

INFINITY PHARMACEUTICALS, INC.

Form 10-K

March 16, 2011

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**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, 2010

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-31141

**INFINITY PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of

**33-0655706**  
(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**  
(Title of each class)

**NASDAQ Global Select Market**  
(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 ☐  
(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, 2010 was \$106,868,142 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Market on that date.

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Number of shares outstanding of the registrant's Common Stock as of February 28, 2011: 26,545,580

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

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than May 2, 2011 in connection with our 2011 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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### **Forward-Looking Information**

*This report contains forward-looking statements regarding our expectations regarding discovery and development milestones in 2011, our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy, and other objectives for future operations. You can identify these forward-looking statements by their use of words such as anticipate, believe, estimate, expect, forecast, intend, plan, project, target, will and other words and terms of similar meaning. 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 our actual results 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 a drug discovery and development company that is utilizing our strength in small molecule drug technologies to discover and develop medicines for difficult-to-treat diseases. Our discovery program has generated four clinical stage drug candidates spanning programs in the inhibition of the Hedgehog signaling pathway, heat shock protein 90, or Hsp90, chaperone system, and fatty acid amide hydrolase, or FAAH. In July 2010, we also obtained global development and commercialization rights to develop inhibitors of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K.

**Hedgehog Pathway Inhibitor Program.** Our lead product candidate is IPI-926, 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. We are actively enrolling patients in the Phase 2 portion of a Phase 1b/2 clinical trial evaluating IPI-926 in combination with gemcitabine, also known as Gemzar®, in patients with previously untreated, metastatic, pancreatic cancer, and have initiated a Phase 2 clinical trial evaluating IPI-926 as a single agent in patients with metastatic or locally advanced, inoperable chondrosarcoma. We expect to present data from the Phase 1b portion of the pancreatic cancer trial later this year. We are also evaluating IPI-926 in a Phase 1 clinical trial in patients with advanced or metastatic solid tumors, including patients with basal cell carcinoma, or BCC. Preliminary data from this trial were presented at the European Society for Medical Oncology Congress in October 2010 and we expect to present follow-up data at a medical meeting later in 2011. 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 Chaperone Inhibitor Program.** Our next most advanced program is directed at Hsp90 which is emerging as a major therapeutic target of interest for the treatment of a broad range of cancers. Inhibition of the Hsp90 chaperone knocks out a critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. Thus, Hsp90 chaperone inhibition may represent an important approach to treating certain cancers. Our lead Hsp90 inhibitor, IPI-504, is a novel, small molecule, semi-synthetic analog of the natural product geldanamycin that is delivered as a water-based, intravenous infusion. IPI-504 is currently being

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evaluated in two ongoing clinical trials, both of which are focused on patients with non-small cell lung cancer, or NSCLC. One trial is a Phase 1b trial in combination with docetaxel, also known as Taxotere®, that initially enrolled patients with advanced solid tumors and expanded in 2009 to focus on patients with advanced NSCLC. The second trial is an investigator sponsored trial in NSCLC patients with anaplastic lymphoma kinase, or ALK, gene rearrangements. We anticipate reporting final data from the Phase 1b trial during 2011. We also expect to present data from a completed Phase 2 clinical trial evaluating IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer at a medical meeting in 2011.

In parallel with the development of IPI-504, we are pursuing development of IPI-493, a proprietary, orally available inhibitor of Hsp90. IPI-493 has demonstrated anti-tumor activity in multiple preclinical models of human cancer, including NSCLC, breast cancer, colon cancer, and hematological malignancies. We are evaluating IPI-493 in two Phase 1, dose escalation studies to determine the optimal dose and schedule for future development.

In 2011, we anticipate reporting data from our Hsp90 program and announcing a path forward based on data from our ongoing clinical trials and relevant preclinical studies. We have worldwide development and commercialization rights for our Hsp90 chaperone inhibitor program.

**PI3K Inhibitor Program.** In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained global development and commercialization rights to Intellikine's portfolio of inhibitors targeting the delta and/or gamma isoforms of PI3K. We believe that specifically targeting PI3Kdelta and PI3Kgamma may provide multiple opportunities to develop differentiated therapies against inflammatory and autoimmune diseases as well as hematologic cancers. Our lead compound in this program, IPI-145, is an orally-available, small molecule, dual-selective inhibitor of PI3Kdelta and PI3Kgamma. IPI-145 has demonstrated activity in several preclinical models of inflammation. We intend to commence clinical development of IPI-145 in the second half of 2011. Mundipharma has commercialization rights outside of the United States for products arising from our PI3K inhibitor program.

**FAAH Inhibitor Program.** Finally, we have a program directed toward 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. The lead compound in our FAAH program is IPI-940, a novel, orally available inhibitor of FAAH with potential application for the treatment of a broad range of painful or inflammatory diseases. In October 2010, we reported top-line data from a Phase 1 randomized clinical trial of IPI-940 in 48 healthy adult volunteers demonstrating marked FAAH inhibition and increased anandamide levels. In addition, IPI-940 was well tolerated, with no observed dose-limiting toxicities or clinically significant changes in clinical laboratory values, vital signs or electrocardiogram parameters. Additional Phase 1 development of IPI-940 is ongoing.

In October 2010, Mundipharma and its independent associated company Purdue Pharmaceutical Products L.P., or Purdue, exercised their rights to assume worldwide development and commercialization activities for products arising out of the FAAH program and will fund 100% of all subsequent research, development and commercialization expenses. We anticipate completing transition activities for the FAAH program in 2011 to facilitate Phase 2 clinical trials in pain by 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,

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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. Since January 3, 2011, our common stock has traded on the NASDAQ Global Select Market.

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 what we believe to be an innovative approach 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. More importantly, our goal is to successfully integrate these disciplines to rapidly identify drug candidates and assess their potential utility.

Our four current clinical candidates which have broad potential applicability in the fields of oncology and pain emerged from our internal research efforts. Behind 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. We are drawn to targets that have the potential to represent fundamentally new approaches to how disease is treated, and where we can use our scientific capabilities to identify differentiated drug candidates with clearly-defined development paths. And because discovery doesn't 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 products.

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 all 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 have a substantial royalty interest in the U.S. commercialization of IPI-940, which is primarily directed to pain.

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Our product development programs as of February 28, 2011 are illustrated in the following chart:

During 2011, we expect to advance our product development pipeline by achieving the following program milestones:

### *Hedgehog Pathway Inhibitor Program*

Continuing enrollment in the Phase 2 portion of the Phase 1b/2 clinical trial evaluating IPI-926 in combination with gemcitabine in patients with pancreatic cancer and the Phase 2 clinical trial evaluating IPI-926 as a single agent in patients with chondrosarcoma

Presenting data from the Phase 1b portion of the pancreatic cancer trial

Beginning additional clinical development

Initiating a broad investigator-sponsored clinical trial program

### *Hsp90 Chaperone Inhibitor Program*

Presenting Phase 1 data of IPI-504 in combination with docetaxel in patients with solid tumors, including an expansion cohort in patients with non-small cell lung cancer

Announcing a path forward for our Hsp90 program

### *PI3K Inhibitor Program*

Beginning a Phase 1 clinical trial in the second half of 2011

### *FAAH Inhibitor Program*

Completing transition activities to facilitate Phase 2 trials in pain by Purdue



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### *Discovery Program*

Expanding our pipeline by naming a new development candidate

#### ***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 mechanisms:

Targeting the tumor microenvironment: In certain cancers, such as pancreatic cancer, the tumor cells signal to stromal cells in the microenvironment, which provides support for tumor growth and survival. Inhibition of the Hedgehog pathway may deplete the stroma, increase the vascularity of the tumor, and render the tumor more accessible to chemotherapy.

Targeting residual disease: In some cancers, such as NSCLC, prostate cancer 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.

Targeting the tumor cell: In some cancers, such as BCC, and some medulloblastomas, genetic mutation is responsible for malignant activation of the Hedgehog pathway. In these cancers, inhibition of the Hedgehog pathway may result in tumor cell death and tumor regression.

We are developing IPI-926, 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. When systemically administered in multiple preclinical animal models representing a wide variety of cancers, IPI-926 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 actively enrolling patients in the Phase 2 portion of a Phase 1b/2 trial evaluating IPI-926 in combination with gemcitabine in patients with previously untreated, metastatic, pancreatic cancer. Pancreatic cancer is the fourth leading cause of cancer death in the United States, and it is estimated that more than 40,000 people are diagnosed with pancreatic cancer in the United States annually. Notoriously difficult-to-treat, pancreatic cancer has the highest mortality rate of all major cancers. The one-year relative survival rate for pancreatic cancer is 20 percent and the five-year relative survival rate is just five percent. The average life expectancy for patients with metastatic disease is three to six months. Unfortunately, pancreatic cancer is one of the few cancers for which the survival rate has not improved substantially over nearly 40 years.

The Phase 2 portion of the trial is a multi-center, randomized, double-blind, study that will compare treatment with IPI-926 in combination with gemcitabine to treatment with placebo and gemcitabine. The primary endpoint is overall survival. Secondary endpoints include progression free survival, time to progression, and overall response rate. The trial is expected to enroll approximately 120 patients. The Phase 2 portion of the trial follows the successful completion of Phase 1b portion of the trial, which evaluated once-daily oral administration of IPI-926 at escalating doses in combination with weekly intravenous administration of gemcitabine and established 160 mg/m<sup>2</sup> as the dose of IPI-926 that will be used in the Phase 2 portion of the ongoing trial. We expect to present data from the Phase 1b portion of the trial later in 2011.

We have also initiated a Phase 2 clinical trial evaluating IPI-926 as a single agent in patients with metastatic or locally advanced, inoperable chondrosarcoma. Chondrosarcoma is a rare, life-threatening bone cancer. In the United States, chondrosarcoma accounts for approximately one-third of the 2,000 cases of primary bone cancer

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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 Phase 2 clinical trial is designed to compare the safety and efficacy of IPI-926 to matching placebo in patients with metastatic or locally advanced, inoperable chondrosarcoma. The primary endpoint of the trial is progression-free survival. Secondary endpoints include time to progression, overall survival, overall response rate and response duration. Patients in the placebo treatment arm who experience disease progression will have the option to cross over and receive IPI-926 in an open-label arm of the trial. We have received orphan drug designation from the U.S. Food and Drug Administration, or FDA, for IPI-926 for the treatment of chondrosarcoma.

We are also evaluating IPI-926 in a Phase 1 clinical trial in patients with advanced or metastatic solid tumors, including patients with BCC. Preliminary data from this trial were presented at the European Society for Medical Oncology Congress in October 2010. At the time of the data presentation, 60 patients had been enrolled, including 24 patients with BCC. In the BCC cohort, 17 patients were enrolled who were naïve to treatment with a Hedgehog pathway inhibitor. At that time, four clinical partial responses had been observed in this group of patients. Only one patient with BCC naïve to treatment with a Hedgehog pathway inhibitor had discontinued from the trial due to progression of disease, and this patient was on trial for more than 18 months. The patients who have remained on study are continuing to be followed, and we expect to present follow-up data on these patients at a medical meeting later in 2011. In addition, among patients with non-BCC solid tumors enrolled in the trial, three patients had stable disease that was durable for at least six months. IPI-926 was generally well tolerated in this trial, with the most common adverse events observed being Grade 1 and 2 fatigue and nausea. Pharmacokinetic data also confirmed the potential for once daily dosing.

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 Chaperone Inhibitor Program***

Hsp90 is emerging as a major therapeutic target of interest for the treatment of a broad range of cancers. Proteins are the essential building blocks and machines of the human body, and in order for proteins to function properly they must be stable and properly folded. The chaperone system of proteins, of which Hsp90 is a member, 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. Inhibition of the Hsp90 chaperone knocks out a critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. Thus, Hsp90 chaperone inhibition may represent an important approach to treating certain cancers.

We are developing two drug candidates in our Hsp90 chaperone inhibitor program: IPI-504 (retaspimycin hydrochloride), an intravenously-administered small molecule, and IPI-493, which is administered orally. We are conducting various clinical and preclinical studies of IPI-504 and IPI-493. These studies are focused on establishing a dose and schedule of administration that optimizes safety and efficacy of these candidates, and identifying patient populations, or subpopulations, most likely to benefit from Hsp90 chaperone inhibition.

**IPI-504.** Our lead Hsp90 inhibitor, IPI-504 (retaspimycin hydrochloride), is a novel, small molecule, semi-synthetic analog of the natural product geldanamycin that is delivered as a water-based, intravenous infusion. IPI-504 has also been shown in preclinical studies to inhibit Hsp90 potently and selectively, thereby inhibiting cancer cell growth. In addition, preclinical studies suggest that IPI-504 preferentially targets and accumulates in

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tumor tissues. For these reasons, we believe that IPI-504 has broad potential for the treatment of patients with a wide variety of solid and hematological tumors, including cancers that are resistant to other drugs.

We have two ongoing clinical trials evaluating IPI-504, both of which are focused on patients with NSCLC. Lung cancer is the leading cause of cancer death in the United States for both men and women and an estimated 222,520 new cases were expected in 2010. NSCLC is the most common form of lung cancer, accounting for about 85% of all lung cancers, and has a five year survival rate of just 17%.

We are continuing to evaluate patients in a Phase 1b clinical trial of IPI-504 in combination with docetaxel, also known as Taxotere®. The trial initially enrolled patients with advanced solid tumors, and expanded in late 2009 to focus on patients with advanced NSCLC. Preliminary data from the trial presented during the 2009 American Society of Clinical Oncology, or ASCO, Annual Meeting show that, to date, the combination regimen has been generally well tolerated in patients with a variety of solid tumor malignancies. Pharmacokinetic data showed no effect of IPI-504 on the clearance of docetaxel from the body. Data reported also show evidence of anti-tumor activity, with one partial response in a patient with metastatic pancreatic cancer refractory to gemcitabine, and six additional patients who experienced stable disease for at least three months. We anticipate reporting final data from this trial during 2011.

Data from a Phase 2 clinical trial of IPI-504 administered as a single agent in patients with NSCLC were reported during the ASCO Annual Meeting and published in the *Journal of Clinical Oncology* in 2010. The trial was designed to evaluate the safety, tolerability, and anti-tumor activity of IPI-504 in patients with Stage IIIb/IV NSCLC whose tumors have relapsed or become refractory to prior treatment with a tyrosine kinase inhibitor. A total of 76 patients were enrolled and stratified by their EGFR mutation status. A subset of patients also underwent EGFR, KRAS and BRAF genotyping analysis, as well as a fluorescent in situ hybridization assay to detect ALK gene rearrangements. The results of the Phase 2 trial show an objective response rate of seven percent in the overall study population: ten percent in patients who were EGFR wild-type, four percent in those with EGFR mutations, and twelve percent among KRAS wild-type patients. Among the patients with ALK rearrangements, there was a 67 percent response rate, with two of three patients experiencing partial responses and the third patient experiencing a 24 percent disease reduction, all three of whom received IPI-504 for at least six months. IPI-504 was generally well-tolerated in this trial. Most adverse events were Grade 1 or Grade 2. The most commonly reported adverse events (regardless of relationship to drug) were fatigue, nausea, diarrhea, vomiting and cough. Validation of these findings is ongoing in an investigator-sponsored trial at Massachusetts General Hospital by Dr. Lecia Sequist, the principal investigator of the Phase 2 trial.

In 2010, we also completed an interim review of data from the first cohort of patients enrolled in a Phase 2 clinical trial evaluating IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer. This review showed that IPI-504 was well-tolerated when administered at 300 mg/m<sup>2</sup> once weekly in combination with trastuzumab in this heavily pre-treated patient population. Clinical activity was also observed at this dose and schedule, but it was insufficient to satisfy our rigorous stage gate for continuation of this trial. While we believe that the insufficient clinical activity in this trial was the result of IPI-504 being administered at a less than optimal dose in this combination, we do not intend to continue development of IPI-504 in breast cancer in light of the evolving therapeutic landscape. We expect to present data from this clinical trial at a medical meeting in 2011.

**IPI-493.** In parallel with the development of IPI-504, we are pursuing development of IPI-493, a proprietary, orally available inhibitor of Hsp90. IPI-493 has demonstrated anti-tumor activity in multiple preclinical models of human cancer, including NSCLC, breast cancer, colon cancer, and hematological malignancies. IPI-493 has also demonstrated favorable pharmaceutical properties, including potent inhibition of Hsp90, selectivity for cancer cells over normal cells and high oral bioavailability. We are evaluating IPI-493 in two Phase 1, dose escalation studies to determine the optimal dose and schedule for future development. One study is designed to assess the safety, tolerability, pharmacokinetic parameters and pharmacodynamic markers of biological activity of IPI-493 in patients with advanced hematologic malignancies. The second study is being conducted in patients with advanced solid tumors.

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In 2011, we anticipate reporting data from our Hsp90 program and announcing a path forward based on data from our ongoing clinical trials and relevant preclinical studies.

We have worldwide development and commercialization rights for our Hsp90 chaperone inhibitor program, which includes IPI-504 and IPI-493, subject to the payment of a single-digit royalty on net sales to our former partner, MedImmune, Inc., an affiliate of AstraZeneca plc.

### ***PI3K Inhibitor Program***

In July 2010, we entered into a development and license agreement with Intellikine under which we obtained global development and commercialization rights to Intellikine's portfolio of inhibitors targeting the delta and/or gamma isoforms of PI3K. The PI3Ks are a family of enzymes involved in cellular functions, including cell proliferation and survival, cell differentiation, intracellular trafficking and immunity. The delta and gamma isoforms of PI3K are restricted to immune system cells. Therefore, specifically targeting PI3Kdelta and PI3Kgamma may provide multiple opportunities to develop differentiated therapies against inflammatory and autoimmune diseases as well as hematologic cancers.

Our lead compound in this program, IPI-145, is an orally-available, small molecule, dual-selective inhibitor of PI3Kdelta and PI3Kgamma. IPI-145 has demonstrated activity in several preclinical models of inflammation. We intend to commence clinical development of IPI-145 in the second half of 2011. Mundipharma has commercialization rights outside the United States for products arising from our PI3K inhibitor program.

### ***FAAH Inhibitor Program***

FAAH plays a role in the endocannabinoid system, which is made up of a group of enzymes and receptors shown to play an important role in modulating painful and inflammatory conditions affecting the central nervous system and the body as a whole. In response to painful stimuli or inflammation, the endocannabinoid system is activated and endocannabinoids are produced. Many endocannabinoids are fatty acid amides, or FAAs, which produce the body's own powerful analgesic and anti-inflammatory responses. FAAH breaks down FAAs, rendering the beneficial effects of FAAs short-lived. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and have applicability in a broad range of painful or inflammatory conditions.

IPI-940, a novel, orally available inhibitor of FAAH with potential application for the treatment of a broad range of painful or inflammatory conditions. In October 2010, we reported top-line data from a Phase 1 randomized clinical trial of IPI-940 in 48 healthy adult volunteers. The study assessed the pharmacokinetics, pharmacodynamics, safety and tolerability of IPI-940 following single oral administration at escalating dose levels. In the study, administration of IPI-940 resulted in marked FAAH inhibition and increased anandamide levels. In addition, IPI-940 was well tolerated, with no observed dose-limiting toxicities or clinically significant changes in clinical laboratory values, vital signs or electrocardiogram parameters. Additional Phase 1 development of IPI-940 is ongoing.

In October 2010, Mundipharma and Purdue exercised their rights to assume worldwide development and commercialization activities for products arising out of the FAAH program and will fund 100% of all subsequent research, development and commercialization expenses. In 2011, we anticipate completing transition activities to facilitate Phase 2 clinical trials in pain by Purdue.

### ***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

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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 2009 and 2010 was derived from our alliance with Purdue and Mundipharma.

***Purdue and Mundipharma.*** In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. The alliance currently includes product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of all our discovery projects in all disease fields that are conducted during a prescribed funded discovery period. In December 2010, Mundipharma exercised an option to extend the duration of the funded discovery period through December 31, 2012 and Mundipharma has the option to extend this period for an additional year. Our Hsp90 program is expressly excluded from the alliance. 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. Following entry into the strategic alliance agreements in November 2008, we consider Mundipharma, Purdue and associated entities to be related parties for financial reporting purposes because of their equity ownership in our company.

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. In October 2010, Mundipharma and Purdue exercised their rights to assume worldwide development and commercialization activities for products arising out of the FAAH program and will fund 100% of all subsequent research, development and commercialization expenses. For the remaining programs included in the alliance, Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the period between November 19, 2008 and December 31, 2009 was \$50 million and the contractually budgeted amounts for the year ended December 31, 2010 was \$65 million. The contractually budgeted amounts for 2011 and 2012 are \$85 million and \$110 million, respectively. Any activities we conduct related to the transition of the FAAH program to Purdue and Mundipharma will be reimbursed in addition to the contractually budgeted amount. For the remaining programs in the alliance, we have the right to exceed the contractually budgeted amount at our own expense, which we did in 2010 due primarily to the license of our PI3K inhibitor program, and which we expect to be the case in 2011 on account of enhanced clinical trial activities for IPI-926 and the commencement of clinical development of IPI-145. After the transition date for each product candidate, we will share with Mundipharma all research and development costs for such product candidate equally. We are recognizing revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recognized \$67.0 million, \$46.5 million and \$2.7 million in such revenue in the years ended December 31, 2010, 2009 and 2008, respectively.

In December 2010, we amended our strategic alliance agreement with Mundipharma. Under the original agreement Mundipharma had the right to opt out of any early discovery project or any preclinical or clinical development 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. Under the amendment, these time-based decisions have been modified to become event-based for the Hedgehog program only. Mundipharma will continue to have time-based annual opt-out rights in November of each year for the other programs in the alliance.

Under the amendment, Mundipharma's next funding commitment for the Hedgehog program must be made by the 30th day following the outcome of an end-of-Phase 2 meeting with the FDA pertaining to the ongoing clinical trial of IPI-926 in patients with pancreatic cancer (or, if the end-of-Phase 2 meeting is not held by

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November 1, 2013, then by November 30, 2013). Mundipharma is obligated to fully fund the Hedgehog program until it is required to make this further commitment. If Mundipharma elects to opt-out of continued development funding at this time, then Mundipharma would be obligated to make an immediate payment of \$23.65 million to us, which we can use on any research or development 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 IPI-926 that are ongoing at the time of the opt-out, so that aggregate residual funding could total \$47.3 million. If Mundipharma elects to continue participation in the Hedgehog program when it makes its next commitment, Mundipharma would thereafter have the annual November opt-out right, and one-year residual funding obligation, contained in the original agreement.

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.

Except as set forth above with respect to FAAH products and opt-out products, 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 arise out of the research program or products that are directed to the same target or pathway as a product included in the research program, unless and until a party terminates its rights with respect to such products.

If we in-license any product or product candidate during the funded discovery period for which GLP (Good Laboratory Practice) toxicology studies have been initiated and commercialization rights outside of the United States are available for grant by us to Mundipharma, Mundipharma will have the option to include such in-licensed product or product candidate in the alliance 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, in order for Mundipharma to obtain commercialization rights for such in-licensed product or product candidate in all countries outside of the United States, and by funding research and development costs in the same manner as products or product candidates arising out of our internal discovery programs. The agreement with Mundipharma provides for the agreed-upon research and development budgets to be updated to reflect the inclusion of any in-licensed products or product candidates. There will be no royalties paid between the parties on in-licensed candidates. If we in-license any product or product candidate during the funded discovery period for which GLP toxicology studies have not been initiated, as we did with our PI3K program in 2010, such products are automatically included in the alliance as having arisen out of our internal discovery projects within the then-existing contractually budgeted amounts.

Except with respect to products that have been in-licensed by us, 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 last-to-expire of specified patent rights and the

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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, Purdue or Mundipharma, 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. 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 Purdue or Mundipharma in the event of a change in control of Infinity or in the event that, during the funded research period, either Adelene Q. Perkins or Julian Adams is no longer a full-time executive of Infinity. Upon termination of either strategic alliance agreement by us or either Purdue or Mundipharma, either party to the other strategic alliance agreement may terminate that agreement.

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and line of credit agreement 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 an aggregate of six million shares of our common stock, plus warrants to purchase up to an aggregate of six million shares of our common stock at exercise prices ranging from \$15 to \$40 per share, for aggregate proceeds of \$75 million. As of December 31, 2010, none of these warrants have been exercised, and warrants to purchase up to five million shares of our common stock remain exercisable.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us during the three-year period that began on April 1, 2009. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

**Intellikine.** In July 2010, we entered a development and license agreement with 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. We paid Intellikine a \$13.5 million upfront license fee. 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, we provide financial support for research activities that may be conducted by Intellikine under a two year research program 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 may extend the research program for an additional year upon written notice to Intellikine at least 180 days prior to the last day of the initial two-year research term. We are also 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 Intellikine tiered royalties 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.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. Mundipharma, under the terms

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of its strategic alliance agreement with us, has commercialization rights outside the United States for products arising out of our PI3K inhibitor program. For a product directed primarily to an oncology indication, Intellikine 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.

Intellikine may terminate its participation rights in any oncology product with 12 months' prior written notice to us, after which Intellikine's participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Intellikine 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 Intellikine may research, develop or commercialize products directed to the PI3K delta and/or gamma isoforms which meet certain selectivity criteria.

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, Intellikine 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.

## **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 18 issued or allowed patents related to our clinical-stage programs expiring on various dates between 2024 and 2028 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 ten issued U.S. patents covering IPI-504 and related molecules, which expire on various dates between 2024 and 2025. IPI-493 and related formulations are protected by one issued or allowed U.S. patent, which expires no earlier than 2027. These patents and allowed patent applications include composition of matter, pharmaceutical composition, method of treatment, and synthetic method claims.

We have six issued or allowed U.S. patent applications covering IPI-926 and related molecules, which expire on various dates between 2025 and 2028. These patents include composition of matter, pharmaceutical composition, method of treatment, and synthetic method claims.

In addition, as of February 28, 2011, 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 2030. These patents and patent applications disclose composition of matter, pharmaceutical composition, methods of use and synthetic methods.



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Our policy is to obtain and enforce the patents and proprietary technology rights that are key 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 market commercial products, either on their own or through collaborative efforts.

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, Inc., through its collaboration with Curis, Inc., which we believe is conducting several Phase 2 clinical trials of GDC-0449, including a pivotal Phase 2 clinical trial in patients with basal cell carcinoma;

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

Novartis AG, which we believe is conducting a Phase 2 and multiple Phase 1 clinical trials of LDE 225 and a Phase 1 trial of LEQ-506;

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

Millennium Pharmaceuticals, Inc. (a subsidiary of Takeda Pharmaceutical Company Limited), which we believe is conducting a Phase 1 clinical trial of TAK-441.

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 STA-9090;

Vernalis plc, which we believe is conducting multiple Phase 1 and 2 clinical trials of AUY-922 in collaboration with Novartis;

Astex Therapeutics Limited, which we believe is conducting multiple Phase 1 clinical trials of AT-13387;

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

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

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

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

Novartis AG, which we believe is conducting a Phase 1 clinical trial of HSP990; and

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

We believe that the following companies, among others, are seeking to develop compounds targeting PI3K:

Calistoga Pharmaceuticals, which has entered into an agreement to be acquired by Gilead Sciences, Inc., and which we believe is conducting multiple Phase 1 and Phase 2 clinical trials of CAL-101 and a Phase 1 clinical trial of CAL-263;

Novartis AG, which we believe is conducting Phase 1 clinical trials of BEZ235, BGT226 and BKM120;

Pfizer, Inc., which we believe is conducting Phase 1 clinical trials of PF-04691502 and PF-05212384;

Semafore Pharmaceuticals, Inc., which we believe is conducting a Phase 1 clinical trial of SF1126;

Bayer AG, which we believe is conducting a Phase 1 clinical trial of an unnamed PI3K inhibitor;

GlaxoSmithKline plc., which we believe is conducting a Phase 1 clinical trial of GSK2126458;

Sanofi-aventis (through its collaboration with Exelixis, Inc.), which we believe is conducting multiple Phase 1 and Phase 2 clinical trials of XL147 and multiple Phase 1 clinical trials of XL765;

Genentech, Inc., which we believe is conducting multiple Phase 1 clinical trials of GDC-0941; and

Oncothyreon Inc., which we believe is conducting a Phase 1/2 clinical trial of PX-866.

Finally, we believe Ironwood Pharmaceuticals, Inc. is conducting a Phase 1/2 clinical trial of IW-6118.

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.

## **Research and Development**

As of February 28, 2011, our research and development group consisted of 133 individuals, of whom over 35 percent hold Ph.D. or M.D. degrees and over an additional 20 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, 2010, 2009 and 2008 was approximately \$99.2 million, \$77.9 million and \$47.5 million, respectively. Reimbursement for our strategic collaborator-sponsored research and development expenses totaled approximately \$67.0 million, \$46.5 million and \$20.1 million, for the years

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ended December 31, 2010, 2009 and 2008, respectively. In calculating strategic collaborator-sponsored research and development expenses, we have included all reimbursement for our research and development efforts, whether the amounts are included in revenue or as a credit to research and development expense, 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

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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 IPI-926. This product is currently supplied from naturally available plant material. If IPI-926 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 locations where this plant naturally occurs and to establish a sustainable method 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 IPI-504 and IPI-493. 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. There is no 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 Good Laboratory Practices regulations;

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 pre-clinical tests must comply with federal regulations and requirements including



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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, 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

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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, 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 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.



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### ***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 institutional review board 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 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 has granted Orphan Drug designation to IPI-926 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

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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 28, 2011, we had 168 full-time citizen-owners, 133 of whom were engaged in research and development and 35 of whom were engaged in management, administration and finance. Over 52 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.

## **Executive Officers**

The following table lists the positions, names and ages of our executive officers as of February 28, 2011:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Adelene Q. Perkins	51	President and Chief Executive Officer
Julian Adams, Ph.D.	56	President of Research & Development
Vito J. Palombella, Ph.D.	48	Chief Scientific Officer
Gerald E. Quirk, Esq.	43	Vice President, Corporate Affairs and General Counsel
Pedro Santabarbara, M.D., Ph.D.	58	Chief Medical Officer
Winselow S. Tucker, Jr.	43	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 the 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, now a business unit of Wyeth Pharmaceuticals, Inc., 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.

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*Julian Adams, Ph.D.* has served as our President of Research & Development since October 2007, our Chief Scientific Officer between October 2003 and May 2010, and as our President from February 2006 until October 2007. 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 received a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology in the field of synthetic organic chemistry.

*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 from January 2004 to September 2006 at Infinity. Prior to joining Infinity, Dr. Palombella was Director of Molecular Biology 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-κB 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 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®. Prior to 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.

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*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 Tasigna® (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.

## **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 Business Conduct and Ethics and the charters of the Audit, Compensation and Nominating & Corporate Governance Committees of our board of directors are all available on the corporate governance section of our website at <http://investor.ipi.com>. 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, including statements about our growth and future operating results, discovery and development of products, strategic alliances and intellectual property. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We often use the words believe, anticipate, plan, expect, intend, may, similar expressions to help identify forward-looking statements. We cannot assure you that our assumptions and expectations will prove to have been correct. For example, there can be no guarantee that our strategic alliance with Mundipharma and 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. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, including 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 clinical candidates is high. To date, the data supporting our clinical development strategy for IPI-926, IPI-504, IPI-493, and IPI-940 are derived solely from laboratory and

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preclinical studies and, in the case of IPI-926 and IPI-504, limited early-to-mid-stage clinical trials. Later clinical trials may not yield data consistent with earlier clinical trials, as was the case in our Phase 3 clinical trial of IPI-504 in patients with gastrointestinal stromal tumors, or GIST, which we elected to close in April 2009 when an early review of safety data showed a higher than anticipated mortality rate among patients enrolled in the treatment arm. In such a case, it may be necessary for us to change our development strategy or abandon development of that drug candidate, either of which would result in delays and additional costs. We are conducting various clinical and preclinical studies of IPI-504 and IPI-493. These studies are focused on seeking to establish a dose and schedule of administration that optimizes safety and efficacy of these candidates, and identifying patient populations, or subpopulations, most likely to benefit from Hsp90 chaperone inhibition. If these studies do not yield results we believe are necessary to warrant further development, we may elect to discontinue further development of the applicable drug candidate. It is impossible to predict when or if IPI-926, IPI-504, IPI-493, IPI-940, IPI-145 or any of our other 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 IPI-926, IPI-940 and product candidates arising out of our Hedgehog pathway, fatty acid amide hydrolase, or FAAH, phosphoinositide-3 kinase, or PI3K, and early discovery programs, and with Purdue to develop and commercialize product candidates arising out of our FAAH program in the United States. 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. In addition, we have a collaboration with Intellikine to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K. Under this alliance, Intellikine has committed to provide significant chemistry and biochemistry capabilities. The success of these alliances 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 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 funded research period, 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 PI3K program, and early discovery programs in November of each calendar year, subject to

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12 months of continued funding. In addition, Mundipharma has the right to opt-out of continued development funding of our Hedgehog pathway program within 30 days following the outcome of an end-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, pertaining to the ongoing clinical trial of IPI-926 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), subject to prescribed residual funding obligations. If Mundipharma elects to continue participation in the Hedgehog program when it makes its next commitment, Mundipharma 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 successfully develop, introduce, market and sell new products. In some cases, we will not be involved in these processes and 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 program and our early stage development programs, and Purdue and Mundipharma are jointly responsible for all development and commercialization activities for products arising out of the FAAH program. Any of our current or future alliance partners may fail to develop or effectively commercialize products using our products or technologies 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.

Further, while our agreement with Intellikine precludes Intellikine from developing or commercializing products directed to the PI3K delta and/or gamma isoforms that meet certain selectivity criteria, Intellikine 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, 2010, we had an accumulated deficit of \$229.0 million. We have spent, and expect to continue to spend, significant resources to fund the research and development of IPI-926, IPI-504, IPI-493, IPI-940, 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.

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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 cash and investments, together with research and development funding from Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, and the \$50 million line of credit that has been made available to us by Purdue Pharma L.P., 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 or if we do not receive the payments we expect to receive from Mundipharma and Purdue. 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 acquire a third party or license rights to additional drug candidates or new technologies from one or more third parties;

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 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 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





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achievement of our research, development and commercialization objectives. For example, Purdue and Mundipharma each have the right to terminate its strategic alliance with us if, during the funded research period, 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.

### ***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 acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any one of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to exploit acquired technologies, or the loss of key employees from either our business or the acquired business.

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

As of December 31, 2010, we had approximately \$101 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. These investments are subject to general credit, liquidity, market and interest rate risks. We may realize losses in the fair value of these investments or a complete loss of these investments. In 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 condition and results of operations.

### ***On March 15, 2011, we restated our financial statements for the years ended December 31, 2009 and 2008 and for the quarters ended March 31, June 30 and September 30, 2010 and 2009. The restatement could cause our stock price to decline and could subject us to securities litigation.***

Following a routine review by the staff of the SEC of our annual report on Form 10-K for the year ended December 31, 2009, and based upon the determination of the audit committee of our board of directors, we recently restated our financial statements for the years ended December 31, 2009 and 2008, and for the quarters ended March 31, June 30 and September 30, 2010 and 2009 as reflected in an amended 2009 annual report on Form 10-K/A and amended quarterly reports on Form 10-Q/A for the applicable periods. We have restated (i) our consolidated balance sheets as of December 31, 2009 and 2008 by increasing amounts reported in deferred revenue (short term and long term) and total current liabilities and total liabilities, and reducing amounts reported in additional paid-in capital, or APIC, and accumulated deficit and total stockholders' equity; (ii) our consolidated statements of operations for the year ended December 31, 2009 by increasing amounts reported in collaborative research and development revenue

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from Purdue entities and total revenue and decreasing amounts reported in loss from operations, loss before income taxes, net loss, and basic and diluted loss per common share; and (iii) our consolidated statements of operations for the year ended December 31, 2008 by increasing amounts reported in collaborative research and development revenue from Purdue entities, total revenue, income from operations, net income, and basic and diluted earnings per common share. As a result of these restatements, amounts in our consolidated statements of cash flows and stockholders equity for the years ended December 31, 2009 and 2008 have also been corrected. Our total cash flows from operations in these periods remain unchanged.

The restatement relates to our accounting for the initial recognition of a loan commitment representing the future availability to us, on below-market terms, of the \$50 million line of credit extended to us by Purdue, and its independent associated company, Purdue Pharma L.P., or PPLP, in November 2008 upon entry into a strategic alliance with Purdue and Mundipharma. This written loan commitment, or loan commitment asset, met the definition of a financial instrument and we therefore recorded it as an asset. We determined that the fair value of the loan commitment asset was \$17.3 million. We recorded the fair value of this asset in 2008 and began amortizing this balance to interest expense over the life of the loan arrangement, or ten years, on April 1, 2009, the date at which we could first draw upon the line of credit.

Once we concluded that the loan commitment asset should be recorded at fair value, we were required to record an offsetting credit. Based on our evaluation of the relevant accounting guidance, we initially recorded the offset to the loan commitment asset to APIC, in part because Purdue and its associated companies would be principal stockholders at the time we could benefit from favorable terms of the line of credit.

Following discussions with the SEC staff, we have determined the offset to the loan commitment asset should have been recorded as deferred revenue rather than APIC. We are amortizing the deferred revenue to revenue over the 14 year period beginning in November 2008 (approximately \$300,000 per quarter), which is our estimated period of performance under the strategic alliance.

The restatement could result in a decline in our stock price and securities class action litigation. In the past, securities class action litigation has often been brought in connection with restatements of financial statements. 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 business, results of operations and financial condition.

***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.

For example, in March 2011, we restated our financial statements for certain prior periods to correct the way we had previously recorded the offset to the loan commitment asset related to a line of credit extended to us by Purdue and PPLP. For a further discussion of this restatement, see the foregoing discussion in the risk factor captioned "On March 15, 2011, we restated our financial statements for the years ended December 31, 2009 and 2008 and for the quarters ended March 31, June 30 and September 30, 2010 and 2009. The restatement could cause our stock price to decline and could subject us to securities litigation."

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*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 success depends primarily upon our, and our strategic alliance partners', ability to develop and commercialize our drug candidates successfully. Our Hedgehog pathway inhibitor, IPI-926 is being evaluated in the Phase 2 portion of a Phase 1b/2 clinical trial and Phase 1 clinical trial. Our two drug candidates in our Hsp90 program are IPI-504, which is currently being evaluated in a Phase 1b clinical trial as well as an investigator-sponsored trial, and IPI-493, which is being evaluated in two Phase 1 clinical trials. We are completing Phase 1 development of IPI-940, our FAAH inhibitor. We also have other drug candidates in various stages of preclinical development and discovery research, including IPI-145, the lead compound in our PI3K inhibitor program.

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. 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 IPI-926, IPI-504, IPI-493, IPI-940 and any other drug candidate we may seek to develop in the future, including IPI-145, 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 3 clinical trial of IPI-504 in GIST; and

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

We are conducting various clinical and preclinical studies of IPI-504 and IPI-493. These studies are focused on seeking to establish a dose and schedule of administration that optimizes safety and efficacy of these candidates, and identifying patient populations, or subpopulations, most likely to benefit from Hsp90 chaperone inhibition. If these studies do not yield results we believe are necessary to warrant further development, we may elect to discontinue further development of the applicable drug candidate.

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

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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 close our Phase 3 clinical trial of IPI-504 in GIST, 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 or deficient quality of 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

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

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.

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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 results of operations and financial condition.

***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 our clinical trials 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

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 results of operations and financial condition.

*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

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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 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 other 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 IPI-926. 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 or establishing a sustainable method for growing this plant in a controlled environment. A material shortage of this plant could adversely impact or disrupt the manufacture of IPI-926, thus impacting our clinical trial activities and, if IPI-926 is successfully developed, our ability to satisfy commercial demand for the product, thus adversely affecting our financial position and results of operations.



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

We currently have commercialization rights in the United States for products arising out of our all of our programs, except the FAAH program, and worldwide commercialization rights for our Hsp90 chaperone inhibitor program, including IPI-504 and IPI-493. 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 and sales capabilities, our ability to successfully commercialize any drug candidates that we successfully develop will be adversely affected, as will our financial condition and results of operations. Even if we do develop such capabilities, we will compete with other companies that have more experienced and well-funded marketing and sales 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;

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 collaborators, 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, good manufacturing practices, 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

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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 which 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 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.

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### ***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. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell our products profitably. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our potential products, which would adversely affect our business strategy, operations and financial results. For example, in March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010. This law, which we refer to as the PPACA, may have far reaching consequences for biopharmaceutical companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services and drugs. These structural changes could entail modifications to the existing system of private payors and government programs, such as Medicare and Medicaid, creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the United States could impact the reimbursement for prescribed drugs, including our product candidates. If reimbursement for our approved product candidates, if any, is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

In addition, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare will cover and reimburse for pharmaceutical products. This legislation could also decrease the coverage and price that we may receive for our products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a profitable basis.

Further federal and state proposals and health care reforms could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Our results of operations could be materially adversely affected by the PPACA, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

### ***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 health care 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

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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.

## **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, F. Hoffmann-La Roche Ltd. and its subsidiary Genentech, Inc., 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 for compounds targeting the Hedgehog pathway, which is the target of IPI-926. These companies include without limitation, Genentech, Inc. (through its collaboration with Curis, Inc.), Bristol Myers

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Squibb Company (through its collaboration with Exelixis, Inc.), Novartis AG, Pfizer, Inc. and Millennium Pharmaceuticals, Inc. (a subsidiary of Takeda Pharmaceutical Company Limited). In addition, we believe the following companies are developing compounds that target Hsp90, which is the target of IPI-504 and IPI-493: Synta Pharmaceuticals Corp., Vernalis plc (in collaboration with Novartis), Astex Therapeutics Limited, Exelixis, Inc., Myrexix, Inc., Kyowa Hakko Kirin Co. Ltd., Celgene Corporation, Novartis AG and Debiopharm Group. Also, we believe that Calistoga Pharmaceuticals, which has entered into an agreement to be acquired by Gilead Sciences, Inc., Novartis AG, Pfizer, Inc., Semafore Pharmaceuticals, Inc., Bayer AG, GlaxoSmithKline plc, sanofi-aventis (through its collaboration with Exelixis, Inc.), Genentech, Inc. and Oncothyreon Inc. are developing drugs that target PI3K. Finally, we believe that Ironwood Pharmaceuticals, Inc. is developing inhibitors of FAAH.

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 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,

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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. Our lead oral Hsp90 candidate, IPI-493, contains an active pharmaceutical ingredient for which we believe composition of matter protection is unavailable. Consequently, we have filed patent applications directed to IPI-493 and other novel formulations of this active pharmaceutical ingredient, as well as methods of their use, which may not provide the same level of protection as composition of matter patent protection on the active pharmaceutical ingredient itself.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions 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 patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. 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. In addition, the U.S. Congress has considered, and may consider in the future, legislation that could change United States law regarding, among other things, post-grant review of issued patents and the calculation of damages once patent infringement has been determined by a court of law. If enacted into law, these provisions could severely weaken patent protection in the United States.

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

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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 IPI-504. These third parties have pending applications related to these analogs, but we have the first published application covering IPI-504. 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 IPI-504 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.

***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. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.



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***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 chaperone inhibitor program, we are conducting a clinical trial evaluating the administration of IPI-504 in combination with docetaxel, and we may conduct additional trials with IPI-504 in combination with other therapeutic agents. We are aware of issued patents and published applications directed to combinations of Hsp90 chaperone inhibitors with a variety of other therapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 chaperone 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 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.

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### ***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 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 Intellikine, 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 IPI-926, IPI-504, IPI-493, IPI-940 and our other 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;

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 Purdue and Mundipharma and our development and license agreement with Intellikine, Inc.;

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;

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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 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 health care 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 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

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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.

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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 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 32% 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. The first lease covering a total of approximately 67,000 square feet of laboratory and office space has a term ending in December 2012. 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 has a term ending in December 2012 with an option to extend through 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. (Removed and Reserved)**

**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 on the NASDAQ Global Market of 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.

	2010		2009	
	High	Low	High	Low
First quarter	\$ 6.68	\$ 5.75	\$ 8.87	\$ 7.08
Second quarter	7.96	5.85	8.75	4.77
Third quarter	6.33	4.42	8.99	5.40
Fourth quarter	6.99	5.09	6.60	5.34

**Holders**

As of February 28, 2011, there were 130 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, 2005 through December 31, 2010 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, 2005, and that all dividends were reinvested. No cash dividends have been declared or paid on our common stock.

As a result of the merger of Discovery Partners International, Inc. with IPI on September 12, 2006, we changed our corporate name from Discovery Partners International, Inc. to Infinity Pharmaceuticals, Inc. Stock performance shown in the graph below prior to September 12, 2006 reflects results of Discovery Partners International, Inc. prior to the merger.

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.

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**Comparison of 5-Year Cumulative Total Return**  
**among Infinity Pharmaceuticals, Inc. (known as Discovery Partners International, Inc. prior to 9/12/06),**  
**the NASDAQ Stock Market (U.S.) Index,**  
**and the NASDAQ Biotechnology Index**

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**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. Our financial statements prior to September 12, 2006 reflect results of IPI prior to its merger with Discovery Partners International, Inc. Amounts below are in thousands, except for shares and per share amounts.

	Year Ended December 31,				
	2010	2009	2008	2007	2006
<b>Statement of Operations Data:</b>					
Collaborative research and development revenue:					
From Purdue entities	\$ 71,331	\$ 50,765	\$ 3,027	\$	\$
Other(1)			80,558	24,536	18,494
Total revenue	71,331	50,765	83,585	24,536	18,494
Operating expenses:					
Research and development	99,231	77,857	47,466	33,793	35,792
General and administrative	21,070	19,456	16,837	14,034	9,464
Total operating expenses	120,302	97,313	64,303	47,827	45,256
Income (loss) from operations	(48,971)	(46,548)	19,282	(23,291)	(26,762)
Interest income (expense), net	(1,447)	744	3,321	6,393	953
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				
Debt extinguishment charge					(1,551)
Income (loss) before income taxes	(49,684)	(31,609)	23,798	(16,898)	(27,360)
Income tax benefit (expense)	700	330			(1,088)
Net income (loss)	\$ (48,984)	\$ (31,279)	\$ 23,798	\$ (16,898)	\$ (28,448)
Earnings (loss) per common share:(2)					
Basic	\$ (1.86)	\$ (1.20)	\$ 1.18	\$ (0.87)	\$ (3.81)
Diluted	\$ (1.86)	\$ (1.20)	\$ 1.15	\$ (0.87)	\$ (3.81)
Weighted average number of common shares outstanding:(2)					
Basic	26,321,398	26,096,515	20,236,743	19,511,485	7,463,426
Diluted	26,321,398	26,096,515	20,765,536	19,511,485	7,463,426

- (1) Revenue for the year ended December 31, 2008 was impacted by the acceleration of revenue recognition for the up-front license fees received from Novartis Institutes for BioMedical Research and MedImmune, Inc.
- (2) Basic and diluted earnings (loss) per common share and weighted average number of common shares outstanding were impacted by the conversion of preferred stock and issuance of common stock in connection with the merger on September 12, 2006 between IPI and Discovery Partners International, Inc.

	2010	2009	As of December 31, 2008	2007	2006
<b>Selected Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities, including long-term	\$ 100,959	\$ 130,737	\$ 126,772	\$ 114,189	\$ 101,697
Working capital	75,378	119,408	119,360	97,097	121,264
Total assets	124,566	157,318	160,618	129,725	154,648
Accumulated deficit	(229,010)	(180,026)	(148,747)	(172,546)	(155,305)

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Total stockholders' equity	49,484	90,312	103,121	51,143	62,425
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### **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 a drug discovery and development company that is utilizing our strength in small molecule drug technologies to discover and develop medicines for difficult-to-treat diseases. Our discovery program has generated four clinical stage drug candidates spanning programs in the inhibition of the Hedgehog signaling pathway, heat shock protein 90, or Hsp90, chaperone system, and fatty acid amide hydrolase, or FAAH. In July 2010, we also obtained global development and commercialization rights to develop inhibitors of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K.

***Hedgehog Pathway Inhibitor Program.*** Our lead product candidate is IPI-926, 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. We are actively enrolling patients in the Phase 2 portion of a Phase 1b/2 clinical trial evaluating IPI-926 in combination with gemcitabine, also known as Gemzar®, in patients with previously untreated, metastatic, pancreatic cancer and have initiated a Phase 2 clinical trial evaluating IPI-926 as a single agent in patients with metastatic or locally advanced, inoperable chondrosarcoma. We expect to present data from the Phase 1b portion of the pancreatic cancer trial later this year. We are also evaluating IPI-926 in a Phase 1 clinical trial in patients with advanced or metastatic solid tumors, including patients with basal cell carcinoma, or BCC. Preliminary data from this trial were presented at the European Society for Medical Oncology Congress in October 2010 and we expect to present follow-up data at a medical meeting later in 2011. 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 Chaperone Inhibitor Program.*** Our next most advanced program is directed at Hsp90 which is emerging as a major therapeutic target of interest for the treatment of a broad range of cancers. Inhibition of the Hsp90 chaperone knocks out a critical source of support for cancer cells, leading to tumor growth inhibition and cancer cell death. Thus, Hsp90 chaperone inhibition may represent an important approach to treating certain cancers. Our lead Hsp90 inhibitor, IPI-504, is a novel, small molecule, semi-synthetic analog of the natural product geldanamycin that is delivered as a water-based, intravenous infusion. IPI-504 is currently being evaluated in two ongoing clinical trials, both of which are focused on patients with non-small cell lung cancer, or NSCLC. One trial is a Phase 1b trial in combination with docetaxel, also known as Taxotere®, that initially enrolled patients with advanced solid tumors and expanded in 2009 to focus on patients with advanced NSCLC. The second trial is an investigator sponsored trial in NSCLC patients with anaplastic lymphoma kinase, or ALK, gene rearrangements. We anticipate reporting final data from the Phase 1b trial during 2011. We also expect to present data from a completed Phase 2 clinical trial evaluating IPI-504 in combination with Herceptin® (trastuzumab) in patients with HER2-positive metastatic breast cancer at a medical meeting in 2011.

In parallel with the development of IPI-504, we are pursuing development of IPI-493, a proprietary, orally available inhibitor of Hsp90. IPI-493 has demonstrated anti-tumor activity in multiple preclinical models of human cancer, including NSCLC, breast cancer, colon cancer, and hematological malignancies. We are evaluating IPI-493 in two Phase 1, dose escalation studies to determine the optimal dose and schedule for future development.

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In 2011, we anticipate reporting data from our Hsp90 program and announcing a path forward based on data from our ongoing clinical trials and relevant preclinical studies. We have worldwide development and commercialization rights for our Hsp90 chaperone inhibitor program.

**PI3K Inhibitor Program.** In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained global development and commercialization rights to Intellikine's portfolio of inhibitors targeting the delta and/or gamma isoforms of PI3K. We believe that specifically targeting PI3Kdelta and PI3Kgamma may provide multiple opportunities to develop differentiated therapies against inflammatory and autoimmune diseases as well as hematologic cancers. Our lead compound in this program, IPI-145, is an orally-available, small molecule, dual-selective inhibitor of PI3Kdelta and PI3Kgamma. IPI-145 has demonstrated activity in several preclinical models of inflammation. We intend to commence clinical development of IPI-145 in the second half of 2011. Mundipharma has commercialization rights outside of the United States for products arising from our PI3K inhibitor program.

**FAAH Inhibitor Program.** Finally, we have a program directed toward 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. The lead compound in our FAAH program is IPI-940, a novel, orally available inhibitor of FAAH with potential application for the treatment of a broad range of painful or inflammatory conditions. In October 2010, we reported top-line data from a Phase 1 randomized clinical trial of IPI-940 in 48 healthy adult volunteers demonstrating marked FAAH inhibition and increased anandamide levels. In addition, IPI-940 was well tolerated, with no observed dose-limiting toxicities or clinically significant changes in clinical laboratory values, vital signs or electrocardiogram parameters. Additional Phase 1 development of IPI-940 is ongoing.

In October 2010, Mundipharma and its independent associated company Purdue Pharmaceutical Products L.P., or Purdue, exercised their rights to assume worldwide development and commercialization activities for products arising out of the FAAH program and will fund 100% of all subsequent research, development and commercialization expenses. We anticipate completing transition activities for the FAAH program in 2011 to facilitate Phase 2 clinical trials in pain by Purdue.

## **Collaboration Agreements**

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

In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. The alliance currently includes product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of all our discovery projects in all disease fields that are conducted during a prescribed funded discovery period. In December 2010, Mundipharma exercised an option to extend the duration of the funded discovery period through December 31, 2012 and Mundipharma has the option to extend this period for an additional year. Our Hsp90 program is expressly excluded from the alliance. 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. Following entry into the strategic alliance agreements in November 2008, we consider Mundipharma, Purdue and associated entities to be related parties for financial reporting purposes because of their equity ownership in our company.

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. In October 2010, Mundipharma and Purdue exercised their rights to assume worldwide development and commercialization activities for products arising out of the FAAH program and will fund 100% of all subsequent research, development and commercialization

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expenses. For the remaining programs included in the alliance, Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us until the later of December 31, 2013 and the commencement of the first Phase 3 clinical trial of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the period between November 19, 2008 and December 31, 2009 was \$50 million and the contractually budgeted amounts for the year ended December 31, 2010 was \$65 million. The contractually budgeted amounts for 2011 and 2012 are \$85 million and \$110 million, respectively. Any activities we conduct related to the transition of the FAAH program to Purdue and Mundipharma will be reimbursed in addition to the contractually budgeted amount. We recognized \$2.0 million in revenue related to reimbursed research and development services for the transition of the FAAH program for the year ended December 31, 2010. The transition of the FAAH program and the associated revenue for reimbursed research and development services will continue into the fiscal year ended December 31, 2011. For the remaining programs in the alliance, we have the right to exceed the contractually budgeted amount at our own expense, which we did in 2010 due primarily to the license of our PI3K inhibitor program, and which we expect to be the case in 2011 on account of enhanced clinical trial activities for IPI-926 and the commencement of clinical development of IPI-145. After the transition date for each product candidate, we will share with Mundipharma all research and development costs for such product candidate equally. We are recognizing revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recognized \$67.0 million, \$46.5 million and \$2.7 million in such revenue in the years ended December 31, 2010, 2009 and 2008, respectively.

In December 2010, we amended our strategic alliance agreement with Mundipharma. Under the original agreement Mundipharma had the right to opt out of any early discovery project or any preclinical or clinical development 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. Under the amendment, these time-based decisions have been modified to become event-based for the Hedgehog program only. Mundipharma will continue to have time-based annual opt-out rights in November of each year for the other programs in the alliance.

Under the amendment, Mundipharma's next funding commitment for the Hedgehog program must be made by the 30th day following the outcome of an end-of-Phase 2 meeting with the U.S. Food and Drug Administration pertaining to the ongoing clinical trial of IPI-926 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). Mundipharma is obligated to fully fund the Hedgehog program until it is required to make this further commitment. If Mundipharma elects to opt-out of continued development funding at this time, then Mundipharma would be obligated to make an immediate payment of \$23.65 million to us, which we can use on any research or development 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 IPI-926 that are ongoing at the time of the opt-out, so that aggregate residual funding could total \$47.3 million. If Mundipharma elects to continue participation in the Hedgehog program when it makes its next commitment, Mundipharma would thereafter have the annual November opt-out right, and one-year residual funding obligation, contained in the original agreement.

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.

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Except as set forth above with respect to FAAH products and opt-out products, 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 arise out of the research program or products that are directed to the same target or pathway as a product included in the research program, unless and until a party terminates its rights with respect to such products.

If we in-license any product or product candidate during the funded discovery period for which GLP (Good Laboratory Practice) toxicology studies have been initiated and commercialization rights outside of the United States are available for grant by us to Mundipharma, Mundipharma will have the option to include such in-licensed product or product candidate in the alliance 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, in order for Mundipharma to obtain commercialization rights for such in-licensed product or product candidate in all countries outside of the United States, and by funding research and development costs in the same manner as products or product candidates arising out of our internal discovery programs. The agreement with Mundipharma provides for the agreed-upon research and development budgets to be updated to reflect the inclusion of any in-licensed products or product candidates. There will be no royalties paid between the parties on in-licensed candidates. If we in-license any product or product candidate during the funded discovery period for which GLP toxicology studies have not been initiated, as we did with our PI3K program in 2010, such products are automatically included in the alliance as having arisen out of our internal discovery projects within the then-existing contractually budgeted amounts.

Except with respect to products that have been in-licensed by us, 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 last-to-expire 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, Purdue or Mundipharma, 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. 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 Purdue or Mundipharma in the event of a change in control of Infinity or in the event that, during the funded discovery period, either Adeline Perkins or Julian Adams is no longer a full-time executive of Infinity. Upon termination of either strategic alliance agreement by us or either Purdue or Mundipharma, either party to the other strategic alliance agreement may terminate that agreement.

In connection with the entry into the strategic alliance agreements, we also entered into a securities purchase agreement and line of credit agreement 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 a first equity closing in November 2008 an aggregate of four

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million shares of our common stock at a purchase price of \$11.25 per share, for an aggregate purchase price of \$45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two 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 \$30 million. Of the second closing securities, an equal number were purchased by each purchaser.

For the fiscal year ended December 31, 2008, we recorded \$41.1 million as deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue in November 2008. This amount was comprised of \$23.8 million for the excess of the amount paid by Purdue and PPLP for our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share) and \$17.3 million representing the fair value of the PPLP's commitment to extend a line of credit at below market terms (the loan commitment asset) as discussed below. In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities to be a forward contract with immaterial intrinsic value, which was recorded in stockholders' equity. This forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009, we recorded an additional \$18.2 million as deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue, representing the excess of the \$30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities (\$5.29 per share for the common stock and approximately \$1.3 million for the warrants) as of the day before the first equity closing.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us during the three-year period that began on April 1, 2009. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019, which we refer to as the maturity date, and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement 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 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 \$1.7 million and \$1.3 million of related amortization expense for the years ended December 31, 2010 and 2009, respectively. Beginning with the fiscal year ended December 31, 2008 we recorded the offset to the loan commitment asset to deferred revenue. As of December 31, 2010, no amounts have been borrowed under this line of credit.

Since the shares of our common stock were purchased by Purdue and PPLP at a premium to the closing stock price on November 19, 2008, and the fair value of the rights and licenses transferred as part of the collaboration arrangement could not be reliably determined, we have attributed the premium over the closing price of our common stock using the residual method to the grant of rights and licenses to Mundipharma and Purdue. In addition, we have attributed the value of the loan commitment asset of \$17.3 million using the residual method to the grant of rights and licenses to Mundipharma and Purdue. There is no obligation for us to repay the \$59.3 million allocated to the grant of rights and licenses and we are recognizing the deferred revenue ratably over 14 years, which is our estimated period of performance under the arrangement. We will periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized \$4.3 million, \$4.3 million and \$0.3 million in such revenue in the years ended December 31, 2010, 2009 and 2008, respectively.

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**Intellikine.** In July 2010, we entered a development and license agreement with 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. We paid Intellikine a \$13.5 million upfront license fee. 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, we provide financial support for research activities that may be conducted by Intellikine under a two year research program 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 may extend the research program for an additional year upon written notice to Intellikine at least 180 days prior to the last day of the initial two-year research term. We are also 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 Intellikine tiered royalties 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.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. 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. For a product directed primarily to an oncology indication, Intellikine 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.

Intellikine may terminate its participation rights in any oncology product with twelve months' prior written notice to us, after which Intellikine's participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Intellikine 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 Intellikine may research, develop or commercialize products directed to the PI3K delta and/or gamma isoforms which meet certain selectivity criteria.

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, Intellikine 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.

**MedImmune/AZ.** Prior to December 2008, we had been a party to a product development and commercialization agreement with MedImmune, Inc., a division of AstraZeneca plc, or MedImmune/AZ, to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. This agreement was a cost sharing arrangement in which we shared development costs equally with MedImmune/AZ. In November 2007, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hedgehog pathway program on a royalty-free basis. In December 2008, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hsp90 chaperone inhibitor program. In January 2009, we reached an agreement with MedImmune/AZ 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/AZ in the year ended December 31, 2009.



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The profit and cost-sharing provisions of our arrangement with MedImmune/AZ are no longer applicable, and we have full control over all future development and commercialization activities under our Hsp90 and Hedgehog pathway programs, subject to the payment of single-digit royalties to MedImmune/AZ on worldwide net sales, if any, of each of IPI-504 and IPI-493. We do not have a royalty obligation to MedImmune/AZ on any future sales of IPI-926.

## **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. As the agreements with Mundipharma and Purdue 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 results of operations and financial position, 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;

laboratory supplies and materials;

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;

depreciation of equipment; and

allocated costs of facilities.

Under our collaboration with MedImmune/AZ, we shared research and development expenses equally with MedImmune/AZ. In December 2008, we reacquired from MedImmune/AZ worldwide development and commercialization rights to our Hsp90 chaperone inhibitor program. Amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of the parties' collaboration agreement incurred prior to our reacquisition of the Hsp90 chaperone inhibitor program were recorded as a reduction of research and development expense in our

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statements of operations. Amounts reimbursed by MedImmune/AZ incurred following the reacquisition of the Hsp90 chaperone inhibitor program were recorded as income from residual funding after reacquisition of Hsp90 program in our statements of operations. This cost-sharing arrangement also applied to our Hedgehog pathway inhibitor program through May 31, 2008.

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

General and administrative expense primarily consists of compensation of personnel in executive, finance, accounting, legal, information technology infrastructure, corporate communications, 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 PPLP starting on April 1, 2009. Reimbursable amounts from MedImmune/AZ incurred following the reacquisition of the Hsp90 program in December 2008 were recorded as income from residual funding, which is included in other income and expense.

### **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. 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 3 to our consolidated financial statements for a description of our significant accounting policies.

### ***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. We divide agreements containing multiple elements into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). For these agreements, we allocate the consideration we receive among the separate units based on their respective fair values or, in some cases, the residual method, and we apply the applicable revenue recognition criteria to each of the separate units.

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 typically the research or development term. 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 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.

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We recognize milestone payments as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions is not met, we defer the recognition of revenue underlying the milestone payment and recognize it over the remaining estimated period of performance under the contract as we complete our performance obligations.

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 revenues to date.

We exercise our judgment in determining whether an agreement contains multiple elements and, if so, how much revenue is allocable to each element. In addition, we exercise our judgment in determining when our significant obligations have been met under such agreements and the specific time periods over which we recognize revenue, such as non-refundable, up-front license fees. To the extent that actual facts and circumstances differ from our initial judgments, our revenue recognition with respect to such transactions would change accordingly and any such change could affect our reported operating results.

### ***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, costs associated with the licensing of research and development programs, stock-based compensation expense, contract services, and other outside expenses. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, others in which we are reimbursed for work performed on behalf of the collaborator, and another in which we reimburse the collaborator for work it has performed. We record all of our expenses as research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments from the collaborator for its share of the development effort as a reduction of research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we make payments to the collaborator, we record our payments to the collaborator for its share of the development effort as additional 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, as is the case with our agreement with Intellikine, we record the reimbursement 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.

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### ***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.

The carrying amounts reflected in the condensed consolidated balance sheets for notes receivable from employees, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value due to their short term maturities.

### ***New Accounting Pronouncements***

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2010-17, *Milestone Method of Revenue Recognition* ( ASU No. 2010-17 ), which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Prior to the issuance of ASU No. 2010-17, authoritative guidance on the use of the milestone method did not exist. ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. Alternatively, ASU No. 2010-17 can be adopted retrospectively for all prior periods. We do not expect the adoption of ASU No. 2010-17 to have a material impact on our financial statements or results of operations.

In October 2009, the FASB issued Accounting Standard Update No. 2009-13, *Multiple-Element Revenue Arrangements* ( ASU No. 2009-13 ), which updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25 in two ways. The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. ASU No. 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. ASU No. 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We do not expect the adoption of ASU No. 2009-13 to have a material impact on our financial statements or results of operations.

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The following table summarizes our results of operations for the years ended December 31, 2010, 2009 and 2008, in thousands, together with the change in each item as a percentage.

	2010	% Change	2009	% Change	2008
Revenue	\$ 71,331	41%	\$ 50,765	(39)%	\$ 83,585
Research and development expense	(99,231)	27%	(77,857)	64%	(47,466)
General and administrative expense	(21,070)	8%	(19,456)	16%	(16,837)
Interest expense	(1,910)	47%	(1,300)	6,090%	(21)
Interest and investment income	463	(77)%	2,044	(39)%	3,342
Income from settlement with NIH		(100)%	1,745		
Income from residual funding after reacquisition of Hsp90 program		(100)%	12,450	942%	1,195
Income from Therapeutic Discovery Grants	733				
Income tax benefit	700	112%	330		

*Revenue*

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 entered into with Mundipharma and Purdue in November 2008, 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 entered into with Mundipharma and Purdue in November 2008; 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, 2008 consisted of approximately:

\$56.7 million associated with the amortization and acceleration of the up-front license fee received from MedImmune/AZ;

\$15.0 million related to a milestone payment from MedImmune/AZ upon initiation of our Phase 3 trial of IPI-504 in patients with GIST;

\$8.1 million related to the amortization and acceleration of the non-refundable license fee, and \$0.8 million related to the reimbursable research and development services we performed, under a former research collaboration with Novartis; and

\$2.7 million related to reimbursed research and development services we performed 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 2011 will be derived from reimbursed research and development services and amortization of deferred revenue under our alliance with Purdue and Mundipharma.

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### *Research and Development Expense*

Research and development expenses represented approximately 82% of our total operating expenses for the year ended December 31, 2010, 80% of our total operating expenses for the year ended December 31, 2009, and 74% of our total operating expenses for the year ended December 31, 2008.

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

an up-front license fee of \$13.5 million related to in-licensing our PI3K program from Intellikine and \$1.2 million of related reimbursement for research and development services performed by Intellikine;

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 as our Hedgehog and FAAH programs have advanced; and

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

The increase in research and development expense for the year ended December 31, 2009 compared to the year ended December 31, 2008 is primarily attributable to:

a decrease of \$16.7 million in amounts reimbursed by MedImmune/AZ under the cost-sharing provisions of our collaboration agreement;

an increase of \$5.5 million in pharmaceutical development expenses as our Hsp90 and Hedgehog programs have advanced;

an increase of \$3.2 million in compensation and benefits, including stock-based compensation, for our research and development personnel, which was primarily driven by the hiring of new research and development personnel and annual base salary increases, and partially offset by a decrease in accrued amounts under our contingent cash compensation program;

an increase of \$1.6 million in consulting expenses primarily related to the clinical development of IPI-504; and

an increase of \$1.5 million in preclinical expenses as our FAAH program has advanced.

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, 2010. 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 chaperone inhibitor program was conducted in collaboration with MedImmune/AZ, and from August 2006 through November 2007, our Hedgehog pathway inhibitor program was conducted in collaboration with MedImmune/AZ. Under this collaboration, we shared research and development expenses equally with MedImmune/AZ. Pursuant to our cost-sharing agreement, reimbursable amounts from MedImmune/AZ were credited to research and development expenses for our Hsp90 program through December 10, 2008 and for our Hedgehog pathway inhibitors program through May 31, 2008. The expenses for the Hsp90 chaperone inhibitor and Hedgehog pathway inhibitor programs include credits of approximately \$16.7 million for the year ended December 31, 2008.



(Dollars in Millions)

Program	Year Ended December 31, 2010	Year Ended December 31, 2009	Year Ended December 31, 2008	January 1, 2006 to December 31, 2010
Hedgehog pathway inhibitor	\$ 33.4	\$ 22.8	\$ 10.8	\$ 80.3
Hsp90 chaperone inhibitor	13.9	32.7	20.4	87.5
FAAH inhibitor	18.7	9.4		28.1
PI3K Inhibitor*	18.0			18.0
Bcl-2			0.6	9.5

\* Includes a license fee of \$13.5 million

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We expect expenses for our Hedgehog pathway inhibitor program to increase as we seek to make progress in the clinical development of IPI-926. We also expect expenses for our PI3K inhibitor program to increase as we anticipate commencing clinical development in 2011. In addition, we expect expenses for our FAAH program to decrease as we transition the development activities to Purdue and Mundipharma. For these and other reasons, 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 or 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, 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, 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, 2010 as compared to the year ended December 31, 2009 is 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 non-employee chair; and

an increase of \$0.6 million in legal expenses, principally related to patent expenses including our newly acquired PI3K program; and

a decrease of \$1.2 million in consulting expenses, principally related to a decrease in early commercial development activities.

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The increase in general and administrative expense for the year ended December 31, 2009 as compared to the year ended December 31, 2008 is primarily attributable to:

an increase of \$1.0 million in compensation and benefits, including stock-based compensation expense for general and administrative employees, which was primarily driven by the hiring of new general and administrative personnel, and annual base salary increases, and partially offset by a decrease in accrued amounts under our contingent cash compensation program; and

an increase of \$0.5 million in consulting expenses, principally related to early commercial development and public relations services.

### *Interest Expense*

Interest expense increased for the year ended December 31, 2010 compared to the years ended December 31, 2009 and 2008 primarily as a result of amortizing the loan commitment asset from Purdue. We expect interest expense in 2011 to be comparable to 2010.

### *Interest and Investment Income*

Interest and investment income decreased in the year ended December 31, 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 2011 to be comparable to 2010.

Interest and investment income decreased in the year ended December 31, 2009 as compared to the year ended December 31, 2008 primarily as a result of lower yields on our cash equivalents and available-for-sale securities.

### *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*

Following our reacquisition of the Hsp90 program in December 2008, MedImmune/AZ remained obligated to fund an amount equivalent to its share of the Hsp90 program costs for the ensuing six-month period. Reimbursable amounts from the date of reacquisition (December 11, 2008) to December 31, 2008 were recorded as income from residual funding after reacquisition of Hsp90 program. In January 2009, we agreed with MedImmune/AZ to settle the residual funding obligations through lump sum payments totaling \$12.5 million, which we also 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

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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 2008 or 2009 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 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, 2010, 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, 2010	December 31, 2009
Cash, cash equivalents and available-for-sale securities including long term	\$ 100,959	\$ 130,737
Working capital	75,378	119,408

	Years ended December 31,		
	2010	2009	2008
Cash (used in) provided by:			
Operating activities	\$ (26,585)	\$ (4,757)	\$ (10,422)
Investing activities	30,480	(7,496)	(18,184)
Capital expenditures (included in investing activities above)	(1,949)	(2,528)	(1,392)
Financing activities	235	11,966	22,016

**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 are reimbursed by Purdue and Mundipharma up to a contractually specified annual cap, which was \$65 million in 2010 and is \$85 million in 2011. 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/AZ in December 2008. In addition, we exceeded the contractually budgeted amount for 2010 research and development funding from Purdue and Mundipharma due primarily to the license of our PI3K inhibitor program from Intellikine. Our cash used in operating activities for the period ended December 31, 2010 includes a \$5 million license payment for our PI3K program. In addition, the change in accounts payable, accrued expenses and other liabilities for the year ended December 31, 2010 includes an additional license payment of \$8.5 million paid in January 2011 for our PI3K program as well as an increase in our contingent cash compensation program and an increase to our clinical studies accrual. The change in deferred revenue for the year ended December 31, 2010 is 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. For example, in 2011, we expect to exceed the contractually budgeted amount for research and development funding from Purdue and Mundipharma.

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In November 2008, we entered into strategic alliances 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 Purdue, Mundipharma and MedImmune/AZ.

Our reacquisition of the Hsp90 program from MedImmune/AZ in December 2008 resulted in a \$56.7 million decrease in deferred revenue. In February 2008, Novartis chose not to exercise its options for two one-year extensions of the research period under our Bcl collaboration, resulting in an \$8.1 million decrease in deferred revenue.

Our investing activities for the years ended December 31, 2010, 2009 and 2008 include the purchase of and proceeds from maturities and sales of available-for-sale securities and purchases of property and equipment. Net cash provided by investing activities for the year ended December 31, 2010 included \$201.1 million in purchases of available-for-sale securities, proceeds of \$226.3 million from maturities of available-for-sale securities and proceeds of \$7.2 million from sales of available-for-sale securities. Capital expenditures in the year ended December 31, 2010 of \$1.9 million primarily consisted of laboratory equipment and software.

We will need substantial additional funds to support our planned operations. We expect to receive up to \$85.0 million and \$110.0 million in contractually committed research and development funding under our strategic alliance with Mundipharma for the years ended December 31, 2011 and 2012, 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 Purdue and Mundipharma and the \$50.0 million line of credit that has been made available to us by PPLP, are sufficient to fund our planned operations into 2014. We expect to draw down on the \$50.0 million line of credit by March 31, 2012. 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.

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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.

***Contractual Obligations***

As of December 31, 2010, we had the following contractual obligations:

Contractual Obligations	Payments Due by Period (in thousands)						2016 and beyond
	Total	2011	2012	2013	2014	2015	
Capital lease, including interest	\$ 6	\$ 6	\$	\$	\$	\$	\$
Software contract obligation	165	140	25				
License fee to Intellikine	8,500	8,500					
Operating lease obligations	9,854	5,068	4,786				
<b>Total contractual cash obligations</b>	<b>\$ 18,525</b>	<b>\$ 13,714</b>	<b>\$ 4,811</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>

The above table does not include contracts with contract research organizations as they are generally cancellable, with notice, at our option.

**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 \$467,000 decrease in the fair value of our investments as of December 31, 2010, as compared to an approximate \$446,000 decrease as of December 31, 2009. 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.

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

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

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

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 16, 2011



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

	December 31,	
	2010	2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 20,416,997	\$ 16,287,229
Available-for-sale securities	79,804,921	113,758,778
Notes receivable from employees	35,057	55,059
Prepaid expenses and other current assets	2,872,000	3,511,968
Total current assets	103,128,975	133,613,034
Property and equipment, net	5,147,545	5,694,150
Loan commitment asset from Purdue entities, net	14,288,175	16,020,075
Long-term available-for-sale securities	736,739	690,506
Notes receivable from employees	16,717	38,036
Restricted cash	1,122,633	1,146,788
Other assets	125,138	115,244
Total assets	\$ 124,565,922	\$ 157,317,833
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,606,303	\$ 1,441,231
Accrued expenses	20,363,884	8,549,382
Deferred revenue from Purdue entities	4,780,418	4,214,260
Total current liabilities	27,750,605	14,204,873
Deferred revenue from Purdue entities, less current portion	46,361,745	50,576,445
Other liabilities	970,057	2,224,713
Total liabilities	75,082,407	67,006,031
Commitments and contingencies (note 12)		
<b>Stockholders' equity:</b>		
Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2010 and 2009		
Common Stock, \$.001 par value; 100,000,000 shares authorized, and 26,519,217 and 26,238,954 shares issued and outstanding, at December 31, 2010 and December 31, 2009, respectively	26,519	26,239
Additional paid-in capital	278,412,580	270,274,176
Accumulated deficit	(229,009,563)	(180,025,904)
Accumulated other comprehensive income	53,979	37,291
Total stockholders' equity	49,483,515	90,311,802
Total liabilities and stockholders' equity	\$ 124,565,922	\$ 157,317,833

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

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

	<b>Years Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Collaborative research and development revenue:			
From Purdue entities	\$ 71,330,987	\$ 50,765,462	\$ 3,027,063
Other			80,558,125
Total revenue	71,330,987	50,765,462	83,585,188
Operating expenses:			
Research and development	99,231,414	77,856,836	47,466,410
General and administrative	21,070,279	19,456,341	16,836,541
Total operating expenses	120,301,693	97,313,177	64,302,951
Income (loss) from operations	(48,970,706)	(46,547,715)	19,282,237
Other income (expense):			
Interest expense	(1,909,726)	(1,300,184)	(21,368)
Income from NIH reimbursement		1,745,386	
Income from residual funding after reacquisition of Hsp90 program		12,450,000	1,195,586
Income from Therapeutic Discovery Grants	733,438		
Interest and investment income	463,014	2,044,430	3,342,424
Total other income (expense)	(713,274)	14,939,632	4,516,642
Income (loss) before income taxes	(49,683,980)	(31,608,083)	23,798,879
Income tax benefit	700,321	329,566	
Net income (loss)	\$ (48,983,659)	\$ (31,278,517)	\$ 23,798,879
Earnings (loss) per common share:			
Basic	\$ (1.86)	\$ (1.20)	\$ 1.18
Diluted	\$ (1.86)	\$ (1.20)	\$ 1.15
Weighted average number of common shares outstanding:			
Basic	26,321,398	26,096,515	20,236,743
Diluted	26,321,398	26,096,515	20,765,536

*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,		
	2010	2009	2008
<b>Operating activities</b>			
Net income (loss)	\$ (48,983,659)	\$ (31,278,517)	\$ 23,798,879
Adjustments to reconcile net income (loss) to net cash used in operating activities			
Depreciation	2,183,997	2,153,916	1,971,937
Stock-based compensation including 401(k) match	7,883,519	7,037,253	5,840,065
Gain on sale and disposals of property and equipment		(79,256)	(56,620)
Gain on sale of available-for-sale securities		(28,051)	(107,313)
Net (accretion) amortization of available-for-sale securities	1,496,004	129,973	(1,753,531)
Impairment of available-for-sale securities		15,666	49,428
Impairment of property and equipment	311,200		84,219
Amortization of loan commitment asset from Purdue entities	1,731,900	1,298,925	
Other, net	79,653	60,196	55,114
Changes in operating assets and liabilities:			
Accounts receivable and unbilled accounts receivable		7,414,570	(2,314,334)
Prepaid expenses and other assets	599,134	(1,075,479)	74,063
Accounts payable, accrued expenses and other liabilities	11,761,744	(4,380,234)	3,229,754
Deferred revenue	(3,648,542)	13,974,116	(41,294,078)
Net cash used in operating activities	(26,585,050)	(4,756,922)	(10,422,417)
<b>Investing activities</b>			
Purchases of property and equipment	(1,948,592)	(2,527,627)	(1,392,377)
Proceeds from sale of property and equipment		79,256	57,113
Purchases of available-for-sale securities	(201,094,734)	(166,565,338)	(172,033,407)
Proceeds from maturities of available-for-sale securities	226,283,903	125,375,803	137,134,757
Proceeds from sales of available-for-sale securities	7,239,262	36,141,736	18,050,075
Net cash provided by (used in) investing activities	30,479,839	(7,496,170)	(18,183,839)

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

	Years Ended December 31,		
	2010	2009	2008
<b>Financing activities</b>			
Proceeds from issuance of common stock to Purdue entities	\$	\$ 11,830,000	\$ 21,160,000
Proceeds from issuances of common stock related to stock incentive plans	224,796	201,726	713,115
Repurchase of common stock			(8,115)
Release of restricted cash	26,642		564,986
Payments on equipment loan and other debt			(373,403)
Capital lease payments	(6,459)	(5,954)	(10,499)
New employee loans	(10,000)	(60,000)	(30,000)
Net cash provided by financing activities	234,979	11,965,772	22,016,084
Net increase (decrease) in cash and cash equivalents	4,129,768	(287,320)	(6,590,172)
Cash and cash equivalents at beginning of period	16,287,229	16,574,549	23,164,721
Cash and cash equivalents at end of period	\$ 20,416,997	\$ 16,287,229	\$ 16,574,549
<b>Supplemental cash flow disclosure</b>			
Interest paid	\$ 741	\$ 1,247	\$ 14,351
Income taxes paid	\$	\$ 75,000	\$ 92,000

*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	Accumulated	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount	Paid-in Capital	Deficit		
Balance at December 31, 2007	19,710,773	\$ 19,711	\$ 223,466,502	\$ (172,546,266)	\$ 202,956	\$ 51,142,903
Exercise of stock options	306,744	307	712,808			713,115
Issuance of common stock to Purdue entities	4,000,000	4,000	21,156,000			21,160,000
Restricted stock issued that vested in the year			75,621			75,621
Early exercise of options into restricted stock			(121,989)			(121,989)
Repurchase and retirement of common stock	(4,531)	(5)				(5)
Stock-based compensation expense			5,435,829			5,435,829
401(k) plan match and other issued in common stock	51,871	52	404,184			404,236
Comprehensive income:						
Unrealized gain on marketable securities					512,400	512,400
Net income				23,798,879		23,798,879
Comprehensive income						24,311,279
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 income:						
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

*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, 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 income:						
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.*

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

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

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

Infinity Pharmaceuticals, Inc. is a drug discovery and development company that is utilizing our strength in small molecule drug technologies to discover and develop 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. Restatement Related to Loan Commitment Asset**

We previously restated our financial statements for the years ended December 31, 2009 and 2008 and for the quarters ended March 31, June 30 and September 30, 2010 and 2009 as reflected in an amended 2009 annual report on Form 10-K/A and amended quarterly reports on Form 10-Q/A for the applicable periods. The restatement related to our accounting for the initial recognition of a loan commitment representing the future availability to us, on below-market terms, of the \$50 million line of credit extended to us by Purdue Pharmaceutical Products L.P., or Purdue, and its independent associated company, Purdue Pharma L.P., or PPLP, in November 2008 upon entry into a strategic alliance with Purdue and its independent associated company, Mundipharma International Corporation Limited, or Mundipharma (see notes 8 and 13). This written loan commitment, or loan commitment asset, met the definition of a financial instrument and we therefore recorded it as an asset. We determined that the fair value of the loan commitment asset was \$17.3 million. We recorded the fair value of this asset in 2008 and began amortizing this balance to interest expense over the life of the loan arrangement, or ten years, on April 1, 2009, the date at which we could first draw upon the line of credit. We initially recorded the offset to the loan commitment asset to additional paid-in capital, or APIC. In the restatement, we recorded the offset to deferred revenue rather than APIC. We are amortizing the deferred revenue to revenue over a 14 year period beginning in November 2008, which is our estimated period of performance under the strategic alliance.

##### **3. 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, including those related to revenue recognition and accrued expenses. 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 short-term available-for-sale securities primarily consist of money market funds, U.S. government-sponsored enterprise obligations, corporate obligations, U.S. Treasury obligations and mortgage-backed securities. We consider all highly liquid investments with maturities of three months or less at the time of

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

#### **Notes to Consolidated Financial Statements (Continued)**

purchase to be cash equivalents. Cash equivalents, which consist primarily of a money market fund and a U.S. government-sponsored enterprise obligation, 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 available-for-sale 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, 2010 and 2009 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, 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.

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.

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, U.S. Treasury 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.



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

#### **Notes to Consolidated Financial Statements (Continued)**

All of our revenues to date have been generated under research collaboration agreements. During the years ended December 31, 2010 and 2009, all of our revenues are associated with our strategic alliance with Mundipharma and Purdue.

During the year ended December 31, 2008:

Revenues associated with the amortization and acceleration of the up-front license fee we received from MedImmune, Inc., a division of AstraZeneca plc, or MedImmune/AZ, and a milestone payment from MedImmune/AZ upon initiation of the first patient in a pivotal trial, accounted for approximately 85% of our revenue;

Revenues associated with the up-front license fee and reimbursable research and development services we received from Novartis Institutes for BioMedical Research, Inc. and Novartis International Pharmaceutical Ltd. accounted for approximately 11% of our revenue; and

Revenues associated with our strategic alliances with Mundipharma and Purdue accounted for approximately 4% of our revenue.

#### **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 life of lease 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 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 7 for discussion on impairment charges recognized during the periods presented.

#### **Fair Value**

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.



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**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements (Continued)**

The carrying amounts reflected in our consolidated balance sheets for notes receivable from employees, prepaid expenses and other current assets, accounts payable and accrued expenses approximate fair value due to their short term maturities.

**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. We divide agreements containing multiple elements into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). For these agreements, we allocate the consideration we receive among the separate units based on their respective fair values or, in some cases, the residual method, and we apply the applicable revenue recognition criteria to each of the separate units.

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 typically the research or development term. 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 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 milestone payments as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions is not met, we defer the recognition of revenue underlying the milestone payment and recognize it over the remaining estimated period of performance under the contract as we complete our performance obligations.

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 revenues 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.

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, 2010 and 2009.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****Basic and Diluted Net Income (Loss) per Common Share**

Basic net income or loss per share is based upon the weighted average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net income or 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 and warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of 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 years ended December 31, 2010 and 2009 because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	2010	At December 31, 2009	2008
Stock options	6,087,491	4,954,708	4,762,819
Warrants	5,246,629	6,246,629	246,629
Unvested restricted shares		16,396	47,558

Basic and diluted earnings (loss) per share were determined as follows:

	2010	Year Ended December 31, 2009	2008
<b>Basic</b>			
Net income (loss)	\$ (48,983,659)	\$ (31,278,517)	\$ 23,798,879
Weighted average common shares outstanding	26,321,398	26,096,515	20,236,743
Basic earnings (loss) per share	\$ (1.86)	\$ (1.20)	\$ 1.18
<b>Diluted</b>			
Net income (loss)	\$ (48,983,659)	\$ (31,278,517)	\$ 23,798,879
Weighted average common shares outstanding	26,321,398	26,096,515	20,236,743
Effect of dilutive options			528,793
Weighted average common shares outstanding assuming dilution	26,321,398	26,096,515	20,765,536
Diluted earnings (loss) per share	\$ (1.86)	\$ (1.20)	\$ 1.15

**Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income (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.

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

#### **Notes to Consolidated Financial Statements (Continued)**

#### **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, costs associated with the licensing of research and development programs, stock-based compensation expense, contract services, and other outside expenses. We expense research and development costs as they are incurred. We have entered into certain collaboration agreements in which expenses are shared with the collaborator, others in which we are reimbursed for work performed on behalf of the collaborator, and another in which we reimburse the collaborator for work it has performed. We record all of our expenses as research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we receive payments from the collaborator, we record payments from the collaborator for its share of the development effort as a reduction of research and development expense. If the arrangement is a cost-sharing arrangement and there is a period during which we make payments to the collaborator, we record our payments to the collaborator for its share of the development effort as additional 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, as is the case with our agreement with Intellikine, Inc., or Intellikine, we record the reimbursement as research and development expense. We expense upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use.

#### **New Accounting Pronouncements**

In April 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update No. 2010-17, *Milestone Method of Revenue Recognition* ( ASU No. 2010-17 ), which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Prior to the issuance of ASU No. 2010-17, authoritative guidance on the use of the milestone method did not exist. ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. Alternatively, ASU No. 2010-17 can be adopted retrospectively for all prior periods. We do not expect the adoption of ASU No. 2010-17 to have a material impact on our financial statements or results of operations.

In October 2009, the FASB issued Accounting Standard Update No. 2009-13, *Multiple-Element Revenue Arrangements* ( ASU No. 2009-13 ), which updates the existing multiple-element revenue arrangements guidance currently included in Accounting Standards Codification No. 605-25 in two ways. The first change relates to the determination of when the individual deliverables included in a multiple-element arrangement may be treated as separate units of accounting. This is significant as it will likely result in the requirement to separate more deliverables within an arrangement, ultimately leading to less revenue deferral. The second change modifies the manner in which the transaction consideration is allocated across the separately identified deliverables. ASU No. 2009-13 also significantly expands the disclosures required for multiple-element revenue arrangements. ASU No. 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We do not expect the adoption of ASU No. 2009-13 to have a material impact on our financial statements or results of operations.

#### **4. 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

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

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, 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, 2010, an aggregate of 468,100 shares of our common stock are reserved for issuance upon the exercise of outstanding awards and up to 2,839,538 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 Internal Revenue Code or as nonqualified stock options, as well as restricted stock. As of December 31, 2010, an aggregate of 5,083,344 shares of our common stock are reserved for issuance upon the exercise of outstanding awards. 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 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 non-statutory 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, 2010, an aggregate of 527,297 shares of our common stock are 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, 2010	Year Ended December 31, 2009	Year Ended December 31, 2008
Research and development	\$ 3,707,357	\$ 3,501,126	\$ 2,781,662
General and administrative	4,176,162	3,536,127	3,058,403

As of December 31, 2010, there was \$7.0 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.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****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, 2010	Year Ended December 31, 2009	Year Ended December 31, 2008
Risk-free interest rate	2.55%	2.24%	2.00%
Expected annual dividend yield			
Expected stock price volatility	59.42%	56.73%	56.93%
Expected term of options	5.7 years	5.4 years	5.2 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 is commensurate with the expected term of the awards.

*Expected annual dividend yield:* The estimate for annual dividends is 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 determine 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 represents the period of time that the awards are expected to be outstanding. We use historical data and expectations for the future to estimate employee exercise and post-vest termination behavior. 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, 2010, 2009 and 2008, the weighted-average forfeiture rate was estimated to be 10%, 8% and 7%, respectively.

All options granted to employees during the years ended December 31, 2010, 2009 and 2008 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, 2010 is as follows:

Stock Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in millions)
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Outstanding at January 1, 2010	4,954,708	\$	9.48		
Granted	1,742,630		6.43		
Exercised	(85,406)		2.63		
Forfeited	(524,441)		9.23		
Outstanding at December 31, 2010	6,087,491	\$	8.72	7.38	\$ 1.6
Vested or expected to vest at December 31, 2010	5,898,134	\$	8.78	7.34	\$ 1.6
Exercisable at December 31, 2010	3,895,708	\$	9.72	6.66	\$ 1.5

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**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements (Continued)**

The weighted-average fair value per share of options granted during the years ended December 31, 2010, 2009 and 2008 were \$3.58, \$3.70 and \$3.66, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2010 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2010 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008 was \$257,846, \$550,292 and \$723,552, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2010 was \$224,796.

The total fair value of the shares of restricted stock that vested during the years ended December 31, 2010, 2009 and 2008 (measured on the date of vesting) was \$93,039, \$213,008 and \$318,497, respectively.

During the year ended December 31, 2008, two of our employees exercised options to purchase an aggregate of 46,391 shares of common stock under the 2001 Plan that had not yet vested. The stock received for these exercises has since fully vested.

No related income tax benefits were recorded during the years ended December 31, 2010, 2009 or 2008.

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

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 grant of the right to exercise his vested 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.

During the year ended December 31, 2009, 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 \$42,213 in stock-based compensation expense during the year ended December 31, 2009 with respect to the modification of this award.

During the year ended December 31, 2008, one member of our board of directors retired, but was granted the right to exercise his vested stock options for an additional two-year period. In connection with this extension, we recognized an additional \$21,495 in stock-based compensation expense during the year ended December 31, 2008 with respect to the modification of this award.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****5. Cash, Cash Equivalents and Available-for-Sale Securities**

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

	<b>Cost</b>	<b>December 31, 2010 Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
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
<b>Total available-for-sale securities</b>	<b>80,487,745</b>	<b>90,030</b>	<b>(36,115)</b>	<b>80,541,660</b>
<b>Total cash, cash equivalents and available-for-sale securities</b>	<b>\$ 100,904,678</b>	<b>\$ 90,094</b>	<b>\$ (36,115)</b>	<b>\$ 100,958,657</b>

	<b>Cost</b>	<b>December 31, 2009 Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Estimated Fair Value</b>
Cash and cash equivalents due in 90 days or less	\$ 16,287,229	\$	\$	\$ 16,287,229
Available-for-sale securities				
Corporate obligations due in one year or less	31,505,149	13,461	(205)	31,518,405
U.S. Treasury securities due in one year or less	2,268,546	3,684		2,272,230
Mortgage-backed securities due after ten years	699,376		(8,870)	690,506
U.S. government-sponsored enterprise obligations due in one year or less	64,841,354	71,583	(494)	64,912,443
U.S. government-sponsored enterprise obligations due in one to five years	15,097,568		(41,868)	15,055,700
<b>Total available-for-sale securities</b>	<b>114,411,993</b>	<b>88,728</b>	<b>(51,437)</b>	<b>114,449,284</b>
<b>Total cash, cash equivalents and available-for-sale securities</b>	<b>\$ 130,699,222</b>	<b>\$ 88,728</b>	<b>\$ (51,437)</b>	<b>\$ 130,736,513</b>

There were 21 debt securities that had been in an unrealized loss position for less than 12 months at December 31, 2010. The aggregate unrealized loss on these securities was \$36,115 and the fair value was \$48,563,595. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these 21 securities to be primarily attributable to current economic conditions. We do not intend to sell these securities prior to their maturity. Additionally, it is not more likely than not that we will be required to sell these securities before the recovery of their amortized cost bases, which may be maturity. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired at December 31, 2010.

During the year ended December 31, 2009, we determined that one debt security was other-than-temporarily impaired and accordingly recorded a loss of \$15,666. During the year ended December 31, 2008, we determined that one debt security was other-than-temporarily impaired and accordingly recorded a loss of \$49,428. Both of these securities had been in an unrealized loss position for 12 or more months. We did not

recognize any cumulative effect as an adjustment to the opening balance of accumulated deficit with a corresponding adjustment to accumulated other comprehensive income.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

We had no material realized gains or losses on our available-for-sale securities for the year ended December 31, 2010. Realized gains on our available-for-sale securities were \$28,051 and \$107,313 for the years ended December 31, 2009 and 2008, respectively.

**6. 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.

In January 2010, we adopted a newly issued accounting standard which requires additional disclosure about the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and the reasons for the transfers. This standard also clarifies existing disclosure requirements related to the level of disaggregation of fair value measurements for each class of assets and liabilities and disclosures about inputs and valuation techniques used to measure fair value for both recurring and nonrecurring Level 2 and Level 3 fair value measurements. The adoption of this standard did not impact our financial position or results of operations as it requires enhanced disclosure only. In addition, effective for interim and annual periods beginning after December 15, 2010, this standard requires additional disclosure about activity in Level 3 fair value measurements.

The following table provides the assets carried at fair value measured on a recurring basis as of December 31, 2010:

	<b>Level 1</b>	<b>Level 2</b>
Cash and cash equivalents	\$ 20,416,997	\$
Corporate obligations (including commercial paper)		43,629,818
Mortgage-backed securities		736,739
U.S. government-sponsored enterprise obligations		36,175,103
<b>Total</b>	<b>\$ 20,416,997</b>	<b>\$ 80,541,660</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.

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*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. Treasury securities:* benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data and vendor trading platform data.

**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

*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, 2010. There were no transfers of assets or liabilities between Level 1 and Level 2 during the year ended December 31, 2010. We had no available-for-sale securities that were classified as Level 3 at any point during the years ended December 31, 2010 or 2009.

**7. Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2010	2009
Laboratory equipment	\$ 15,204,481	\$ 14,216,196
Computer hardware and software	6,012,426	5,437,027
Office equipment and furniture and fixtures	736,403	722,683
Leasehold improvements	4,313,786	4,253,799
	26,267,096	24,629,705
Less accumulated depreciation	(21,119,551)	(18,935,555)
	\$ 5,147,545	\$ 5,694,150

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 IPI-504. We determined the fair value of the equipment based on quoted market prices. We did not impair any fixed assets during the year ended December 31, 2009. During the year ended December 31, 2008, we impaired laboratory equipment totaling \$84,219, as we ceased using the equipment. These impairment charges are included in research and development expense for the years in which they were impaired.

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 and \$101,985 for the years ended December 31, 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.

During the year ended December 31, 2008, we disposed of certain laboratory equipment, which had a cost of \$1,325,196 and accumulated depreciation of \$1,324,703 for proceeds of \$57,113, resulting in a gain of \$56,620.

**8. 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 13 for discussion on the strategic alliance agreements and the line of credit agreement.





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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 this additional value as a loan commitment asset at its fair value of \$17.3 million 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. The loan commitment asset is measured at fair value on a nonrecurring basis and will only be re-measured at fair value for nonrecurring events such as an impairment loss. Beginning with the period ended December 31, 2008, we recorded the offset to this asset as deferred revenue.

We are amortizing this asset to interest expense over the life of the loan arrangement, or 10 years commencing on April 1, 2009, the date we could begin drawing on the line. We recorded approximately \$1.7 million and \$1.3 million of related amortization expense in the years ended December 31, 2010 and 2009, respectively. As of December 31, 2010, no amounts have been borrowed under this line of credit.

**9. Restricted Cash**

We held \$1,122,633 in restricted cash as of December 31, 2010 and \$1,146,788 in restricted cash as of December 31, 2009. 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. During the year ended December 31, 2008, we amended the amount of a standby letter of credit with the permission of our facility lessor, and we accordingly reduced our restricted cash by \$564,986.

**10. Accrued Expenses**

Accrued expenses consisted of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Accrued drug manufacturing costs	\$ 1,921,224	\$ 2,212,156
Accrued license fee payable to Intellikine	8,500,000	
Accrued toxicology studies	1,153,006	691,197
Accrued compensation and benefits	4,495,189	2,576,970
Accrued clinical studies	2,375,823	920,429
Other	1,918,642	2,148,630
<b>Total accrued expenses</b>	<b>\$ 20,363,884</b>	<b>\$ 8,549,382</b>

**11. Other Long-Term Liabilities**

Other long-term liabilities consisted of the following:

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Deferred rent	\$ 603,402	\$ 1,125,369
Accrued tax liability		684,322
Other	366,655	415,022
<b>Total other long-term liabilities</b>	<b>\$ 970,057</b>	<b>\$ 2,224,713</b>



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****12. Commitments and Contingencies**

We lease our office and laboratory space under noncancelable facility lease agreements that expire in December 2012. We have the right to extend our primary office and laboratory lease for up to two consecutive five-year terms. We can exercise our right to extend on the same terms and conditions under the original leases by giving the landlord notice before the term of the lease expires.

Future minimum payments, excluding operating costs and taxes, under the facility lease, are approximately as follows:

	<b>Facility Lease</b>
Years Ending December 31:	
2011	\$ 5,056,907
2012	4,776,917
2013	
2014	
2015	
<b>Total minimum lease payments</b>	<b>\$ 9,833,824</b>

Rent expense of \$4,658,843, \$4,526,260 and \$4,455,781, before considering sublease income, was incurred during the years ended December 31, 2010, 2009 and 2008, respectively. Deferred rent is being amortized to rent expense over the life of the lease. During the years ended December 31, 2010, 2009 and 2008, we subleased a portion of our facility space for total sublease income of \$662,556, \$512,510 and \$565,845, 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, 2011.

**13. Collaborations****Purdue and Mundipharma**

In November 2008, we entered into strategic alliance agreements with each of Purdue and Mundipharma to develop and commercialize pharmaceutical products. The alliance currently includes product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of all our discovery projects in all disease fields that are conducted during a prescribed funded discovery period. In December 2010, Mundipharma exercised an option to extend the duration of the funded discovery period through December 31, 2012 and Mundipharma has the option to extend this period for an additional year. Our Hsp90 program is expressly excluded from the alliance. 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. Following entry into the strategic alliance agreements in November 2008, we consider Mundipharma, Purdue and associated entities to be related parties for financial reporting purposes because of their equity ownership in our company.

Under the strategic alliance agreements, we have responsibility and decision-making authority for the performance of early discovery projects and the development of all product candidates on a worldwide basis. There are no joint steering or similar committees for the alliance. In October 2010, Mundipharma and Purdue exercised their rights to assume worldwide development and commercialization activities for products arising out of the FAAH program and will fund 100% of all subsequent research, development and commercialization expenses. For the remaining programs included in the alliance, Mundipharma is obligated to pay 100% of our contractually budgeted amounts for research and development expenses incurred by us until the later of



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**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements (Continued)**

December 31, 2013 and the commencement of the first Phase 3 clinical trial of such product candidate, which we refer to as the transition date. The contractually budgeted amount for the period between November 19, 2008 and December 31, 2009 was \$50 million and the contractually budgeted amounts for the year ended December 31, 2010 was \$65 million. The contractually budgeted amounts for 2011 and 2012 are \$85 million and \$110 million, respectively. Any activities we conduct related to the transition of the FAAH program to Purdue and Mundipharma will be reimbursed in addition to the contractually budgeted amount. We recognized \$2.0 million in revenue related to reimbursed research and development services for the transition of the FAAH program for the year ended December 31, 2010. The transition of the FAAH program and the associated revenue for reimbursed research and development services will continue into the fiscal year ended December 31, 2011. For the remaining programs in the alliance, we have the right to exceed the contractually budgeted amount at our own expense, which we did in 2010 due primarily to the license of our PI3K inhibitor program, and which we expect to be the case in 2011 as a result of increased clinical trial activities for IPI-926 and the commencement of clinical development of IPI-145. After the transition date for each product candidate, we will share with Mundipharma all research and development costs for such product candidate equally. We are recognizing revenue for reimbursed research and development services we perform for Mundipharma and Purdue. We recognized \$67.0 million, \$46.5 million and \$2.7 million in such revenue in the years ended December 31, 2010, 2009 and 2008, respectively. In the first month of each quarter, Purdue and Mundipharma each prepay 25% of the annual agreed upon research and development service amount, which we record as deferred revenue and recognize as revenue as expenses are incurred over the period of effort.

In December 2010, we amended our strategic alliance agreement with Mundipharma. Under the original agreement, Mundipharma had the right to opt out of any early discovery project or any preclinical or clinical development 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. Under the amendment, these time-based decisions have been modified to become event-based for the Hedgehog program only. Mundipharma will continue to have time-based annual opt-out rights in November of each year for the other programs in the alliance.

Under the amendment, Mundipharma's next funding commitment for the Hedgehog program must be made by the 30th day following the outcome of an end-of-Phase 2 meeting with the U.S. Food and Drug Administration pertaining to the ongoing clinical trial of IPI-926 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). Mundipharma is obligated to fully fund the Hedgehog program until it is required to make this further commitment. If Mundipharma elects to opt out of continued development funding at this time, then Mundipharma would be obligated to make an immediate payment of \$23.65 million to us, which we can use on any research or development 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 IPI-926 that are ongoing at the time of the opt-out, so that aggregate residual funding could total \$47.3 million. If Mundipharma elects to continue participation in the Hedgehog program when it makes its next commitment, Mundipharma would thereafter have the annual November opt-out right, and one-year residual funding obligation, contained in the original agreement.

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.

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**INFINITY PHARMACEUTICALS, INC.**

**Notes to Consolidated Financial Statements (Continued)**

Except with respect to products that have been in-licensed by us, 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 last-to-expire 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, Purdue or Mundipharma, 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.

In connection with the entry into the strategic alliance agreements in November 2008, we also entered into a securities purchase agreement and line of credit agreement (see note 8) with Purdue and 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 a first equity closing in November 2008 an aggregate of four million shares of our common stock at a purchase price of \$11.25 per share, for an aggregate purchase price of \$45 million. Of such shares, two million shares of our common stock were purchased by each purchaser. In January 2009, we conducted a second equity closing where we issued and sold an aggregate of two 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 \$30 million. An equal number of shares and warrants were purchased by each purchaser.

For the fiscal year ended December 31, 2008, we recorded \$41.1 million as deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue in November 2008. This amount was comprised of \$23.8 million for the excess of the amount paid by Purdue and PPLP for the four million shares of our common stock (\$11.25 per share) over the closing market price on the day before the first equity closing (\$5.29 per share) and \$17.3 million for the value of the loan commitment asset (see note 8) related to a line of credit extended to us by PPLP at below market terms as discussed below. In 2008, we considered our obligation, absent material adverse changes, to issue Purdue and PPLP the second closing securities as a forward contract with immaterial intrinsic value, which was recorded in stockholders' equity. This forward contract closed in January 2009 upon the issuance of the second closing securities. In January 2009, for financial statement purposes, we recorded an additional \$18.2 million as deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue representing the excess of the \$30 million paid by Purdue and PPLP for the second closing securities over the fair market value of these securities (\$5.29 per share for the common stock and approximately \$1.3 million for the warrants) as of the day before the first equity closing.

Since the shares of our common stock were purchased by Purdue and PPLP at a premium to the closing stock price on November 19, 2008, and the fair value of the rights and licenses transferred as part of the collaboration arrangement could not be reliably determined, we have attributed the premium over the closing price of our common stock using the residual method to the grant of rights and licenses to Mundipharma and Purdue. In addition, we have attributed the value of the loan commitment asset of \$17.3 million using the residual method to the grant of rights and licenses to Mundipharma and Purdue. There is no obligation for us to

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

#### **Notes to Consolidated Financial Statements (Continued)**

repay the \$59.3 million allocated to the grant of rights and licenses and we are recognizing the deferred revenue ratably over 14 years, which is our estimated period of performance under the arrangement. We will periodically review this estimate and make adjustments as facts and circumstances dictate. We recognized \$4.3 million, \$4.3 million and \$0.3 million in such revenue in the years ended December 31, 2010, 2009 and 2008, respectively.

The line of credit agreement provides for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. The loans may be drawn by us through March 31, 2012. The loans, which may be used by us for any proper corporate purpose, mature on April 1, 2019 and will be subordinate to any senior indebtedness that we may incur. Borrowings made under the line of credit agreement will bear interest, payable on the maturity date, at a fluctuating rate set at the prime rate on the business day prior to the funding of each loan and will be reset on the last business day of each month ending thereafter. Interest will be compounded on each successive three-month anniversary of the funding of each loan. Outstanding loans may be prepaid without penalty or premium prior to the maturity date. Amounts borrowed under the credit agreement, once borrowed, may not be borrowed again. We have certain rights to repay outstanding amounts under the line of credit agreement in shares of our common stock.

#### **Intellikine**

In July 2010, we entered into a development and license agreement with 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. We paid Intellikine a \$13.5 million upfront license fee. 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, we provide financial support for research activities that may be conducted by Intellikine under a two year research program 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 may extend the research program for an additional year upon written notice to Intellikine at least 180 days prior to the last day of the initial two-year research term. We are also 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 Intellikine tiered royalties 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.

Under the agreement, we obtained rights to direct all development and commercialization activities worldwide for products arising from the agreement for all therapeutic indications. Mundipharma has commercialization rights outside the United States for products arising out of our PI3K inhibitor program. For a product directed primarily to an oncology indication, Intellikine 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.

Intellikine may terminate its participation rights in any oncology product with twelve months prior written notice to us, after which Intellikine's participation rights would revert back to the original milestone- and royalty-based payment structure, provided that Intellikine 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 Intellikine may research, develop or commercialize products directed to the PI3K delta and/or gamma isoforms which meet certain selectivity criteria.

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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, Intellikine 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.

**MedImmune/AZ**

Prior to December 2008 we had been a party to a product development and commercialization agreement with MedImmune/AZ to jointly develop and commercialize cancer drugs targeting Hsp90 and the Hedgehog pathway. MedImmune /AZ made non-refundable, up-front payments totaling \$70.0 million to us in order to obtain co-exclusive rights to the Hsp90 and Hedgehog pathway development programs. Upon entry into the agreement in August 2006, we began recognizing the up-front license fee as revenue on a straight-line basis over seven years, which was based on our estimate of the period under which product candidates would be developed under the collaboration. In November 2007, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hedgehog pathway program on a royalty-free basis. In December 2008, we regained from MedImmune/AZ worldwide development and commercialization rights under our Hsp90 chaperone inhibitor program. Following the reacquisition of the Hsp90 chaperone inhibitor program in December 2008, we had no substantial performance obligations to MedImmune/AZ and as such, we recognized the remaining portion of the up-front license fee of \$56.7 million as revenue during the year ended December 31, 2008. The change in accounting estimate for the research term resulted in a positive net income impact of \$46.7 million and \$2.31 in basic earnings per share for the year ended December 31, 2008. We also recorded reimbursable amounts from MedImmune/AZ through December 31, 2008 as income from residual funding, a component of other income in our statement of operations. MedImmune/AZ's funding obligation under the Hsp90 chaperone inhibitor program was to continue until June 2009. In January 2009, we reached an agreement with MedImmune/AZ 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/AZ in the year ended December 31, 2009.

This agreement was a cost sharing arrangement in which we shared development costs equally with MedImmune/AZ. Consequently, we recorded reimbursable amounts for MedImmune/AZ's share of the development effort up through the date of our reacquisition of the Hsp90 chaperone inhibitor program on December 10, 2008 as a reduction of research and development expense. Of the amounts reimbursable by MedImmune/AZ in the year ended December 31, 2008, \$16.7 million was credited against research and development expenses and \$1.2 million was recorded as income from residual funding.

**14. Income Taxes**

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.



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Our income tax benefit or expense for the years ended December 31, 2010, 2009 and 2008 differed from the expected U.S. federal statutory income tax expense as set forth below:

	2010	2009	2008
Expected federal tax expense (benefit)	\$ (16,892,553)	\$ (10,724,857)	\$ 8,070,539
Permanent differences	909,480	1,522,097	1,393,377
State taxes, net of deferral benefit	(2,869,250)	(1,715,554)	1,488,302
Tax credits and related adjustments	561,730	(2,928,454)	(3,533,790)
Alternative minimum tax		(282,191)	
Effect of change in state tax rate on deferred tax assets and deferred tax liabilities	425,153	47,828	780,028
Expired state net operating loss	1,895,009	1,085,004	1,794,332
Change in tax reserves	(700,321)		
Adjustments to deferred tax assets and deferred tax liabilities		(47,347)	77,963
Change in valuation allowance	15,945,922	12,619,791	(10,070,751)
Other	24,509	94,117	
Income tax benefit	\$ (700,321)	\$ (329,566)	\$

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

	Year Ended December 31,	
	2010	2009
Deferred tax assets:		
Net operating loss carryforwards	\$ 42,892,580	\$ 39,560,917
Tax credits	13,713,014	14,274,743
Deferred revenue	19,866,253	14,950,097
Intangible assets	5,166,742	
Accrued expenses	1,170,791	309,667
Amortization	700,103	690,840
Stock-based compensation	7,282,278	5,456,411
Other	581,945	177,856
Valuation allowance	(91,373,706)	(75,420,531)
Net deferred tax assets	\$	\$

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2010, 2009 and 2008 because management believes that it is more likely than not that these assets will not be realized. 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. The valuation allowance decreased by approximately \$11,188,000 during the year ended December 31, 2008 primarily as a result of the utilization of previously unbenefitted deferred tax assets and an increase in deferred tax liabilities.



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Subject to the limitations described below, at December 31, 2010, we had cumulative net operating loss carryforwards of approximately \$121,434,000 and \$41,276,000 available to reduce federal and state taxable income, which expire through 2030 and have begun to expire and through 2030, respectively. In addition, we have cumulative federal and state tax credit carryforwards of \$10,423,000 and \$4,984,000, respectively, available to reduce federal and state income taxes which expire through 2030 and 2025, respectively. The net operating loss carryforwards include approximately \$1,690,000 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, 2010.

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

	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 2007, although carryforward attributes that were generated prior to tax year 2007 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.

**15. 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 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.



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

#### **Notes to Consolidated Financial Statements (Continued)**

##### **Treasury Stock Retirements**

We retire treasury stock periodically with the approval of our board of directors. These were all non-cash transactions, with the offset to additional paid-in capital. Amounts retired have been immaterial for all periods presented.

##### **Warrants**

In connection with various loan and financing agreements during the period from December 2001 through December 2006, we issued warrants to purchase shares of convertible preferred stock, which subsequently became warrants to purchase shares of common stock as a result of 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 have been 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, we issued warrants to purchase shares of convertible preferred stock, which became warrants to purchase shares of common stock as a result of 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, 2010, 2009 and 2008. These warrants are currently exercisable and 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 shares of our common stock expired unexercised on July 1, 2010. The remaining warrants are exercisable to purchase up to an aggregate of:

2,000,000 shares of our common stock at any time up to July 1, 2011, with an initial exercise price of \$20.00 per share, with such exercise price increasing over time depending on when such warrants are exercised, up to a maximum exercise price of \$30.00 per share, and

3,000,000 shares of our common stock at any time up to July 2, 2012, with an initial exercise price of \$30.00 per share, with 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.

##### **16. 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 is not related to our ordinary course of operations, we have recorded the amount as other income.



**Table of Contents****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)****17. 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 amount received is not related to our ordinary course of operations, we have recorded the amount as other income.

**18. 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, 2010, 2009 and 2008, we matched 50% of the first six percent of participant contributions with shares of our common stock. The cost of our matching contributions during the years ended December 31, 2010, 2009 and 2008 was \$564,377, \$530,573 and \$404,236, respectively.

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

	Quarter Ended March 31, 2010	Quarter Ended June 30, 2010 (In Thousands, Except Shares and Per Share Amounts)	Quarter Ended September 30, 2010	Quarter Ended December 31, 2010
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
Total operating expenses	24,127	24,227	43,747	28,200
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
Total other income (expense)	(228)	(408)	(399)	321
Net loss before income taxes	(8,055)	(5,941)	(21,650)	(14,038)
Income tax benefit			700	
Net loss	\$ (8,055)	\$ (5,941)	\$ (20,950)	\$ (14,038)
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****INFINITY PHARMACEUTICALS, INC.****Notes to Consolidated Financial Statements (Continued)**

	Quarter Ended March 31, 2009	Quarter Ended June 30, 2009 (In Thousands, Except Shares and Per Share Amounts)	Quarter Ended September 30, 2009	Quarter Ended December 31, 2009
Collaborative research and development revenue from Purdue entities	\$ 9,736	\$ 13,472	\$ 14,082	\$ 13,476
Operating expenses:				
Research and development	21,242	20,713	18,499	17,404
General and administrative	5,330	5,681	4,571	3,874
Total operating expenses	26,572	26,394	23,070	21,278
Loss from operations	(16,836)	(12,922)	(8,988)	(7,802)
Other (expense) income:				
Interest expense		(433)	(433)	(433)
Income from residual funding after reacquisition of Hsp90 program	12,450			
Income from NIH reimbursement		1,745		
Interest and investment income	743	592	401	308
Total other income (expense)	13,193	1,904	(32)	(125)
Net loss before income taxes	(3,643)	(11,018)	(9,020)	(7,927)
Income tax benefit				330
Net loss	\$ (3,643)	\$ (11,018)	\$ (9,020)	\$ (7,597)
Basic and diluted net loss per common share	\$ (0.14)	\$ (0.42)	\$ (0.34)	\$ (0.29)
Basic and diluted weighted average number of common shares outstanding	25,910,687	26,118,758	26,154,557	26,198,415

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### **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, 2010. 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, 2010, 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 the Company's 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 the Company's internal control over financial reporting occurred during the fiscal quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, the Company's 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, the company's principal executive and principal financial officers and effected by the company's 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

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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, 2010. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Based on its assessment, management believes that, as of December 31, 2010, 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, 2010, 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, 2010, based on the COSO criteria.

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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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010 of Infinity Pharmaceuticals, Inc. and our report dated March 16, 2011 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 16, 2011

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

In 2010, we retained external accounting and financial reporting consultants to assist us in evaluating accounting for complex transactions. During the quarter ended December 31, 2010, we concluded that the engagement of these consultants remediated a material weakness in internal control over financial reporting that was identified as of December 31, 2009. No other 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, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Item 9B. Other Information**

Not applicable.

## **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 18, 2011 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 18, 2011 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 18, 2011 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 18, 2011 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 the Stockholders to be held on May 18, 2011 is incorporated herein by reference.

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**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>	62
<u>Consolidated Balance Sheets at December 31, 2010 and 2009</u>	63
<u>Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008</u>	64
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008</u>	65
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008</u>	67
<u>Notes to Consolidated Financial Statements</u>	69

**(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 16, 2011

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 16, 2011
/s/ CHRISTOPHER M. LINDBLOM <b>Christopher M. Lindblom</b>	Controller and Assistant Treasurer <i>(Principal Accounting Officer)</i>	March 16, 2011
/s/ STEVEN H. HOLTZMAN <b>Steven H. Holtzman</b>	Chair of the Board of Directors	March 16, 2011
/s/ MARTIN BABLER <b>Martin Babler</b>	Director	March 16, 2011
/s/ ANTHONY B. EVNIN, PH.D. <b>Anthony B. Evnin, Ph.D.</b>	Director	March 16, 2011
/s/ ERIC S. LANDER, PH.D. <b>Eric S. Lander, Ph.D.</b>	Director	March 16, 2011
/s/ PATRICK P. LEE <b>Patrick P. Lee</b>	Director	March 16, 2011
/s/ ARNOLD J. LEVINE, PH.D. <b>Arnold J. Levine, Ph.D.</b>	Director	March 16, 2011
/s/ THOMAS J. LYNCH, JR. M.D. <b>Thomas J. Lynch, Jr., M.D.</b>	Director	March 16, 2011
/s/ FRANKLIN H. MOSS, PH.D. <b>Franklin H. Moss, Ph.D.</b>	Director	March 16, 2011
/s/ IAN F. SMITH <b>Ian F. Smith</b>	Director	March 16, 2011
/s/ JAMES B. TANANBAUM, M.D. <b>James B. Tananbaum, M.D.</b>	Director	March 16, 2011
/s/ MICHAEL C. VENUTI, PH.D. <b>Michael C. Venuti, Ph.D.</b>	Director	March 16, 2011

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**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.



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<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	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.
10.10	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.
10.11*	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.
10.12*	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.
10.13*	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.
10.14*	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.
10.15	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.
10.16*	Form of Restricted Stock Agreement entered into with each of the officers and directors identified on the schedule thereto. Previously filed as Exhibit 10.24 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.

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<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*	Form of Stock Restriction Agreement entered into with Steven H. Holtzman on October 27, 2008 and with Julian Adams on October 28, 2008. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 000-31141) and incorporated herein by reference.
10.20	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.
10.21	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.
10.22	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.
10.23	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.
10.24	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.
10.25	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.
10.26	Form of Restricted Stock Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.35 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.27	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.
10.28	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.
10.29	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.
10.30	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.

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<b>Exhibit</b>	<b>Description</b>
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.

\* 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.