make operating decisions based upon performance of the enterprise as a whole and utilize our consolidated financial statements for decision making. We operate in one business segment, which focuses on drug discovery and development.

All of our revenues to date have been generated under research collaboration agreements. Revenue associated with the amortization of the deferred revenue associated with the grant of rights and licenses to, and reimbursed research and development services provided for, Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, accounted for all of our revenue during the years ended December 31, 2011, 2010 and 2009. Payments due from Mundipharma and Purdue represented our entire unbilled accounts receivable balance at December 31, 2011. We consider Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes because of their equity ownership (see note 11).



**Table of Contents****Property and Equipment**

Property and equipment are stated at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Application development costs incurred for computer software developed or obtained for internal use are capitalized. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective account and the resulting gain or loss, if any, is included in current operations. Amortization of leasehold improvements and capital leases are included in depreciation expense. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

Laboratory equipment	5 years
Computer equipment and software	3 to 5 years
Leasehold improvements	Shorter of lease term or useful life of asset
Furniture and fixtures	7 years

**Impairment of Long-Lived Assets**

We evaluate our long-lived assets for potential impairment. Potential impairment is assessed when there is evidence that events or changes in circumstances have occurred that indicate that the carrying amount of a long-lived asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends, and product development cycles. An impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows, including its eventual residual value, derived from the asset are less than its carrying value. Impairments, if any, are recognized in earnings. An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows. See note 6 for discussion on impairment charges recognized during the periods presented.

**Fair Value Measurements**

We define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

We value our available-for-sale securities utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including benchmark yields, reportable trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, reference data, new issue data, monthly payment information and collateral performance. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and confirming those securities trade in active markets.

**Revenue Recognition**

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. On January 1, 2011, we adopted on a prospective basis a newly issued accounting standard related to multiple-deliverable revenue arrangements. We will apply this standard to new revenue arrangements or material modifications of existing revenue arrangements. This standard eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon our best estimate of the selling price for an undelivered item when there is no

## **Table of Contents**

other means to determine the fair value of that undelivered item. Previous accounting principles required that the fair value of the undelivered item was the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item was sold separately by the vendor.

Under our strategic alliance with Mundipharma and Purdue, we recognize revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which is the research and development term. We regularly consider whether events warrant a change in the estimated period of performance under an agreement. Such a change would cause us to modify the period of time over which we recognize revenue from the up-front license fee on a prospective basis and would, in turn, result in changes in our quarterly and annual results. We recognize research and development funding as earned over the period of effort as related research costs are incurred in proportion to our forecasted total expenses as compared to the total research funding budget for the year. We recognize the impact of any change in forecasted total expenses as a change in accounting estimate.

On January 1, 2011, we adopted on a prospective basis a newly issued accounting standard related to the milestone method of revenue recognition. We will apply this standard to new revenue arrangements or material modifications to existing revenue arrangements. At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether:

the consideration is commensurate with either (1) our performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone,

the consideration relates solely to past performance, and

the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

We evaluate factors such as the clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. We recognize revenues related to substantive milestones in full in the period in which the substantive milestone is achieved. If a milestone payment is not considered substantive, we recognize the applicable milestone over the remaining period of performance. Our strategic alliance with Mundipharma and Purdue does not include potential milestone payments.

We will recognize royalty revenue, if any, based upon actual and estimated net sales by the licensee of licensed products in licensed territories, and in the period the sales occur. We have not recognized any royalty revenue to date.

## **Income Taxes**

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect on deferred taxes of a change in tax rate is recognized in income or loss in the period that includes the enactment date.

We use our judgment for the recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

**Table of Contents**

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of December 31, 2011 and 2010.

**Basic and Diluted Net Loss per Common Share**

Basic net loss per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted common stock that had been issued but had not yet vested. Diluted net loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of shares of restricted common stock. In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the assumed buyback of additional shares, thereby reducing the dilutive impact of stock options. Common equivalent shares have not been included in the net loss per share calculations for the periods presented because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	2011	At December 31, 2010	2009
Stock options	6,985,460	6,087,491	4,954,708
Warrants	3,246,629	5,246,629	6,246,629
Unvested restricted shares			16,396
<b>Comprehensive Income (Loss)</b>			

Comprehensive income (loss) is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized holding gains and losses arising during the period on available-for-sale securities that are not other-than-temporarily impaired.

**Stock-Based Compensation Expense**

We measure stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the employee's requisite service period on a straight-line basis. We have no awards with market or performance conditions. We use the Black-Scholes valuation model in determining the fair value of equity awards.

**Research and Development Expense**

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, facilities expenses, overhead expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. We also include as research and development expense up-front license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. We are party to collaboration agreements in which we are reimbursed for work performed on behalf of the collaborator, as well as one in which we reimburse the collaborator for work it has performed. We record all appropriate expenses under our collaborations as research and development expense. If the arrangement provides for reimbursement of research and development expenses, as is the case with our alliance with Mundipharma and Purdue, we record the reimbursement as revenue. If the arrangement provides for us to reimburse the collaborator for research and development expenses or achieving a development milestone for which a payment is due, as is

---

**Table of Contents**

the case with our agreement with Intellikine, Inc., or Intellikine, we record the reimbursement or the achievement of the development milestone as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium.

**New Accounting Pronouncements**

In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2011-05, *Comprehensive Income*, or ASU No. 2011-05, which will require companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The update does not change the items which must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. ASU No. 2011-05 is effective for interim and annual periods beginning after December 15, 2011. In December 2011, the FASB issued Accounting Standard Update No. 2011-12, *Comprehensive Income*, or ASU No. 2011-12, which deferred the adoption of changes related to the presentation of reclassification adjustments. Because these updates only require enhanced disclosure, the adoption of ASU No. 2011-05 and ASU No. 2011-12 will not impact our financial position or results of operations.

**3. Stock-Based Compensation**

Under each of the stock incentive plans described below, stock option awards made to new employees upon commencement of employment typically provide for vesting of 25% of the shares underlying the award at the end of the first year of service with the remaining 75% of the shares underlying the award vesting ratably on a monthly basis over the following three-year period subject to continued service. Annual grants to existing employees typically provide for monthly vesting over four years. In addition, under each plan, all options granted expire no later than ten years after the date of grant.

**2010 Stock Incentive Plan**

Our 2010 Stock Incentive Plan, or the 2010 Plan, was approved by our stockholders in May 2010. The 2010 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, or IRC, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based and cash-based awards. Up to 3,000,000 shares of our common stock may be issued pursuant to awards granted under the 2010 Plan, plus an additional amount of our common stock underlying awards issued under the 2000 Stock Incentive Plan, or the 2000 Plan, that expire or are canceled without the holders receiving any shares under those awards. As of December 31, 2011, an aggregate of 1,713,982 shares of our common stock were reserved for issuance upon the exercise of outstanding awards and up to 1,818,294 shares of common stock may be issued pursuant to awards granted under the 2010 Plan.

**2000 Stock Incentive Plan**

Our 2000 Plan provided for the grant of stock options intended to qualify as incentive stock options under the IRC, nonstatutory stock options and restricted stock. As of December 31, 2011, an aggregate of 4,782,321 shares of our common stock were reserved for issuance upon the exercise of outstanding awards granted under our 2000 Plan. Our 2000 Plan was terminated upon approval of the 2010 Plan; therefore, no further grants may be made under the 2000 Plan.

**2001 Stock Incentive Plan**

In connection with the merger between Discovery Partners International, Inc., or DPI, and Infinity Pharmaceuticals, Inc., or IPI, in 2006, which we refer to as the DPI merger, we assumed awards that were

**Table of Contents**

granted under the Infinity Pharmaceuticals, Inc. Pre-Merger Stock Incentive Plan, or the 2001 Plan. The 2001 Plan provided for the grant of incentive stock options and nonstatutory stock options and restricted stock awards. Under the 2001 Plan, stock awards were granted to IPI's employees, officers, directors and consultants. Incentive stock options were granted at a price not less than fair value of the common stock on the date of grant. The board of directors of IPI determined the vesting of the awards. As of December 31, 2011, an aggregate of 486,657 shares of our common stock were reserved for issuance upon the exercise of outstanding assumed awards. The 2001 Plan was not assumed by us following the DPI merger; therefore, no further grants may be made under the 2001 Plan.

**Compensation Expense**

Total stock-based compensation expense, related to all equity awards, comprised the following:

	Year Ended December 31, 2011	Year Ended December 31, 2010	Year Ended December 31, 2009
Research and development	\$ 2,743,254	\$ 3,707,357	\$ 3,501,126
General and administrative	2,698,339	4,176,162	3,536,127

As of December 31, 2011, there was \$6.3 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options, which is expected to be recognized over a weighted-average period of 2.4 years.

**Valuation Assumptions**

We estimate the fair value of stock options at the date of grant using the Black-Scholes valuation model using the following weighted-average assumptions:

	Year Ended December 31, 2011	Year Ended December 31, 2010	Year Ended December 31, 2009
Risk-free interest rate	2.2%	2.6%	2.2%
Expected annual dividend yield			
Expected stock price volatility	58.2%	59.4%	56.7%
Expected term of options	5.9 years	5.7 years	5.4 years

The valuation assumptions were determined as follows:

*Risk-free interest rate:* The yield on zero-coupon U.S. Treasury securities for a period that was commensurate with the expected term of the awards.

*Expected annual dividend yield:* The estimate for annual dividends was zero, because we have not historically paid a dividend and do not intend to do so in the foreseeable future.

*Expected stock price volatility:* We determined the expected volatility by using a weighted average of selected peer companies as well as our available historical price information.

*Expected term of options:* The expected term of the awards represented the period of time that the awards were expected to be outstanding. We used historical data and expectations for the future to estimate employee exercise and post-vest termination behavior.

## Edgar Filing: INFINITY PHARMACEUTICALS, INC. - Form 10-K

We stratify employees into two groups to evaluate exercise and post-vest termination behavior. We estimate forfeitures based upon historical data, adjusted for known trends, and will adjust the estimate of forfeitures if actual forfeitures differ or are expected to differ from such estimates. Subsequent changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods. As of December 31, 2011, 2010 and 2009, the weighted-average forfeiture rate was estimated to be 10%, 10% and 8%, respectively.

**Table of Contents**

All options granted to employees during the years ended December 31, 2011, 2010 and 2009 were granted with exercise prices equal to the fair market value of our common stock on the date of grant. We consider the price of our common stock to be the fair market value.

A summary of our stock option activity for the year ended December 31, 2011 is as follows:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2011	6,087,491	\$ 8.72		
Granted	1,292,301	6.45		
Exercised	(114,815)	5.07		
Forfeited	(279,517)	9.28		
Outstanding at December 31, 2011	6,985,460	\$ 8.34	6.8	\$ 11.8
Vested or expected to vest at December 31, 2011	6,743,084	\$ 8.40	6.7	\$ 11.3
Exercisable at December 31, 2011	4,850,064	\$ 9.11	6.0	\$ 7.0

The weighted-average fair value per share of options granted during the years ended December 31, 2011, 2010 and 2009 were \$3.54, \$3.58 and \$3.70, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2011 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2011 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2011, 2010 and 2009 was \$356,174, \$257,846 and \$550,292, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2011 was \$582,003.

The total fair value of the shares of restricted stock that vested during the years ended December 31, 2011, 2010 and 2009 (measured on the date of vesting) was \$0, \$93,039 and \$213,008, respectively. All outstanding, unvested restricted stock became fully vested during the year ended December 31, 2010.

No related income tax benefits were recorded during the years ended December 31, 2011, 2010 or 2009.

We settle employee stock option exercises with newly issued shares of our common stock.

During the year ended December 31, 2011, one member of our board of directors retired, but was granted the right to exercise his vested stock options for an additional three-year period. In connection with this extension, we recognized an additional \$69,310 in stock-based compensation expense during the year ended December 31, 2011 with respect to the modification of these awards.

During the year ended December 31, 2010, one member of our board of directors who retired and one employee whose employment terminated were granted the right to exercise their vested stock options for an additional three-year period. In connection with these extensions, we recognized an additional \$209,860 in stock-based compensation expense during the year ended December 31, 2010 with respect to the modification of these awards. Also in 2010, the executive chair of our board of directors transitioned from executive chair to non-executive chair. In connection with the transition, the incentive stock options awards previously granted to him under the 2000 Plan were modified such that he would continue to be deemed an eligible participant for purpose of the awards for so long as he remained in continuous service to our company. In addition, he received a grant of 100,000 shares of our common stock under the 2010 Plan and \$400,000 in cash in recognition of services rendered. In connection with the modification of his incentive stock options and the grant of shares to him, we recognized an additional \$649,807 in stock-based compensation expense during the year ended December 31, 2010.





**Table of Contents****4. Cash, Cash Equivalents and Available-for-Sale Securities**

The following is a summary of cash, cash equivalents and available-for-sale securities:

	Cost	December 31, 2011		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
Cash and cash equivalents due in 90 days or less	\$ 24,196,974	\$	\$	\$ 24,196,974
Available-for-sale securities:				
Corporate obligations due in one year or less	60,593,467	28,497	(49,962)	60,572,002
Corporate obligations due in one to five years	5,936,573	8,466	(3,207)	5,941,832
Mortgage-backed securities due after ten years	602,915	56,264		659,179
U.S. government-sponsored enterprise obligations due in one year or less	335,000			335,000
U.S. government-sponsored enterprise obligations due in one to five years	24,249,618	2,045	(19,678)	24,231,985
Total available-for-sale securities	91,717,573	95,272	(72,847)	91,739,998
Total cash, cash equivalents and available-for-sale securities	\$ 115,914,547	\$ 95,272	\$ (72,847)	\$ 115,936,972

	Cost	December 31, 2010		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
Cash and cash equivalents due in 90 days or less	\$ 20,416,933	\$ 64	\$	\$ 20,416,997
Available-for-sale securities:				
Corporate obligations due in one year or less	43,635,770	8,362	(14,314)	43,629,818
Mortgage-backed securities due after ten years	659,473	79,189	(1,923)	736,739
U.S. government-sponsored enterprise obligations due in one year or less	21,670,829	2,479	(4,480)	21,668,828
U.S. government-sponsored enterprise obligations due in one to five years	14,521,673		(15,398)	14,506,275
Total available-for-sale securities	80,487,745	90,030	(36,115)	80,541,660
Total cash, cash equivalents and available-for-sale securities	\$ 100,904,678	\$ 90,094	\$ (36,115)	\$ 100,958,657

We held 17 debt securities at December 31, 2011 that had been in an unrealized loss position for less than 12 months. The gross unrealized losses on these securities were \$72,847 and their fair value was \$44,163,798. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these 17 securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost bases. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2011.

As of December 31, 2011, we held nine financial institution and other corporate debt securities located in Australia, Switzerland, the Netherlands and the United Kingdom with a fair value of \$23,561,448. Two of these securities, which were issued by a financial institution in the Netherlands, had gross unrealized losses of \$21,167 and fair value of \$4,530,350. These securities are short term in nature, with \$21,778,880 scheduled to mature within 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2011.

We had no material realized gains or losses on our available-for-sale securities for the years ended December 31, 2011, 2010 and 2009.



**Table of Contents****5. Fair Value**

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2011 and 2010, respectively.

The following table provides the assets carried at fair value measured on a recurring basis as of December 31, 2011:

	Level 1	Level 2
Cash and cash equivalents	\$ 24,196,974	\$
Corporate obligations (including commercial paper)		66,513,834
Mortgage-backed securities		659,179
U.S. government-sponsored enterprise obligations		24,566,985
<b>Total</b>	<b>\$ 24,196,974</b>	<b>\$ 91,739,998</b>

The fair value of the available-for-sale securities and cash and cash equivalents (including asset types listed below with maturities of three months or less at the time of purchase) is based on the following inputs:

*Corporate Obligations:*

Commercial paper: calculations by custodian based on three month Treasury bill published on last business day of the month.

Other: benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

*Mortgage-backed securities:* benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data, new issue data, monthly payment information and collateral performance.

*U.S. government-sponsored enterprise obligations:* benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data.

There have been no changes to the valuation methods during the year ended December 31, 2011. There were no transfers of assets or liabilities between Level 1 and Level 2 during the year ended December 31, 2011. We evaluate transfers between levels at the end of each reporting period. We had no available-for-sale securities that were classified as Level 3 at any point during the years ended December 31, 2011 or 2010.

Our long term debt due to Purdue entities is recorded at its carrying value at December 31, 2011. The fair value of the long term debt was approximately \$26 million, which was determined using a discounted cash flow model and based on an interest rate we would be charged for a similar loan as of December 31, 2011.



**Table of Contents****6. Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2011	2010
Laboratory equipment	\$ 15,642,568	\$ 15,204,481
Computer hardware and software	6,634,284	6,012,426
Office equipment and furniture and fixtures	736,403	736,403
Leasehold improvements	4,279,135	4,313,786
	27,292,390	26,267,096
Less accumulated depreciation	(22,710,462)	(21,119,551)
	\$ 4,581,928	\$ 5,147,545

We regularly review our property and equipment and evaluate the carrying value for impairment whenever events or changes in circumstances indicate that such values may not be recoverable. An impairment loss is recognized when the carrying amount of a long-lived asset is not recoverable and exceeds its fair value. During the year ended December 31, 2010, we recognized an impairment loss of \$311,200 related to laboratory equipment that had not been placed in service as a consequence of decreased clinical trial activity of retaspimycin HCl. We determined the fair value of the equipment based on quoted market prices. The impairment charge is included in research and development expense for the year ended December 31, 2010. We did not impair any fixed assets during the years ended December 31, 2011 and 2009.

During the year ended December 31, 2011, we extended the lives of certain leasehold improvements related to our office and laboratory space in conjunction with the extension of the lease terms during 2011 (see note 10).

During the year ended December 31, 2009, we capitalized costs associated with internally developed software in the amount of \$524,496. Depreciation expense associated with this software was \$174,832, \$174,832 and \$101,985 for the years ended December 31, 2011, 2010 and 2009, respectively.

During the year ended December 31, 2009, we disposed of certain fully depreciated laboratory equipment and computer equipment, which had an original cost of \$1,475,082, resulting in a gain of \$79,256.

**7. Long-Term Debt and Loan Commitment Asset from Purdue Entities**

In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. In connection with these agreements, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP. See note 11 for discussion on the strategic alliance agreements and the line of credit agreement.

The extension of the line of credit at an interest rate below our incremental borrowing rate represented the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset on our balance sheet in 2008. The fair value of the loan commitment asset was determined using a discounted cash flow model of the differential between the terms and rates of the line of credit and market rates.

We amortized the loan commitment asset to interest expense through the drawdown of the line of credit in November 2011. We recorded approximately \$1.6 million, \$1.7 million and \$1.3 million of related amortization expense in the years ended December 31, 2011, 2010 and 2009, respectively.

In November 2011, we borrowed \$50 million under this line of credit, which we recorded as long-term debt. The loan matures and is payable in full, including principal and any accrued interest, on April 1, 2019, which we



**Table of Contents**

refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. The loan bears interest at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and is reset on the last business day of each month ending thereafter. At the time of the borrowing, prime rate was 3.25%. Interest is compounded on each successive three-month anniversary following the date of borrowing. The loan may be prepaid without penalty or premium prior to the maturity date. Even if we prepay the loan, we do not have the ability to borrow under the line of credit agreement again. We have certain rights to repay the loan in shares of our common stock as a share-settled obligation. Upon drawing down the \$50 million under the line of credit agreement, we reclassified the loan commitment asset as a debt discount which reduced the debt on our balance sheet. The unamortized balance of the loan commitment asset was \$12,700,600 as of the date of borrowing. We are recording interest on the net amount borrowed using the effective interest method. We recorded \$253,395 of related interest expense in the year ended December 31, 2011 subsequent to the borrowing in November 2011 using an effective interest rate of 7.29%. We will owe approximately \$63.4 million in interest and principal at the maturity date, assuming the prime rate of interest remains at 3.25%.

**8. Restricted Cash**

We held \$1,125,388 in restricted cash as of December 31, 2011 and \$1,122,633 in restricted cash as of December 31, 2010. The balances are held on deposit with a bank to collateralize a standby letter of credit in the name of our facility lessor in accordance with our facility lease agreement.

**9. Accrued Expenses**

Accrued expenses consisted of the following:

	December 31,	
	2011	2010
Accrued drug manufacturing costs	\$ 4,888,372	\$ 1,921,224
Accrued license fee payable to Millennium		8,500,000
Accrued toxicology studies	1,231,501	1,153,006
Accrued compensation and benefits	6,287,120	4,495,189
Accrued clinical studies	2,977,394	2,375,823
Other	3,434,780	1,918,642
<b>Total accrued expenses</b>	<b>\$ 18,819,167</b>	<b>\$ 20,363,884</b>

**10. Commitments and Contingencies**

We lease our office and laboratory space under two lease agreements. The term of our primary office and laboratory lease expires in January 2016, and may be terminated by us early under certain circumstances. We have the right to extend this lease for another five-year term on the same terms and conditions as the current lease by giving the landlord notice before the term of the lease expires. Under this lease, we have a tenant improvement allowance of up to \$671,670 for the design and construction of fixed and permanent improvements until December 31, 2013. Our secondary office lease expires in October 2014.

Future minimum payments, excluding operating costs and taxes, under these facility leases, are as follows:

	Facility Leases
Years Ending December 31:	
2012	\$ 5,193,196
2013	4,563,702
2014	4,661,704
2015	4,631,736
2016	397,557
<b>Total minimum lease payments</b>	<b>\$ 19,447,895</b>





**Table of Contents**

Rent expense of \$4,725,878, \$4,658,843 and \$4,526,260, before considering sublease income, was incurred during the years ended December 31, 2011, 2010 and 2009, respectively. Deferred rent is being amortized to rent expense over the life of the lease. During the years ended December 31, 2011, 2010 and 2009, we subleased a portion of our facility space for total sublease income of \$662,556, \$662,556 and \$512,510, respectively. We record sublease payments as an offset to rental expense in our statement of operations. Future minimum sublease income under noncancelable leases is expected to be \$662,556 for the year ended December 31, 2012.

**11. Collaborations**

**Purdue and Mundipharma**

*Scope*

In November 2008, we entered into a strategic alliance with Mundipharma and Purdue to develop and commercialize pharmaceutical products. The alliance is governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue. The agreement with Purdue is focused on the development and U.S. commercialization of products targeting fatty acid amide hydrolase, or FAAH. The agreement with Mundipharma is focused on the development and commercialization outside of the United States of all products and product candidates covered by the alliance, including those targeting FAAH. The alliance currently includes product candidates that inhibit or target the Hedgehog pathway, FAAH, phosphoinositide-3-kinase, or PI3K, and product candidates arising out of our early discovery projects in all disease fields that are conducted during a prescribed discovery period that runs through December 31, 2013. Our heat shock protein 90, or Hsp90, program is expressly excluded from the alliance.

Mundipharma also has the option to include in the alliance certain products or product candidates that we may in-license during the discovery period by paying us a prescribed percentage of the up-front license fee or other acquisition cost, which percentage could be up to 60% of such fee or cost, and by funding research and development costs in the same manner as products or product candidates arising out of our internal discovery programs, as described below. If we in-license any product or product candidate during the discovery period for which GLP (Good Laboratory Practice) toxicology studies have not been initiated, as we did with our PI3K inhibitor program in 2010, such products are automatically included in the alliance just as if they arose out of our internal discovery projects.

We have responsibility and decision-making authority for the development of all of our product candidates and performance of early discovery projects on a worldwide basis. There are no joint steering or similar committees for the alliance. Except with respect to products targeting FAAH, for which Mundipharma and Purdue currently have global commercialization rights, and products for which

Mundipharma has opted out of development as described below, we will have the right and responsibility to market and sell products arising from the alliance in the United States, and Mundipharma will have the right and responsibility to market and sell products arising from the alliance outside of the United States. Other than pursuant to the strategic alliance agreements, neither we, Purdue nor Mundipharma may develop, manufacture or commercialize products that are directed to the same target or pathway as a product included in the strategic alliance, unless and until a party terminates its rights with respect to such products.

Following entry into the strategic alliance agreements, we consider Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes because of their equity ownership in our company.

*Research and Development Funding*

For each alliance program other than FAAH, Mundipharma is obligated to reimburse us for research and development expenses we incur, up to an annual aggregate cap, until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of a product candidate, which we refer to as the transition date.

---

**Table of Contents**

The funding caps for the years ending December 31, 2012 and December 31, 2013 are \$110 million and \$147.5 million, respectively. The funding caps for the years ended December 31, 2011 and 2010 were \$85 million and \$65 million, respectively. The funding cap for the period between November 19, 2008 and December 31, 2009 was \$50 million. We are obligated to fund any activities in excess of the annual funding cap ourselves, which we did in 2010 primarily as the result of costs associated with the licensing of our PI3K inhibitor program, and in 2011 primarily due to expanded clinical trial activities for saridegib, our lead Hedgehog program candidate, and the commencement of clinical development of IPI-145, our lead PI3K inhibitor program candidate. After the transition date for each product candidate, we are obligated to share equally with Mundipharma all research and development costs for such product candidate. We are recognizing revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recognized \$85.0 million, \$65.0 million and \$46.5 million in such revenue in the years ended December 31, 2011, 2010 and 2009, respectively.

In October 2010, following completion of the first Phase 1 clinical trial of IPI-940, Mundipharma and Purdue exercised their rights to assume all worldwide development and commercialization activities and to fund all subsequent research, development and commercialization expenses for products arising out of our FAAH program. All expenses associated with activities we conduct related to the transition of the FAAH program to Purdue and Mundipharma are reimbursed by Purdue and Mundipharma, with such amounts not counting towards the annual funding cap. We recognized \$3.5 million and \$2.0 million in revenue related to reimbursed research and development services for the transition of the FAAH program for the years ended December 31, 2011 and 2010, respectively.

*Opt-out and Termination Rights*

Mundipharma has the right to opt out of any alliance program, except the Hedgehog program, on an annual basis in November of each year. In the event of an opt-out decision, Mundipharma would continue to provide funding for, in the aggregate, 100% of our contractually budgeted research and development expenses for all programs included in the alliance for the calendar year following the date of such opt out, up to an annual cap. This funding commitment for the year ending December 31, 2013 is \$51.3 million for our PI3K and early discovery programs.

With respect to our Hedgehog program, Mundipharma has the right to opt out of this program no later than the 30th day following the outcome of an end-of-Phase 2 meeting with the U.S. Food and Drug Administration pertaining to the clinical trial of saridegib plus gemcitabine in patients with pancreatic cancer (or, if the end-of-Phase 2 meeting is not held by November 1, 2013, then by November 30, 2013). Based on the results of this clinical trial, we do not intend to have an end-of-Phase 2 meeting. Consequently, Mundipharma may next exercise its right to opt out of the Hedgehog program in November 2013. Mundipharma is obligated to fund the Hedgehog program until it is required to make the decision to opt out or continue funding the program. If Mundipharma elects to opt out of participation in the Hedgehog program in November 2013, then Mundipharma would be obligated to make an immediate payment of \$23.65 million to us, which we can use on any program in the alliance. In addition, Mundipharma would be obligated to reimburse us for up to \$23.65 million of additional expenses incurred during 2013 that are associated with the completion of Phase 2 clinical trials of saridegib that are ongoing at that time. If Mundipharma elects to continue participation in the Hedgehog program in November 2013, it would thereafter have the same annual opt-out right, and one-year residual funding obligation, that applies to the other alliance programs.

In addition, we and Mundipharma each have the right to opt out of continued development of a product candidate after it has reached the transition date, with a one year tail funding obligation for 50% of post-transition date research and development expenses for the product candidate. If a party exercises its right to opt out of the development of a product or product candidate after the transition date, the other party may elect to continue the development and assume responsibility for the worldwide commercialization of such product or product candidate, subject to the payment of a royalty.

---

**Table of Contents**

Each of the strategic alliance agreements expire when the parties thereto have no further obligations to each other thereunder. Either party may terminate the strategic alliance agreement to which it is a party on 60 days prior written notice if the other party materially breaches the agreement and fails to cure such breach within the 60-day notice period. The agreements may also be terminated by Mundipharma or Purdue in the event of a change in control of Infinity or in the event that, during the discovery period, either Adelene Perkins or Julian Adams is no longer a full-time executive of Infinity. Upon termination of either strategic alliance agreement by us or either Mundipharma or Purdue, either party to the other strategic alliance agreement may terminate that agreement.

*Royalties*

Except with respect to products that have been in-licensed by us following initiation of GLP toxicology studies, for which no royalties will be payable between the parties, we are obligated to pay Mundipharma a 5% royalty on net sales of the commercialized products until such time as Mundipharma has recovered all research and development expenses paid to us under the research program prior to the applicable transition date. After such cost recovery, we are obligated to pay a tiered, 1% to 3% royalty on U.S. net sales of those products. For products in which Mundipharma has opted-out of development prior to the transition date, we are obligated to pay royalties of 1% to 5% of worldwide net sales as a function of the stage of development of the applicable product candidate at the time of opt out. For products in which either party has opted-out of development following the transition date, the commercializing party is obligated to pay the other party a 5% royalty on net sales. Mundipharma is obligated to pay us a tiered, 10% to 20% royalty on annual net sales outside of the United States of each product arising out of the alliance, and Purdue is obligated to pay us a tiered, 10% to 20% royalty on annual net sales of FAAH products in the United States. Royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the rates above is reduced by one-half. In addition, all royalties payable under the strategic alliance agreements, whether by us, Mundipharma or Purdue, are subject to reduction on account of third party royalty payments or patent litigation damages or settlements, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

*Securities Purchase and Line of Credit Agreements*

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and a line of credit agreement in November 2008 with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. See note 7 for a discussion of the line of credit agreement.

Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of six million shares of our common stock and warrants to purchase up to an aggregate of six million shares of our common stock, for an aggregate purchase price of \$75 million. An equal number of securities were sold to each purchaser.

We recorded an aggregate of \$59.3 million in deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue, which consisted of the excess of the amount paid for the purchased shares over the closing market price on the day before the equity closings and the value of the loan commitment asset (see note 7). We determined that the rights and licenses did not have stand-alone value, and we considered all of the obligations under the arrangement to be a single unit of accounting. There is no obligation for us to repay the \$59.3 million and we are recognizing the deferred revenue ratably over 14 years, which is our estimated period of performance under the arrangement. We periodically review this estimate and may make adjustments as facts and circumstances dictate. We recognized \$4.3 million in such revenue in each of the years ended December 31, 2011, 2010 and 2009.

---

**Table of Contents**

**Millennium**

In July 2010, we entered into a development and license agreement with a predecessor company to Millennium under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. We paid a \$13.5 million up-front license fee to obtain rights to this program. The entirety of this fee is included as research and development expense in the year ended December 31, 2010, although \$8.5 million of this fee was paid in January 2011. In addition to developing IPI-145, we are seeking to identify additional novel delta, gamma and dual delta/gamma-specific inhibitors of PI3K for future development. We are recognizing these costs as research and development expense as they are incurred. We are obligated to pay up to \$25 million in success-based milestones for the development of two distinct product candidates, and up to \$450 million in success-based milestones for the approval and commercialization of two distinct products. In addition, we are obligated to pay Millennium tiered royalties on net sales ranging from single digits to low teens upon successful commercialization of products licensed to us, which are payable until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction in certain circumstances. During 2011, we paid Millennium \$4.0 million in milestone payments associated with the initiation of two Phase 1 studies of IPI-145, which we recorded as research and development expense during the year ended December 31, 2011.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. For a product in which the first Phase 2 clinical trial conducted is in an oncology indication, which we refer to as an oncology product, Millennium will have the option, at the end of Phase 2 clinical development and upon payment of an option fee, to convert its royalty interest in U.S. sales into the right to share in 50% of profits and losses on U.S. development and commercialization, and to participate in up to 30% of the detailing effort for these products in the United States. Mundipharma has commercialization rights outside the United States for products arising out of our PI3K inhibitor program.

Millennium may terminate such participation upon 12 months' prior written notice to us, after which Millennium's participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Millennium would not be entitled to receive royalty payments for net sales occurring prior to the termination date and certain specified milestone payments.

Other than pursuant to the agreement, neither we nor Millennium may research, develop or commercialize products directed to the delta and/or gamma isoforms of PI3K which meet certain selectivity criteria, except that Millennium may research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

The agreement expires when the parties have no further obligations to each other thereunder, unless earlier terminated. Either party may terminate the agreement on 75 days' prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Additionally, Millennium may terminate the agreement upon 30 days' prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days' prior written notice provided after the end of the research term that is currently set to expire in July 2013.

**MedImmune**

From August 2006 through December 2008, our Hsp90 inhibitor program was conducted in collaboration with MedImmune, a division of AstraZeneca plc, or MedImmune, and from August 2006 through November

**Table of Contents**

2007, our Hedgehog pathway inhibitor program was conducted in collaboration with MedImmune. Under this collaboration, we shared research and development expenses equally with MedImmune. In December 2008, we regained from MedImmune worldwide development and commercialization rights under our Hsp90 inhibitor program. Following the reacquisition of the Hsp90 inhibitor program, we had no substantial performance obligations to MedImmune. MedImmune's funding obligation under the Hsp90 inhibitor program was to continue until June 2009. In January 2009, we reached an agreement with MedImmune to settle the residual funding obligation remaining for 2009 through lump-sum payments totaling \$12.5 million, which were recorded as income from residual funding after reacquisition of Hsp90 program (a component of other income) in the year ended December 31, 2009. We received \$12.5 million in cash from MedImmune in the year ended December 31, 2009.

**12. Income Taxes**

We had no income tax expense or benefit for the year ended December 31, 2011. Our income tax benefits of \$700,321 and \$329,566 for the years ended December 31, 2010 and 2009, respectively, primarily consisted of U.S. federal taxes.

Our income tax benefit or expense for the years ended December 31, 2011, 2010 and 2009 differed from the expected U.S. federal statutory income tax expense as set forth below:

	2011	2010	2009
Expected federal tax benefit	\$ (13,609,214)	\$ (16,892,553)	\$ (10,724,857)
Permanent differences	1,295,279	909,480	1,522,097
State taxes, net of deferral benefit	(2,179,476)	(2,869,250)	(1,715,554)
Tax credits and related adjustments	(1,931,408)	561,730	(2,928,454)
Alternative minimum tax			(282,191)
Effect of change in state tax rate on deferred tax assets and deferred tax liabilities	60,829	425,153	47,828
Expired state net operating loss	1,424,229	1,895,009	1,085,004
Change in tax reserves		(700,321)	
Adjustments to deferred tax assets and deferred tax liabilities	745,150		(47,347)
Change in valuation allowance	14,159,744	15,945,922	12,619,791
Other	34,867	24,509	94,117
Income tax benefit	\$	\$ (700,321)	\$ (329,566)

The significant components of our deferred tax assets are as follows:

	Year Ended December 31,	
	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	\$ 55,875,134	\$ 42,892,580
Tax credits	15,644,421	13,713,014
Deferred revenue	18,210,893	19,866,253
Intangible assets	4,894,624	5,166,742
Accrued expenses	2,042,932	1,170,791
Amortization	712,256	700,103
Stock-based compensation	7,430,307	7,282,278
Other	729,011	581,945
Valuation allowance	(105,539,578)	(91,373,706)
Net deferred tax assets	\$	\$

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2011, 2010 and 2009 because management believes that it is more likely than not that these assets



**Table of Contents**

will not be realized. The valuation allowance increased by approximately \$14,166,000 during the year ended December 31, 2011 primarily as a result of increases in unbenefitted deferred tax assets such as tax losses and credits and intangible assets.

The valuation allowance increased by approximately \$15,953,000 during the year ended December 31, 2010 primarily as a result of increases in unbenefitted deferred tax assets such as deferred revenue and intangible assets. The valuation allowance increased by approximately \$12,677,000 during the year ended December 31, 2009 primarily as a result of increases in unbenefitted deferred tax assets such as deferred revenue and tax credits and decreases in deferred tax liabilities offset by the utilization of previously unbenefitted net operating losses.

Subject to the limitations described below, at December 31, 2011, we had cumulative net operating loss carryforwards of approximately \$157,896,000 and \$49,265,000 available to reduce federal and state taxable income, which expire through 2031 and have begun to expire and through 2031, respectively. In addition, we have cumulative federal and state tax credit carryforwards of \$11,882,000 and \$5,700,000, respectively, available to reduce federal and state income taxes which expire through 2031 and 2026, respectively. The net operating loss carryforwards include approximately \$1,208,000 of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net operating losses. Additionally, our net operating loss carryforwards and tax credits are limited as a result of certain ownership changes, as defined under Sections 382 and 383 of the Internal Revenue Code. This limits the annual amount of these tax attributes that can be utilized to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to an ownership change. Subsequent ownership changes may increase the limitation in future years. The net operating losses and tax credits that will expire unused in the future as a result of Section 382 and 383 limitations have been excluded from the amounts disclosed above.

During the twelve-month period ended December 31, 2010, we reversed our liability for unrecognized tax benefits as an uncertain tax position we took in a prior year is no longer subject to examination due to the expiration of the statute of limitations. We have no interest and penalties accrued as of December 31, 2011.

A reconciliation of the allowance for uncertain tax positions for the years ended December 31, 2011, 2010 and 2009 is as follows:

	2011	2010	2009
Balance at January 1	\$	\$594,000	\$ 594,000
Increase or decrease for tax positions taken during a prior period			
Increase or decrease for tax positions taken during the current period			
Decrease relating to settlements			
Decrease resulting from the expiration of the statute of limitations		(594,000)	
Balance at December 31	\$	\$	\$ 594,000

We file income tax returns in the U.S. federal, Massachusetts, and other state jurisdictions. The statute of limitations for assessment by the Internal Revenue Service, or IRS, and state tax authorities is closed for tax years prior to 2008, although carryforward attributes that were generated prior to tax year 2008 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period.

**13. Stockholders Equity****Stockholder Rights Agreement**

We have a stockholder rights agreement that provides for a dividend distribution of one preferred share purchase right for each outstanding share of our common stock held of record at the close of business on February 24, 2003. The rights are not currently exercisable. Under certain conditions involving an acquisition or

---

**Table of Contents**

proposed acquisition by any person or group holding 15% or more of our outstanding common stock, or in the case of entities associated with Purdue, 33% or more of fully diluted number of shares of common stock outstanding (giving effect to all securities that are then exercisable for, or convertible into, common stock), the rights permit the holders to purchase from us one-thousandth of a share of our Series A junior participating preferred stock at a price of \$76.00, subject to adjustment. The Series A junior participating preferred stock has preferred dividend, liquidation and voting rights. Under certain conditions, the rights may be redeemed by our board of directors in whole, but not in part, at a price of \$0.01 per right.

**Warrants**

In connection with various loan and financing agreements during the period from December 2001 through December 2006, IPI issued warrants to purchase shares of convertible preferred stock, which subsequently became warrants to purchase shares of our common stock in the DPI merger. The fair value of the warrants was estimated using the Black-Scholes valuation model assuming no expected dividends, a volatility ranging from 64% to 95%, a contractual life of ten years, and a risk-free interest rate ranging from 3.1% to 5.5%. The warrants were recorded as a reduction of the associated debt and were amortized to interest expense over the life of the loans. These warrants are fully amortized.

In July 2002, IPI issued warrants to purchase shares of convertible preferred stock, which subsequently became warrants to purchase shares of common stock in the DPI merger, in conjunction with the entry of our facility lease. The fair value of the warrants was estimated using the Black-Scholes valuation model assuming no expected dividends, a volatility of 75%, an estimated contractual life of ten years, and a risk-free interest rate of 5%. The warrants have been recorded in other non-current assets and are being amortized over the lease period as rent expense.

Warrants described above to purchase 246,629 shares of our common stock were outstanding at December 31, 2011, 2010 and 2009. These warrants expire on dates ranging from February 28, 2012 to June 30, 2016 and have exercise prices ranging from \$7.64 to \$13.35 per share.

In connection with the strategic alliance agreements we entered into with Mundipharma and Purdue, in January 2009 we issued warrants to purchase up to an aggregate of six million shares of our common stock. Warrants to purchase up to an aggregate of 1,000,000 and 2,000,000 shares of our common stock expired unexercised on July 1, 2010 and 2011, respectively. The remaining warrants to purchase up to an aggregate of 3,000,000 shares of our common stock are currently exercisable at any time up to July 2, 2012, with an initial exercise price of \$30.00 per share and such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of \$40.00 per share. The fair value of these warrants was estimated as of November 2008 using a binomial valuation model assuming no expected dividends, a volatility of 58%, estimated contractual lives ranging from 1.6 years to 3.6 years and risk-free interest rates ranging from 1.0% to 1.5%. The aggregate fair value of these warrants of approximately \$1.3 million was recorded as additional paid-in capital in the year ended December 31, 2009.

**14. Income from NIH Reimbursement**

During the year ended December 31, 2009, we received \$1.7 million from the National Institutes of Health, or NIH, relating to contract work performed by DPI from August 2004 through June 2006. As the amount received was not related to our ordinary course of operations, we recorded the amount as other income.

**15. Income from Therapeutic Discovery Grants**

During the year ended December 31, 2010, we received tax grants aggregating \$0.7 million under the U.S. Government's Qualifying Therapeutic Discovery Project program for qualified expenses related to our Hedgehog, Hsp90 and FAAH programs. As the amounts received for the awards are not related to our ordinary course of operations, we have recorded the amounts as other income.



**Table of Contents****16. Defined Contribution Benefit Plan**

We sponsor a 401(k) retirement plan in which substantially all of our full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. During the years ended December 31, 2011, 2010 and 2009, we matched 50% of the first six percent of participant contributions with shares of our common stock. Our matching contributions during the years ended December 31, 2011, 2010 and 2009 were \$594,638, \$564,377 and \$530,573, respectively.

**17. Quarterly Financial Information (unaudited)**

	Quarter Ended March 31, 2011	Quarter Ended June 30, 2011	Quarter Ended September 30, 2011	Quarter Ended December 31, 2011
	(In Thousands, Except Shares and Per Share Amounts)			
Collaborative research and development revenue from Purdue entities	\$ 27,187	\$ 19,957	\$ 23,305	\$ 22,324
Operating expenses:				
Research and development	24,278	24,993	29,418	29,893
General and administrative	4,876	6,330	5,470	6,043
Total operating expenses	29,154	31,323	34,888	35,936
Loss from operations	(1,967)	(11,366)	(11,583)	(13,612)
Other (expense) income:				
Interest expense	(433)	(433)	(433)	(542)
Interest and investment income	94	69	71	93
Total other expense	(339)	(364)	(362)	(449)
Net loss	\$ (2,306)	\$ (11,730)	\$ (11,945)	\$ (14,061)
Basic and diluted net loss per common share	\$ (0.09)	\$ (0.44)	\$ (0.45)	\$ (0.53)
Basic and diluted weighted average number of common shares outstanding	26,536,048	26,567,980	26,666,332	26,708,351

**Table of Contents**

	Quarter Ended March 31, 2010	Quarter Ended June 30, 2010	Quarter Ended September 30, 2010	Quarter Ended December 31, 2010
(In Thousands, Except Shares and Per Share Amounts)				
Collaborative research and development revenue from Purdue entities	\$ 16,300	\$ 18,694	\$ 22,496	\$ 13,841
Operating expenses:				
Research and development	19,378	19,011	38,732	22,110
General and administrative	4,749	5,216	5,015	6,090
<b>Total operating expenses</b>	<b>24,127</b>	<b>24,227</b>	<b>43,747</b>	<b>28,200</b>
Loss from operations	(7,827)	(5,533)	(21,251)	(14,359)
Other (expense) income:				
Interest expense	(433)	(433)	(522)	(522)
Income from Therapeutic Discovery Grants				733
Interest and investment income	205	25	123	110
<b>Total other income (expense)</b>	<b>(228)</b>	<b>(408)</b>	<b>(399)</b>	<b>321</b>
Net loss before income taxes	(8,055)	(5,941)	(21,650)	(14,038)
Income tax benefit			700	
<b>Net loss</b>	<b>\$ (8,055)</b>	<b>\$ (5,941)</b>	<b>\$ (20,950)</b>	<b>\$ (14,038)</b>
Basic and diluted net loss per common share	\$ (0.31)	\$ (0.23)	\$ (0.80)	\$ (0.53)
Basic and diluted weighted average number of common shares outstanding	26,244,297	26,285,125	26,333,012	26,421,230

## **Table of Contents**

### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

There have been no disagreements with our independent accountants on accounting and financial disclosure matters.

### **Item 9A. Controls and Procedures** **Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2011. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2011, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our management including our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Management's report on our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) appears below.

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Internal Control Over Financial Reporting**

#### ***(a) Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officer and effected by our board of directors, management and other personnel, 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 and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

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

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. Therefore, even those systems determined to be effective can provide only reasonable assurance

## **Table of Contents**

with respect to financial statement preparation and presentation. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2011. 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*. Based on its assessment, management believes that, as of December 31, 2011, our internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm has issued an attestation report of our internal control over financial reporting. This report appears below.

### ***(b) Attestation Report of the Independent Registered Public Accounting Firm on Internal Control over Financial Reporting***

The Board of Directors and Shareholders of

Infinity Pharmaceuticals, Inc.

We have audited Infinity Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Infinity Pharmaceuticals, 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, Infinity Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on the COSO criteria.

**Table of Contents**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011 of Infinity Pharmaceuticals, Inc. and our report dated March 13, 2012 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 13, 2012

***(c) Changes in Internal Control Over Financial Reporting***

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

Not applicable.

**Table of Contents**

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The sections titled Proposal 1 Election of Directors, Board and Committee Meetings, Section 16(a) Beneficial Ownership Reporting Compliance and Corporate Governance Guidelines; Code of Business Conduct and Ethics appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 16, 2012 are incorporated herein by reference. The information required by this item relating to executive officers may be found in Part I, Item 1 of this report under the heading Business Executive Officers.

**Item 11. Executive Compensation**

The section titled Executive Officer Compensation appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 16, 2012 is incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The sections titled Stock Ownership of Certain Beneficial Owners and Management and Securities Authorized for Issuance under Equity Compensation Plans appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 16, 2012 are incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The sections titled Transactions with Related Persons, Policies and Procedures for Related Persons Transactions, and Determination of Independence appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 16, 2012 are incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services**

The section titled Audit Fees appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on May 16, 2012 is incorporated herein by reference.

**Table of Contents**

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

**(a)(1) Financial Statements**

The financial statements listed below are filed as a part of this Annual Report on Form 10-K.

	<b>Page number</b>
<u>Report of Independent Registered Public Accounting Firm on Financial Statements</u>	60
<u>Consolidated Balance Sheets at December 31, 2011 and 2010</u>	61
<u>Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009</u>	62
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009</u>	63
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2011, 2010 and 2009</u>	65
<u>Notes to Consolidated Financial Statements</u>	67

**(a)(2) Financial Statement Schedules**

Financial statement schedules have been omitted because of the absence of conditions under which they are required or because the required information, where material, is shown in the financial statements or notes thereto.

**(a)(3) Exhibits**

The Exhibits listed in the Exhibit Index are filed as a part of this Annual Report on Form 10-K.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of 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.

**INFINITY PHARMACEUTICALS, INC.**

Date: March 13, 2012

By: /s/ ADELENE Q. PERKINS  
**Adelene Q. Perkins**

*President & Chief Executive Officer*

*(Principal Executive Officer and Principal Financial Officer)*

Pursuant to the requirements of 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ ADELENE Q. PERKINS <b>Adelene Q. Perkins</b>	President, Chief Executive Officer and Director <i>(Principal Executive Officer and Principal Financial Officer)</i>	March 13, 2012
/s/ CHRISTOPHER M. LINDBLOM <b>Christopher M. Lindblom</b>	Vice President, Accounting and Financial Planning; Assistant Treasurer <i>(Principal Accounting Officer)</i>	March 13, 2012
/s/ STEVEN H. HOLTZMAN <b>Steven H. Holtzman</b>	Chair of the Board of Directors	March 13, 2012
/s/ MARTIN BABLER <b>Martin Babler</b>	Director	March 13, 2012
/s/ ANTHONY B. EVNIN, PH.D. <b>Anthony B. Evnin, Ph.D.</b>	Director	March 13, 2012
<b>Gwen A. Fyfe, M.D.</b>	Director	
/s/ ERIC S. LANDER, PH.D. <b>Eric S. Lander, Ph.D.</b>	Director	March 13, 2012
/s/ PATRICK P. LEE <b>Patrick P. Lee</b>	Director	March 13, 2012
/s/ ARNOLD J. LEVINE, PH.D. <b>Arnold J. Levine, Ph.D.</b>	Director	March 13, 2012
/s/ THOMAS J. LYNCH, JR., M.D. <b>Thomas J. Lynch, Jr., M.D.</b>	Director	March 13, 2012
<b>Norman C. Selby</b>	Director	
/s/ IAN F. SMITH <b>Ian F. Smith</b>	Director	March 13, 2012
/s/ JAMES B. TANANBAUM, M.D. <b>James B. Tananbaum, M.D.</b>	Director	March 13, 2012



/s/ MICHAEL C. VENUTI, Ph.D.  
**Michael C. Venuti, Ph.D.**

Director

March 13, 2012

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation of the Registrant. Previously filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
3.2	Amended and Restated Bylaws of the Registrant. Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 17, 2009 (File No. 000-31141) and incorporated herein by reference.
4.1	Form of Common Stock Certificate. Previously filed as Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 000-31141) and incorporated herein by reference.
4.2	Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated February 13, 2003, which includes the form of Certificate of Designation for the Series A Junior Participating Preferred Stock as Exhibit A, the form of Rights Certificate as Exhibit B and the Summary of Rights to Purchase Series A Preferred Stock as Exhibit C. Previously filed as Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on February 24, 2003 (File No. 000-31141) and incorporated herein by reference.
4.3	First Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company dated April 11, 2006. Previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on April 12, 2006 (File No. 000-31141) and incorporated herein by reference.
4.4	Second Amendment to the Rights Agreement between the Registrant and American Stock Transfer & Trust Company, LLC dated November 19, 2008. Previously filed as Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on November 20, 2008 (File No. 000-31141) and incorporated herein by reference.
10.1	Strategic Alliance Agreement, dated as of November 19, 2008, by and between the Registrant and Purdue Pharmaceutical Products L.P. Previously filed as Exhibit 10.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 000-31141) and incorporated herein by reference.
10.2	Strategic Alliance Agreement, dated as of November 19, 2008, by and between the Registrant and Mundipharma International Corporation Limited. Previously filed as Exhibit 10.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 000-31141) and incorporated herein by reference.
10.3	Amendment No. 1 to Strategic Alliance Agreement, dated as of December 10, 2010, by and between the Registrant and Mundipharma International Corporation Limited. Previously filed as Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed December 14, 2010 (File No. 000-31141) and incorporated herein by reference.
10.4	Securities Purchase Agreement, dated as of November 19, 2008, by and among the Registrant, Purdue Pharma L.P. and Purdue Pharmaceutical Products L.P. Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 20, 2008 (File No. 000-31141) and incorporated herein by reference.
10.5	Line of Credit Agreement, dated as of November 19, 2008, by and between the Registrant and Purdue Pharma L.P., directly and as assignee of Purdue Pharmaceutical Products L.P. Previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on November 20, 2008 (File No. 000-31141) and incorporated herein by reference.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>
10.6	Development and License Agreement, dated as of July 7, 2010, by and between the Registrant and Intellikine, Inc. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 (File No. 000-31141) and incorporated herein by reference.
10.7	Collaboration Agreement, dated as of August 25, 2006, by and between MedImmune, Inc. and Infinity Discovery, Inc., or IDI, a wholly owned subsidiary of the Registrant. Previously filed as Exhibit 10.1 to MedImmune's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 (File No. 0-19131) and incorporated herein by reference.
10.8	Lease Agreement dated July 2, 2002 between IDI and ARE-770/784/790 Memorial Drive LLC (the Lease), as amended by First Amendment to Lease dated March 25, 2003, Second Amendment to Lease dated April 30, 2003, Third Amendment to Lease dated October 30, 2003 and Fourth Amendment to Lease dated December 15, 2003. Previously filed as Exhibit 10.36 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.9	Fifth Amendment to Lease dated July 8, 2011 between the Registrant and ARE-770/784/790 Memorial Drive LLC. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed on August 9, 2011 (File No. 000-31141) and incorporated herein by reference.
10.10	Sublease dated August 24, 2004 between IDI and Hydra Biosciences, Inc ( Hydra ), together with Consent to Sublease dated September 16, 2004 by ARE-770/784/790 Memorial Drive LLC, IDI and Hydra Biosciences, Inc., as amended by First Amendment to Sublease dated October 17, 2005, together with Consent to Amendment to Sublease dated as of October 31, 2005 by ARE-770/784/790 Memorial Drive LLC and Second Amendment to Sublease dated as of January 9, 2006, together with Consent to Amendment to Sublease dated as of January 26, 2006 by ARE-770/784/790 Memorial Drive LLC, IDI and Hydra. Previously filed as Exhibit 10.37 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.11	Third Amendment to Sublease dated April 17, 2009 between IDI and Hydra, together with Consent to Third Amendment to Sublease dated May 5, 2009 by ARE-770/784/790 Memorial Drive LLC, IDI and Hydra. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009 (File No. 000-31141) and incorporated herein by reference.
10.12*	Offer Letter between IDI and Julian Adams dated as of August 19, 2003. Previously filed as Exhibit 10.10 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.13*	Amendment to Offer Letter between IDI and Julian Adams dated as of October 25, 2007. Previously filed as Exhibit 99.4 to the Registrant's Current Report on Form 8-K filed on October 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.14*	Offer Letter between IDI and Adelene Perkins dated as of February 6, 2002. Previously filed as Exhibit 10.11 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.15*	Amendment to Offer Letter between IDI and Adelene Perkins dated as of October 25, 2007. Previously filed as Exhibit 99.5 to the Registrant's Current Report on Form 8-K filed on October 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.16	Pre-Merger Stock Incentive Plan. Previously filed as Exhibit 10.18 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>
10.17*	Form of Incentive Stock Agreement entered into with each of the officers identified on the schedule thereto. Previously filed as Exhibit 10.25 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.18*	Form of Nonstatutory Stock Option Agreement entered into with each of the officers identified on the schedule thereto. Previously filed as Exhibit 10.27 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.19	2000 Stock Incentive Plan. Previously filed as Exhibit 10.59 to the Registrant's Registration Statement on Form S-1 filed on May 9, 2000 (File No. 333-36638) and incorporated herein by reference.
10.20	Amendment No. 1 to 2000 Stock Incentive Plan; Amendment No. 2 to 2000 Stock Incentive Plan; Amendment No. 3 to 2000 Stock Incentive Plan. Previously filed as Exhibit 10.32 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.21	Amendment No. 4 to 2000 Stock Incentive Plan. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.22	Amendment No. 5 to 2000 Stock Incentive Plan. Previously filed as Exhibit 99.4 to the Registrant's Registration Statement on Form S-8 filed on May 23, 2008 (File No. 333-151135) and incorporated herein by reference.
10.23	Form of Incentive Stock Option Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.33 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.24	Form of Nonstatutory Stock Option Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.34 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.25	2010 Stock Incentive Plan. Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 28, 2010 (File No. 333-31141) and incorporated herein by reference.
10.26	Form of Incentive Stock Option Agreement under 2010 Stock Incentive Plan. Previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on May 28, 2010 (File No. 333-31141) and incorporated herein by reference.
10.27	Form of Nonstatutory Stock Option Agreement under 2010 Stock Incentive Plan. Previously filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on May 28, 2010 (File No. 333-31141) and incorporated herein by reference.
10.28	Amendment No. 1 to 2010 Stock Incentive Plan. Previously filed as Exhibit 99.2 to the Registrant's Current Report on Form 8-K filed on December 14, 2010 (File No. 333-31141) and incorporated herein by reference.
21.1	Subsidiaries of the Registrant. Filed herewith.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. Filed herewith.
31.1	Certification of principal executive and principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1	Statement of principal executive and principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.

**Table of Contents**

<b>Exhibit</b>	<b>Description</b>
101	The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, (iv) the Consolidated Statements of Stockholders' Equity, and (v) Notes to Consolidated Financial Statements.

\* Indicates management contract or compensatory plan  
Confidential treatment has been requested and/or granted as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.  
Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed as part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.