

INFINITY PHARMACEUTICALS, INC.

Form 10-K

March 05, 2013

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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, 2012

**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  
incorporation or organization)  
**33-0655706**  
(I.R.S. Employer  
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: None**

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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 29, 2012 was \$262,808,692 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

Number of shares outstanding of the registrant's Common Stock as of February 28, 2013: 47,644,646

**Documents incorporated by reference:**

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2013 in connection with our 2013 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 Annual Report on Form 10-K contains forward-looking statements regarding our expectations with respect to the possible achievement of discovery and development milestones in 2013, our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy, and other objectives for future operations. We often use words such as anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, should, continue, and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify these forward-looking statements by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause actual results or events to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our product candidates, our ability to obtain, maintain and enforce intellectual property rights for our product candidates, our dependence on our alliance partners, competition, 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 update any forward-looking statements.*

## **PART I**

### **Item 1. Business Overview**

We are an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines designed to address diseases with significant unmet need. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. Our programs focused on the inhibition of phosphoinositide-3-kinase and heat shock protein 90 are evidence of our innovative approach to drug discovery and development. We have worldwide development and commercialization rights to all of our development candidates and early discovery programs, subject to certain financial obligations to our current licensor and former development partners.

IPI-145, our lead product candidate, is a potent, oral inhibitor of Class I PI3K-delta and PI3K-gamma, which we are investigating in both hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the first PI3K-delta,gamma inhibitor in clinical development. The following is a summary of the clinical development of IPI-145 to date:

#### *Hematologic Malignancies*

We are conducting a Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies.

We are enrolling patients in five additional cohort expansions in the Phase 1 study to further evaluate the safety, pharmacokinetics and activity of IPI-145 in patients with the following hematologic malignancies:

Chronic lymphocytic leukemia, indolent non-Hodgkin lymphoma and mantle cell lymphoma

T-cell lymphomas

Aggressive B-cell lymphomas



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Myeloid neoplasms

T-cell or B-cell acute lymphoblastic leukemia/lymphoma

We are planning to initiate at least two additional trials of IPI-145 in patients with hematologic malignancies in 2013.

### *Inflammation*

We have completed a Phase 1, randomized, double-blind, placebo-controlled trial of IPI-145 in healthy adult subjects designed to support the development of IPI-145 in inflammatory diseases.

We are conducting a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in patients with mild, allergic asthma.

We are planning to initiate in the first half of 2013 a Phase 2, randomized, placebo-controlled study to evaluate the safety and activity of multiple doses of IPI-145 in patients with rheumatoid arthritis.

In January 2013, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443. We expect to complete in the second half of 2013 nonclinical studies designed to enable the initiation of Phase 1 clinical development.

Our second clinical candidate, retaspimycin hydrochloride (HCl), is a novel, potent and selective inhibitor of heat shock protein 90 (Hsp90). We completed patient enrollment in a Phase 2, randomized, double-blind, placebo-controlled clinical trial evaluating retaspimycin HCl in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in 226 patients with second or third-line non-small cell lung cancer (NSCLC), who are naive to docetaxel treatment and have a history of heavy smoking. We stratified patients in our Phase 2 trial by squamous cell carcinoma and adenocarcinoma based on results from our Phase 1b trial in which we observed partial responses in patients with squamous cell carcinoma. In addition, we are prospectively evaluating a novel biomarker that we believe may be predictive of response. We expect to report topline overall survival data from this trial in the first half of 2013.

We are also enrolling patients in a Phase 1b/2 trial to explore the safety and efficacy of retaspimycin HCl in combination with everolimus, an inhibitor of the mammalian target of rapamycin (mTOR), pathway, in NSCLC patients with a KRAS gene mutation. The objective of this Phase 1b/2 trial is to determine the recommended dose for the combination treatment and to evaluate the safety and clinical activity of retaspimycin HCl in combination with everolimus. We expect to provide an update from this Phase 1b/2 trial in the first half of 2013.

## **Corporate Information**

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

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.





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### **Product Development Pipeline**

Our product development programs arise from a combination of internally developed programs and strategic licensing arrangements. Whether our programs are developed internally or obtained from a third party, we focus on targets that have the potential to represent fundamentally new approaches to how disease is treated, and where we believe we can use our scientific capabilities to identify differentiated product candidates with well-defined development paths. We seek to leverage what we believe to be our innovative approaches to drug discovery and translational medicine and our robust internal capabilities across all of the key scientific disciplines, including medicinal chemistry, cell biology, biochemistry, pharmacology and molecular pathology. Our goal is to integrate these disciplines to rapidly identify product candidates and to better understand which populations, or subpopulations, of patients may benefit most from our product candidates. We view biomarkers as a key component of our drug development strategy and are actively researching biomarkers in each of our clinical development programs.

Our clinical candidate directed to the inhibition of Hsp90, emerged from our internal research efforts, and our clinical candidate directed to the inhibition of PI3K arose out of our strategic licensing arrangement with Intellikine, Inc., or Intellikine, which was acquired in January 2012 by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit, or Millenium. In addition to these programs, we have several innovative projects in earlier stages of development.

In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us multiple product opportunities in oncology and inflammatory disease, which are 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 worldwide rights to all product candidates in our portfolio subject to certain financial obligations to Millennium, Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue.

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Our product development programs as of March 1, 2013 are illustrated in the following chart:

***2013 Program Goals***

During 2013, we expect to advance our product development pipeline by achieving the following program milestones:

*IPI-145 in Hematologic Malignancies*

Initiate at least two additional trials in 2013

Report additional data from the ongoing Phase 1 trial in patients with advanced hematologic malignancies in 2013  
*IPI-145 in Inflammation*

Initiate a Phase 2 trial in patients with rheumatoid arthritis in the first half of 2013

Provide update on Phase 2a trial in patients with mild, allergic asthma in the second half of 2013  
*PI3K Pipeline Expansion*

Complete nonclinical studies of IPI-443 in the second half of 2013 to enable Phase 1 development  
*Retaspimycin HCl in NSCLC*

Report topline overall survival data from Phase 2 trial in combination with docetaxel in the first half of 2013

Provide update on Phase 1b/2 trial in combination with everolimus in the first half of 2013

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

The phosphoinositide-3-kinases (PI3Ks) are key cellular signaling proteins that act as a central node for relaying signals from cell surface receptors to downstream biochemical events. The PI3K-delta and PI3K-gamma isoforms are preferentially expressed in leukocytes, where they have distinct and non-overlapping roles in key cellular functions, including cell proliferation, cell differentiation, cell migration and immunity. Targeting PI3K-delta and PI3K-gamma may provide multiple opportunities to develop differentiated therapies for the treatment of inflammatory diseases as well as hematologic malignancies.

Our lead development candidate in this program is IPI-145, a potent, oral inhibitor of Class I PI3K-delta,gamma, for which we are conducting clinical trials in both hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the only PI3K-delta,gamma inhibitor in clinical development.

### ***Hematologic Malignancies***

Hematologic malignancies are cancers of the blood or bone marrow and include leukemia and lymphoma, such as chronic lymphocytic leukemia (CLL), Hodgkin lymphoma, and non-Hodgkin lymphoma (NHL). It is estimated that there will be 128,000 newly diagnosed incident cases of NHL in the seven major pharmaceutical markets (US, France, Germany, Italy, Spain, UK and Japan) in 2013. The distribution of NHL subtypes differs by country. In the United States and major European countries, diffuse large B-cell lymphoma (DLBCL) accounts for the majority of NHL cases ranging from 40-48%. CLL accounts for 29-36% and 16-23% for follicular lymphoma (FL). Mantle cell lymphoma is the rarest subtype, accounting for 3-6% of cases. Even with advances in treatment options for these diseases, the clinical outlook still remains poor for patients. A significant proportion of patients relapse following treatment and become refractory to current agents, representing a significant unmet medical need.

We are currently enrolling patients in a Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies. Data from this study presented in December 2012 at the Annual Meeting of the American Society for Hematology (ASH) showed that IPI-145 was well tolerated with no dose-related trends in adverse events. Data also showed that IPI-145 was clinically active in both B-cell and T-cell hematologic malignancies, including partial responses or complete responses in patients with CLL, Hodgkin lymphoma, and other forms of NHL, including indolent non-Hodgkin lymphoma, mantle cell lymphoma, and T-cell lymphoma. Additionally, clinical activity reported for 16 of 19 responders occurred within the first two cycles of treatment. The maximum tolerated dose of IPI-145 was defined at 75 mg twice daily (BID) in this study. We have begun enrolling patients in five additional cohort expansions to further evaluate the safety, pharmacokinetics and activity of IPI-145 in CLL, indolent non-Hodgkin lymphoma and mantle cell lymphoma; T-cell lymphomas; aggressive B-cell lymphomas; myeloid neoplasms; and T-cell or B-cell acute lymphoblastic leukemia/lymphoma. In addition, we intend to initiate at least two additional trials of IPI-145 in patients with hematologic malignancies in 2013.

### ***Inflammatory and Autoimmune Diseases***

Inflammatory and autoimmune diseases are a group of disorders characterized by the immune system attacking the body's own tissues, which can result in increased inflammation and organ dysfunction. Two examples of autoimmune and inflammatory diseases in particular, asthma and rheumatoid arthritis (RA), affect large sections of the population with an estimated annual number of prevalent cases in the seven major markets in 2011 of 76 million and 5.1 million, respectively. Asthma is characterized by inflammation in the lungs leading to wheezing, shortness of breath, chest tightness and coughing, while symptoms of RA include painful swelling and stiffness of the joints and surrounding tissues. With inadequate treatment, either disease can lead to a poor quality of life, disability, and increased mortality. In preclinical studies, IPI-145 has demonstrated activity in an allergen challenge model of asthma and in multiple models of RA. IPI-145 has also demonstrated activity in preclinical models of other inflammatory and autoimmune diseases including Crohn's disease, lupus and multiple sclerosis.

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IPI-145 is currently being evaluated in a Phase 2a randomized, double-blind, placebo-controlled trial in adult patients with mild, allergic asthma. The endpoints of this multi-dose, cross-over study include safety, pharmacokinetics and forced expiratory volume (FEV<sub>1</sub>), a standard measure of lung function, following allergen challenge. We are also planning to initiate in the first half of 2013 a Phase 2, randomized, placebo-controlled study to evaluate the safety and activity of multiple doses of IPI-145 in adult patients with RA. These trials follow the completion of our Phase 1, randomized, double-blind, placebo-controlled trial of IPI-145 in healthy adult subjects designed to support the development of IPI-145 in inflammatory diseases. Data from this study presented at the American College of Rheumatology (ACR) Annual Meeting in November 2012 showed that IPI-145 was generally well tolerated at all doses studied during the course of the study, with a favorable pharmacokinetic and pharmacodynamic profile and no clinically significant changes in clinical laboratory values or vital signs.

In January 2013, we selected our second potent, oral PI3K-delta,gamma inhibitor, IPI-443. We expect to complete nonclinical studies to enable the initiation of Phase 1 clinical development with this compound in the second half of 2013.

We have global development and commercialization rights to our PI3K program.

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

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

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

We have two ongoing clinical trials evaluating retaspimycin HCl, both of which are focused on patients with NSCLC. According to the American Cancer Society, lung cancer is the second most common form of cancer in the United States, with over 228,000 new cases estimated in 2013, and is the leading cause of cancer-related death. There are two main types of lung cancer: NSCLC and small cell lung cancer. The American Cancer Society estimates that approximately 85 percent of all lung cancers are classified as NSCLC. While NSCLC is notoriously difficult to treat, there have been some therapeutic advances in recent years, largely due to the rapidly evolving understanding of the underlying molecular mechanisms that are responsible for the development of the disease. Despite recent advancements, there are large NSCLC subpopulations which continue to have especially poor prognoses and limited treatment options. These patient subpopulations include patients who have squamous cell carcinoma, a history of heavy smoking, or a KRAS gene mutation, representing up to an estimated 35%, 70% and 30%, respectively, of all NSCLC patients. As our knowledge of genetic mutations and environmental factors that impact the disease progression of NSCLC expands, research is underway to understand how various patient subpopulations respond differently to therapies. Ultimately, our goal is to develop and deliver more effective, targeted (or personalized) treatment approaches that are based on each patient's particular disease characteristics.

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Retaspimycin HCl is the only Hsp90 inhibitor for which clinical responses have been observed when combined with chemotherapy in NSCLC patients who do not have an ALK mutation. For this reason, we are evaluating retaspimycin HCl dosed once weekly in a randomized, double-blind Phase 2 clinical trial in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in 226 patients with second- or third-line NSCLC, who are naive to docetaxel treatment and have a history of heavy smoking. The primary endpoint of the study is overall survival. We also plan to evaluate the relationship between survival and certain patient characteristics, including histology, tobacco exposure, and a novel biomarker. This trial was based, in part, on results from our Phase 1b trial of retaspimycin HCl in combination with docetaxel which showed that retaspimycin HCl, dosed once weekly in combination with docetaxel dosed once every three weeks, was well tolerated and clinically active in heavily pretreated patients with NSCLC. Partial responses were seen in six of 23, or 26 percent, of patients, with higher response rates observed among heavily pretreated patients with squamous cell carcinoma (n=3/7, or 43%) or a history of heavy smoking (n=6/18, or 33%). In this trial, there were no dose reductions or discontinuations in response to liver function tests, gastrointestinal toxicities were low grade, and no significant ocular toxicities were observed. We have completed patient enrollment and expect to report top-line data from this trial in the first half of 2013.

In addition, we are enrolling patients in a Phase 1b/2 trial to explore the safety and efficacy of retaspimycin HCl in combination with everolimus, an mTOR inhibitor, in NSCLC patients with a KRAS mutation. The objective of this Phase 1b/2 trial is to determine the recommended dose for the combination treatment and to evaluate the safety and clinical activity of retaspimycin HCl in combination with everolimus. The endpoint of the Phase 2 trial is overall response rate. In preclinical models, treatment with retaspimycin HCl in combination with an mTOR inhibitor resulted in synergistic activity and tumor regression. We expect to provide an update on this trial in the first half of 2013.

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

### ***Other Programs***

In addition to our clinical stage programs, we have multiple innovative projects in earlier stages of development. Through our internal discovery efforts, we also discovered IPI-940, a novel, orally available inhibitor of FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. We are currently seeking potential partnering opportunities for our FAAH program. In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our lead Hedgehog pathway inhibitor.

### **Strategic Alliances**

Since our inception, strategic alliances have been integral to our growth. These alliances have provided access to breakthrough science, significant research support and funding, and innovative drug development programs, all intended to help us realize the full potential of our product pipeline. Since our inception, all of our revenue has been derived from our strategic alliances, and all of our revenue during 2012, 2011 and 2010 was derived from our former strategic alliance with Mundipharma and Purdue.

### ***Millennium***

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. In January 2012, Intellikine was acquired by Takeda acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In December 2012, we amended and restated our development and license agreement with Millennium.

Under the original agreement, we obtained worldwide development and commercialization rights to Millennium's portfolio of inhibitors of the delta and/or gamma isoforms of PI3K for all indications, and we

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conducted a collaborative research program with Millennium to identify compounds directed to PI3K-delta and/or PI3K-gamma which meet certain selectivity criteria, with such research collaboration under the original agreement set to expire in July 2013. Also under the original agreement, neither we nor Millennium were permitted to research, develop or commercialize products directed PI3K-delta and/or PI3K-gamma which meet certain selectivity criteria, other than the compounds subject to the collaboration, except that Millennium was permitted to research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

Under the terms of the amended and restated agreement, we retained our worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications. We and Millennium will no longer conduct the collaborative research program, and the restrictions on each party's ability to research, develop and commercialize products directed to the delta and/or gamma isoforms of PI3K that meet certain selectivity criteria have terminated, subject, in the case of Millennium, to the exclusive licenses granted to us under the amended and restated agreement.

Additionally, under the amended and restated agreement, Millennium waived the option it had under the original agreement to convert, upon payment of an option fee, its royalty interest in U.S. sales of PI3K products and its right to receive certain milestone payments with respect to such products into the right to share in 50% of profits and losses on U.S. development and commercialization of those PI3K products for which the first Phase 2 clinical trial, as defined in the original agreement, conducted in an oncology indication, and to participate in up to 30% of the detailing effort for these products in the United States. In consideration of such waiver we have agreed to pay to Millennium \$15 million payable in installments. We have paid \$1.7 million of the \$15 million during the year ended December 31, 2012. Additionally, under the amended and restated agreement we have paid Millennium the \$5 million development milestone associated with the initiation of our Phase 2a clinical trial of IPI-145 in patients with asthma during the year ended December 31, 2012.

In addition to developing IPI-145, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443, and we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. We are obligated to pay up to \$15 million in remaining 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. As a result of the amendment, such products may include products we license from a third party. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from seven percent to 11 percent, the same royalty levels as those specified under the original agreement, upon successful commercialization of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction, and limits on the number of products, in certain circumstances.

The amended and restated agreement expires on the later of the expiration of certain patents and the expiration of the royalty payment terms for the products, 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. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium's reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days' prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days' prior written notice. The agreement also provides for customary reciprocal indemnification obligations of the parties.

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

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 termination agreements. The alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting FAAH. The 2008 agreement with Mundipharma was focused on the development and commercialization outside of the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of our early discovery projects in all disease fields. Our Hsp90 program was expressly excluded from the alliance.

Under the terms of the 2012 termination agreements:

All intellectual property rights that we had previously licensed to Mundipharma and Purdue to develop and commercialize products under the previous strategic alliance agreements terminated, with the result that we have worldwide rights to all product candidates that had previously been covered by the strategic alliance.

We have no further obligation to provide research and development services to Mundipharma and Purdue as of July 17, 2012.

Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH.

We are obligated to pay Mundipharma and Purdue a four percent royalty in the aggregate (subject to reduction as below), on worldwide net sales of products that were covered by the alliance until such time as they have recovered approximately \$260 million, representing the research and development funding paid to us for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a one percent royalty on net sales in the United States of products that were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products subject to the alliance that are subject to significant further development.

Royalties are payable under these agreements 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 royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

### ***Line of Credit Agreement***

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP, that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. In November 2011, we borrowed \$50 million under this line of credit. On September 7, 2012, upon completion of the sale and issuance of common stock to PPLP under the 2012 securities purchase agreement described below, the line of credit agreement with PPLP terminated in its entirety, and approximately \$51.0 million in principal and interest owed to PPLP under the line of credit agreement was extinguished.

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### *2008 Securities Purchase Agreement*

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a securities purchase agreement with Purdue and PPLP. Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of 6,000,000 shares of our common stock and warrants to purchase up to an aggregate of 6,000,000 shares of our common stock, for an aggregate purchase price of \$75 million. An equal number of securities were sold to each purchaser. As of December 31, 2012, all warrants that were issued in connection with the strategic alliance expired without having been exercised.

### *2012 Securities Purchase Agreement*

On July 17, 2012, in connection with the termination of the strategic alliance with Mundipharma and Purdue, we executed a securities purchase agreement with PPLP, which we refer to as the 2012 securities purchase agreement, under which we agreed to sell and issue 5,416,565 shares of our common stock to PPLP and two entities associated with PPLP, which we collectively refer to as the BRP entities, at a price of \$14.50 per share for an aggregate consideration of approximately \$78.5 million. The consideration was composed of the extinguishment of approximately \$51.0 million in principal and interest owed to PPLP under the line of credit agreement and \$27.5 million in cash. We completed the sale and issuance on September 7, 2012 at which time the line of credit agreement with PPLP terminated in its entirety.

The 2012 securities purchase agreement also provides that, at any time during the period beginning January 1, 2013 and ending December 31, 2018, in the event we propose to make an underwritten offering of our common stock, subject to certain limitations, the Purdue entities will have piggyback registration rights, which require us, at the election of the Purdue entities, to use our reasonable best efforts to cause to be included in such underwritten offering, common stock then held by the Purdue entities representing up to 20% of the total estimated maximum dollar amount of our common stock proposed to be sold in such underwritten offering.

In addition, the BRP entities have agreed that during the period between July 17, 2012 and December 31, 2013, if requested by us and/or the managing underwriters, placement agents or initial purchasers for any offering of our stock proposed by us during such period, not to, among other things, offer, sell or otherwise transfer or dispose of, directly or indirectly, any common stock held by the BRP entities or to enter into any agreement that transfers, in whole or in part, any of the economic consequences of ownership of any common stock held by the BRP entities, during such period as may be requested by such managing underwriters, the placement agents or the initial purchasers, and to execute a lock-up agreement reflecting such restrictions, provided that all of our officers, directors and affiliates enter into similar agreements with equivalent terms.

The 2012 securities purchase agreement also terminated, as of July 17, 2012, all attendance rights to meetings of our board of directors held by the Purdue entities.

The BRP entities and each associated company holding shares of our common stock have agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017, and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting. However, with respect to any proposal to amend our corporate charter or approve certain extraordinary transactions, all shares of our common stock that are owned by those entities that were not issued pursuant to the 2012 securities purchase agreement will be voted in proportion to the manner in which all of our stockholders (other than those entities) vote in respect of such proposal, regardless of the recommendation of our board of directors.

## **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



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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 32 issued or allowed patents related to our clinical-stage programs expiring on various dates between 2024 and 2030 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 one issued U.S. patent covering IPI-145 and related molecules, which expires in 2030, excluding any patent term extension. This patent includes composition of matter and pharmaceutical composition claims. In addition, we have over 135 patent applications pending worldwide related to our PI3K program. Any patents that may issue from our pending patent applications would expire between 2029 and 2033, excluding any patent term extension. These patent applications disclose compositions of matter, pharmaceutical compositions, methods of use and synthetic methods.

We have 15 issued U.S. patents covering retaspimycin HCl and related molecules, which expire on various dates between 2024 and 2025, excluding any patent term extension. These patents and allowed patent applications include composition of matter, pharmaceutical composition, method of treatment, formulations, and synthetic method claims.

We have 13 issued or allowed U.S. patent applications covering saridegib and related molecules, which expire on various dates between 2025 and 2029, excluding any patent term extension. These patents include composition of matter, pharmaceutical composition, method of treatment, and synthetic method claims.

We have three issued or allowed U.S. patent applications covering IPI-940 and related molecules, which expire on various dates between 2027 and 2028, excluding any patent term extension. These patents include composition of matter, pharmaceutical composition, and method of treatment claims.

In addition, as of January 30, 2013, 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 2033, excluding any patent term extension. These patents and patent applications disclose compositions of matter, pharmaceutical compositions, methods of use and synthetic methods.

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

## **Competition**

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in research and development of drugs for the treatment of the same diseases and conditions as our current and potential future product candidates. Many of these companies have substantially greater financial and other resources, larger research and development staffs and more extensive marketing and manufacturing organizations than we do. In addition, some of them have considerably more experience than us in preclinical testing, clinical trials and other regulatory

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approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also develop products that may be competitive with our product candidates, either on their own or through collaborative efforts.

We 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 product candidates, and there may be other companies working on competitive projects of which we are not aware.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals, and begin commercialization of their products sooner than we may for our own product candidates. These competitive products may have superior safety or efficacy, or be manufactured less expensively, than our product 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 product candidates or achieve a competitive position in the market. This would adversely affect our business.

### *PI3K Inhibitor Program*

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

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

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

TG Therapeutics, Inc. which we believe is conducting a Phase 1 clinical trial of TGR-1202.

In addition, many companies are developing product candidates directed to disease targets such as Bruton's Tyrosine Kinase, or BTK, Janus Kinase, or JAK, and Spleen Tyrosine Kinase, or Syk, in the fields of hematology-oncology and inflammation, including in the specific diseases for which we are currently developing IPI-145, or for which we may develop IPI-145 or other PI3K inhibitors in the future. Such companies include Pharmacyclics, Inc. which we believe is conducting multiple clinical trials of ibrutinib (PCI-32765) in hematologic malignancies and AbbVie, Inc., which we believe is conducting clinical trials of ABT-199 in hematologic malignancies.

### *Hsp90 Inhibitor Program*

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

Synta Pharmaceuticals Corp., which we believe is conducting a Phase 3 and multiple Phase 2 clinical trials of ganetespiib;

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

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

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

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

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

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### **Research and Development**

As of February 28, 2013, our research and development group consisted of 124 individuals, of whom over 33 percent hold Ph.D. or M.D. degrees and over an additional 24 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, 2012, 2011 and 2010 was approximately \$118.6 million, \$108.6 million and \$99.2 million, respectively. Reimbursement for our strategic collaborator-sponsored research and development expenses for the years ended December 31, 2012, 2011 and 2010 totaled approximately \$45.0 million, \$88.5 million and \$67.0 million, respectively. In calculating strategic collaborator-sponsored research and development expenses, we have included all reimbursement for our research and development efforts and excluded license fees. Our remaining research and development expense is company-sponsored.

### **Manufacturing and Supply**

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

### **Sales and Marketing**

We currently have limited marketing, and no commercial sales or distribution, capabilities. We do, however, currently have worldwide development and commercialization rights for products arising out of all of our programs. In order to commercialize any of these drugs if and when they are approved for sale, we will need to, and we intend to, develop the necessary marketing, sales and distribution capabilities.

### **Government Regulation**

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, storage, recordkeeping, approval, promotion, labeling, advertising, distribution, marketing, post-approval monitoring and reporting, sampling, and export and import of pharmaceutical products such as those we are developing. We cannot provide assurance that any of our product 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 in compliance with the FDA's Good Laboratory Practices (GLP) 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;

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

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

Prior to the 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 product candidate is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, bioavailability, absorption, distribution, excretion and metabolism. These studies may be conducted in healthy volunteers or patients with the disease being studied.

Phase 2: The product 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 product 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 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 product candidates within any specific time period, if at all. Clinical testing must meet requirements for IRB oversight, informed consent and good clinical practices (GCP). 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.

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

Upon submission of the NDA, the FDA will make a threshold determination of whether the application is sufficiently complete to permit review, and, if not, will issue a refuse-to-file letter. If the application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the prescription drug user fee law in effect at that time. 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 product candidate subject to the completion of post-marketing studies, commonly referred to as Phase 4 trials, to monitor the effect of the approved product. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a special risk management plan. The FDA has broad post-market regulatory and enforcement powers, including the ability to issue warning letters, levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

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

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

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consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

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

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

Approval of a drug in the United States does not guarantee approval in any other country and vice versa. Thus, we will have to complete approval processes that are similar to those in the United States in virtually every foreign market in order to conduct clinical or preclinical research and to commercialize our product 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.

In common with the United States, the various phases of preclinical and clinical research are subject to significant regulatory controls within the European Union. Variations in the national regimes exist. Most jurisdictions, however, require regulatory and IRB approval of interventional clinical trials. Most European regulators also require the submission of adverse event reports during a study and a copy of the final study report. Under European Union regulatory systems, for products that have an Orphan Drug designation or which target cancer, such as the product 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

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competitor's product for the same indication or disease. We intend to seek Orphan Drug status for our product candidates as appropriate, but an Orphan Drug designation may not provide us with a material commercial advantage.

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

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

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

### **Employees**

As of February 28, 2013, we had 154 full-time employees, 124 of whom were engaged in research and development and 30 of whom were engaged in management, administration and finance. Over 55 percent of our employees 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 in doing so in the future. None of our employees 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 employees are good.



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

The following table lists the positions, names and ages of our executive officers as of March 1, 2013:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Adelene Q. Perkins	53	President and Chief Executive Officer
Julian Adams, Ph.D.	58	President of Research & Development
Lawrence E. Bloch, M.D., J.D.	47	Executive Vice President, Chief Financial Officer and Chief Business Officer
Joshua Hamermesh	41	Vice President, Business & Corporate Development
Vito J. Palombella, Ph.D.	50	Chief Scientific Officer
Pedro Santabarbara, M.D., Ph.D.	60	Chief Medical Officer
Winselow S. Tucker, Jr.	45	Vice President, Marketing

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

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

*Lawrence E. Bloch, M.D., J.D.* has served as our Chief Financial Officer and Chief Business Officer since July 2012. Prior to joining Infinity, Dr. Bloch served as chief executive officer of NeurAxon, Inc., a privately-held biopharmaceutical company, from 2007 to 2011. Previously, he served as chief business officer and chief financial officer of NitroMed, Inc., a publicly-held biopharmaceutical company, from 2004 to 2006. From 2000 to 2004, Dr. Bloch served as Chief Financial Officer, and from 1999 to 2002 as Vice President of Business Development, of Applied Molecular Evolution, Inc., a publicly-held biopharmaceutical company. Dr. Bloch began his career as an emergency medicine resident physician at Massachusetts General Hospital and Brigham & Women's Hospital. He holds a J.D. from Harvard Law School, an M.D. from Harvard Medical School and an M.B.A. from Harvard Business School.

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

*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. Prior to his role as Chief Scientific Officer, Dr. Palombella was Vice President, Drug Discovery from September 2006 to May 2010 and Vice President, Biology of IPI from January 2004 to September 2006. Prior to joining Infinity, Dr. Palombella was Director of Molecular Biology and Protein Chemistry at Syntonix Pharmaceuticals where he was responsible for improving and expanding its core Fc receptor-mediated drug delivery technology. Before joining Syntonix, Dr. Palombella was Senior Director of Cell and Molecular Biology at Millennium Pharmaceuticals, which he joined through its acquisition of LeukoSite, at which 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.

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

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

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### **Available Information**

Our Internet website is <http://www.infi.com>. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the U.S. Securities and Exchange Commission. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled Investors/Media, as a source of information about us.

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

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

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

#### **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 product candidates is high. To date, the data supporting our clinical development strategy for our product candidates are derived solely from laboratory and preclinical studies and limited early-to-mid-stage clinical trials. Later clinical trials may not yield data consistent with earlier clinical trials, as was the case with our randomized Phase 2 clinical trial of saridegib in patients with pancreatic cancer, which we elected to discontinue in January 2012 following a preliminary analysis of data that did not confirm what was observed in the single-arm, Phase 1b portion of the study. Similarly, clinical responses seen in patients enrolled at early stages of a clinical trial may not be replicated in patients enrolled in that trial at a later time. In addition, adverse events observed in a small number of patients in early clinical trials may be seen in a greater number of patients in later studies and have greater statistical significance than previously anticipated. In the event that our clinical trials do not yield data consistent with earlier experience, it may be necessary for us to change our development strategy or abandon development of that product candidate, either of which could result in delays, additional costs and a decrease in our stock price. It is impossible to predict when or if any of our product candidates will prove safe or effective in humans or receive regulatory approval. These product 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.

*We have a history of operating losses, expect to incur significant and increasing operating losses in the future, may never become profitable, or if we become profitable we may not remain 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, 2012, we had an accumulated deficit of \$323.0 million. We expect to continue to spend significant resources to fund the research and development of IPI-145, retaspimycin HCl, and our other product candidates. While we

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may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

Our product 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 product candidates successfully completes clinical trials and receives regulatory approval. Since even our most advanced product candidate requires substantial additional clinical development, we do not expect to receive revenue from our product candidates for several years, if ever. 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 are sufficient to fund our current operating plans into 2015. In the absence of changes to our current operating plans, we will need to raise additional funds by that date. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectation, if we acquire a third party or if we acquire or license rights to additional product candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including if:

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

we advance our product candidates into clinical trials for more indications than we currently expect;

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

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

we acquire additional business, technologies, products or product candidates;

the cost of acquiring raw materials for, and of manufacturing, our product 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; or

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

Historically, we relied on our strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for a significant portion of our research and development funding needs. Mundipharma and Purdue provided us with approximately \$260 million in research and development funding during the term of our strategic alliance. Following the termination of the strategic alliance agreements with Mundipharma and Purdue on July 17, 2012, we no longer receive such funding and must use other resources available to us to fund our research and development expenses. Our efforts to raise sufficient capital to replace the funding we previously received under the terminated strategic alliance agreements may not be successful.

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. In addition, the terms of such financings may result in, among other things, dilution for stockholders or the incurrence of indebtedness that may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish

or encumber rights to some of our technologies or product candidates, and we may not be

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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 or to scale back, suspend or terminate our business operations.

*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 executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice, and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. 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 or 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 not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities or funding for the development and commercialization of our product candidates.*

As part of our business strategy, we have historically entered, and expect to enter in the future, alliances with major biotechnology or pharmaceutical companies to jointly develop specific product candidates and to jointly commercialize them if they are approved. In these alliances, we would expect our alliance partner to provide substantial funding, as well as significant capabilities in development, marketing and sales. We may not be successful in entering into any such alliances on favorable terms, if at all. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved drug are disappointing. Furthermore, any delay in entering into alliances could delay the development and commercialization of our product candidates and reduce their competitiveness, even if they reach the market. Any such delay related to our alliances could adversely affect our business.

*If an alliance partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our product candidates could be delayed or terminated.*

If any future alliance partner does not devote sufficient time and resources to its alliance arrangements with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if any alliance partner were to breach or terminate its arrangements with us, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on its own, and we may find it difficult to attract a new alliance partner for such product candidate.

Much of the potential revenue from any alliance we may enter into in the future will likely 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 partner's, ability to successfully develop, introduce,

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market and sell new drugs. In some cases, we will not be involved in these processes, and we will depend entirely on our alliance partners. Any of our future alliance partners may fail to develop or effectively commercialize these drugs 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 product candidates 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 product candidate through clinical development, regulatory approval and commercialization; or

cannot obtain the necessary regulatory approvals.

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

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

Our ability to manage changes to our organization 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 during periods of 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 give rise to inefficiencies that would increase our losses or delay our programs.

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

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

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

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

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

As of December 31, 2012, we had approximately \$326.6 million in cash, cash equivalents and available-for-sale securities. We historically have invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, U.S. Treasury securities and mortgage-backed securities meeting the criteria of our investment policy, which is focused on the preservation of our capital. Corporate obligations may include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. Our investments are subject to general credit, liquidity, market and interest rate risks and instability in the global financial markets. We may realize losses in the fair value of these investments or a complete loss of these investments. In 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 results and the availability of cash to fund our operations.

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

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

Under our strategic alliance termination agreements, Mundipharma and Purdue continue to have the right to audit research and development expenses incurred by us during the term of our former strategic alliance, in order to verify the research and development funding amounts previously paid by Mundipharma and Purdue. Mundipharma requested such an audit in the context of discussions regarding renegotiation of our strategic alliance agreements and such audit is currently ongoing. If, as a result of any audit, it is determined that Mundipharma and Purdue have overpaid research and development expenses, we will be required to refund the amount of such overpayment, plus interest, and if such amount is material we may be required to restate prior period revenue.

*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



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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 product 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 product candidates.*

To date, we have not obtained approval from the FDA or any foreign regulatory authority to market or sell any of our product candidates. Our product 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 product candidates. For example, we are evaluating retaspimycin HCl, in Phase 2 and Phase 1b/2 clinical trials. In addition, we are conducting a Phase 2a and a Phase 1 clinical trial to evaluate IPI-145, the lead compound in our PI3K inhibitor program. We intend to commence additional trials of IPI-145, subject to receiving applicable regulatory clearances to commence these trials. If any of these trials are successful, we will need to conduct further clinical trials and apply for regulatory approval before we may market or sell any of our future products. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we are developing, or may in the future develop, either alone or in collaboration with strategic alliance partners, will obtain marketing approval. 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 product 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 product candidates will qualify for one or more of these programs. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product 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 and other regulatory policy during the period of product candidate development, clinical trials and FDA and other regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenues from the particular product 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 product 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 product 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 or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product 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;

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delays in enrolling patients into clinical trials;

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

the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;

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

unfavorable FDA or other foreign regulatory 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, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;

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

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

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

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product 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.

In June 2012 we voluntarily stopped our Phase 2, double-blind, randomized, placebo-controlled study evaluating saridegib in patients with metastatic or locally advanced, inoperable chondrosarcoma and our exploratory Phase 2 clinical trial evaluating saridegib in patients with myelofibrosis after the studies showed that treatment with saridegib was similar to placebo or did not satisfy our pre-specified criteria for trial expansion. As a result, we terminated our development of saridegib.

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

***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 product 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 safe and 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.

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Our failure to enroll patients in a clinical trial could delay the initiation or completion of the clinical trial beyond current expectations. In addition, the FDA or other foreign regulatory authority could require us to conduct clinical trials with a larger number of patients than has been projected for any of our product 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 product 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 product candidate; and

the availability of numerous alternative treatment options, including clinical trials evaluating competing product candidates, 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 product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

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

An important component of our business strategy is to develop companion diagnostics for each of our product candidates. For example, we are prospectively evaluating a molecular subpopulation of patients in our clinical trial evaluating retaspimycin HCl plus docetaxel in smokers with non-small cell lung cancer, for which development of an appropriate diagnostic test may be an important component of our future development and commercial strategy. There has been limited success to date industry wide in developing companion diagnostics. To be successful, we will need to address a number of scientific, technical and logistical challenges. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our product candidates that receive marketing approval. Given our limited experience in developing diagnostics, we expect to rely, in part, on third parties for their design and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not receive marketing approval and we may not realize the full commercial potential of any product candidates that receive marketing approval.

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

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

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

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

Our product 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 product 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 product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our product 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 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 product 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 product 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 product 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 product 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 product candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product 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 product 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.

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

We have global commercialization rights for products arising out of our all of our development programs. In order to successfully commercialize our product candidates, we will need to, and we intend to, establish adequate marketing, sales and distribution capabilities for commercialization in the United States, and to seek a qualified partner with these capabilities for commercialization outside the United States. We may not successfully establish these capabilities or have sufficient resources to do so. If we do not establish adequate marketing, sales and distribution capabilities or engage a qualified partner, our ability to successfully commercialize any product candidates that we successfully develop will be adversely affected, as will our financial results. Even if we do develop such capabilities, we will compete with other companies that have more experienced and well-funded marketing, sales and distribution operations, and we will incur additional expenses.

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

Even if any of our product 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, which may adversely impact our ability to become profitable.

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

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

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

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

Our ability to commercialize any future products 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 in the U.S. generally require that product candidates 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 products or we may be required to sell our products at prices that are below our expectations.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of our product in determining whether, and at what level, to approve reimbursement for our products. 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 product 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 and Medicaid programs or other reimbursing bodies or payors limit the indications for which our products will be reimbursed to a smaller set than we believe our products 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 products 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 would be materially harmed.

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

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

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

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

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

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

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

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

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

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the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug marketing, prohibits manufacturers from marketing drugs 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 financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our product candidates in compliance with all applicable 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 and inflammatory diseases, which are highly competitive and rapidly changing segments of the pharmaceutical industry. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various diseases in these segments. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products in these segments including Bristol-Myers Squibb Company, the Roche Group and its subsidiary Genentech, Novartis AG and Pfizer, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer and inflammatory diseases. We are also aware of a number of companies seeking to develop product candidates directed to the same biological targets that our own product candidates are designed to inhibit. Specifically, we believe the following companies are developing compounds that target Hsp90, which is the target of retaspimycin HCl: Synta Pharmaceuticals Corp., Novartis AG, Astex Pharmaceuticals, Inc., Daiichi Sankyo, Inc., Debiopharm Group, Exelixis, Inc., and Kyowa Hakko Kirin Co. Ltd. Also, we believe that Gilead Sciences, Inc., Amgen Inc., and TG Therapeutics, Inc. are developing drugs that target the delta and/or gamma isoforms of PI3K, which is the target of IPI-145. In addition, many companies are developing product candidates directed to disease targets such as Bruton's Tyrosine Kinase, or BTK, Janus Kinase, or JAK, and Spleen Tyrosine Kinase, or Syk, in the fields of hematology-oncology and inflammation, including in the specific diseases for which we are currently developing IPI-145, or for which we may develop IPI-145, IPI-443 or other PI3K inhibitors in the future. Such companies include Pharmacyclics, Inc., which we believe is conducting multiple clinical trials of ibrutinib (PCI-32765) in hematologic malignancies, and AbbVie, Inc., which we believe is conducting clinical trials of ABT-199 in hematologic malignancies.

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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 product candidates;

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

product candidates that have been approved or are in later-stage clinical development than our own product 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 product candidates. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than our future products. 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 future products 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 product 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 product 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 product 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 product candidates or future products, 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 future 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, and various radioactive compounds. We are subject to certain federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We incur significant costs to comply with these laws and regulations. In addition, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, regulatory authorities may curtail our use of these materials, and we could be liable for any civil damages that result. These damages may exceed our financial resources or insurance coverage, and may seriously harm our business. Additionally, an accident could damage, or force us to shut down, our operations.

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

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

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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 product candidates.*

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

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical or molecular diagnostics patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. 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.

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

If we do not obtain adequate intellectual property protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we will have been required to undertake to obtain approval by the FDA. Regardless of any patent protection, under the current statutory framework the FDA is prohibited by law from approving any generic version of any of our products for up to five years after it has approved our product. Upon the expiration of that period, or if that time period is altered, the FDA could approve a generic version of our product unless we have patent protection sufficient for us to block that generic version. Without sufficient patent protection, the applicant for a generic version of our product would only be required to conduct a relatively inexpensive study to show that its product is bioequivalent to our product, and would not have to repeat the studies that we conducted to demonstrate that the product is safe and effective. In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries of products that duplicate our products. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of our development efforts are performed in China, India, and other countries outside of the United States through third party contractors. We may not be able to monitor and assess intellectual property developed by these contractors effectively; therefore, we may not be able to appropriately protect this intellectual property and could thus lose valuable intellectual property rights. In addition, the legal protection afforded to

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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 product 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 product candidates or their therapeutic use. In the event that a third party has also filed a U.S. patent application relating to our product 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. 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. If we fail to comply with these requirements, competitors might be able to enter the market earlier than would otherwise have been the case, which could decrease our revenue from that product.

***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 product 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 product 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 product candidates, even when we are aware of third party patents that may be relevant to such product candidates, on the basis that we may challenge or license such patents. For example, in our Hsp90 inhibitor program, we are conducting clinical trials evaluating the administration of retaspimycin HCl in combination with docetaxel and everolimus. We are aware of issued patents and published applications directed to combinations of Hsp90 inhibitors with a variety of therapeutic agents. We are also aware of patents and patent applications directed to methods of treating various disorders using a variety of Hsp90 inhibitors. We are in the process of evaluating the scope and validity of these patents and applications to determine whether we need to obtain one or more licenses. There are no assurances that such licenses will be available on commercially reasonable terms, or at all. If such licenses are not available, we may become subject to patent litigation and,

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while we cannot predict the outcome of any of litigation, it may be expensive and time consuming. If we are unsuccessful in litigation concerning patents owned by third parties, we may be precluded from selling our products.

While we are not currently aware of any litigation or third party claims of intellectual property infringement related to our product 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 product candidates or approved products;

develop non-infringing product candidates, 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.

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

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

In addition, we may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets are, however, difficult to protect. Others may independently discover our trade secrets and proprietary information, and in such case we could not assert any

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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 product 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 product candidates while we attempt to develop alternative technologies, methods and product 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 products licensed under our amended and restated development and license agreement with Millennium, we could lose our license rights under that agreement, including rights to IPI-145.

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

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

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

the results of our current and any future clinical trials of our product 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, including the sale by entities associated with Purdue of the shares of our common stock that they currently own;

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 amended and restated development and license agreement with Millennium;

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

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

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

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

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

issues in manufacturing our product candidates or any approved products;

the loss of key employees;

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

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



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changes in the structure of healthcare payment systems;

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

general and industry-specific economic and/or capital market 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.

***Anti-takeover provisions in our organizational documents and Delaware law may make an acquisition of us difficult.***

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 1,000,000 shares of undesignated preferred stock, of which only 99,000 shares have been designated to date, and to determine the terms of those shares of stock without any further action by our stockholders. If our board of directors exercises this power, it could be more difficult for a third party to acquire a majority of our outstanding voting stock. Our charter and by-laws also contain provisions limiting the ability of stockholders to call special meetings of stockholders.

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

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

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

To our knowledge, as of December 31, 2012, our executive officers, directors, their respective affiliates and certain other significant stockholders, owned approximately 42% of our common stock. These stockholders have the ability to influence our 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

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matters submitted to our stockholders for approval, including the election and removal of directors, changes to our equity compensation plans, 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.

Currently, entities associated with Purdue, which as of December 31, 2012 control approximately 24% of our outstanding common stock, have a limited ability to influence our company through its ownership position. These entities have agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017, and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting. However, with respect to any proposal to amend our corporate charter or approve certain extraordinary transactions, all shares of our common stock that are owned by those entities that are were not issued pursuant to the 2012 securities purchase agreement, which as of December 31, 2012 represents approximately 12.6% of our outstanding common stock, will be voted in proportion to the manner in which all of our stockholders, other than those entities, vote in respect of such proposal, regardless of the recommendation of our board of directors.

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

None.

### **Item 2. Properties**

We currently lease under two lease agreements an aggregate of approximately 74,900 square feet of laboratory and office space among three buildings located at 780, 784, and 790 Memorial Drive in Cambridge, Massachusetts. One lease covering approximately 68,000 square feet of laboratory and office space expires in January 2016. We have the right to extend this lease for another five-year term on the same terms and conditions as the current lease by giving the landlord notice prior to the expiration of the current lease term. We currently sublease approximately 13,000 square feet of this space under a sublease agreement that expires in April 2013. The second lease covers approximately 6,900 square feet of office space and expires in October 2014. Should we require additional space, we believe that a suitable facility would be available to accommodate expansion of our operations on commercially reasonable terms.

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

We are not a party to any material legal proceedings.

### **Item 4. Mine Safety Disclosures**

Not applicable.

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

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

	2012		2011	
	High	Low	High	Low
First quarter	\$ 12.40	\$ 5.50	\$ 6.10	\$ 5.23
Second quarter	14.15	11.02	8.30	5.58
Third quarter	24.00	13.45	10.42	5.81
Fourth quarter	35.32	17.21	10.00	6.50

 **Holders**

As of February 28, 2013, there were 1,599 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, 2007 through December 31, 2012 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, 2007, and that all dividends were reinvested. No cash dividends have been declared or paid on our common stock.

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

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**Comparison of 5-Year Cumulative Total Return  
among Infinity Pharmaceuticals, Inc.,  
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. Amounts below are in thousands, except for shares and per share amounts.

	Year Ended December 31,				
	2012	2011	2010	2009	2008
<b>Statement of Operations Data:</b>					
Collaborative research and development revenue:					
From Purdue entities	\$ 47,114	\$ 92,773	\$ 71,331	\$ 50,765	\$ 3,027
Other(1)					80,558
<b>Total revenue</b>	<b>47,114</b>	<b>92,773</b>	<b>71,331</b>	<b>50,765</b>	<b>83,585</b>
Operating expenses:					
Research and development	118,595	108,582	99,232	77,857	47,466
General and administrative	27,882	22,719	21,070	19,456	16,837
<b>Total operating expenses</b>	<b>146,477</b>	<b>131,301</b>	<b>120,302</b>	<b>97,313</b>	<b>64,303</b>
Gain on termination of Purdue entities alliance	46,555				
<b>Income (loss) from operations</b>	<b>(52,808)</b>	<b>(38,528)</b>	<b>(48,971)</b>	<b>(46,548)</b>	<b>19,282</b>
Interest income (expense), net	(1,349)	(1,514)	(1,447)	744	3,321
<b>Income from NIH reimbursement</b>				<b>1,745</b>	
Income from residual funding after reacquisition of Hsp90 program				12,450	1,195
<b>Income from Therapeutic Discovery Grants</b>			<b>734</b>		
Income from Massachusetts tax incentive award	193				
<b>Income (loss) before income taxes</b>	<b>(53,964)</b>	<b>(40,042)</b>	<b>(49,684)</b>	<b>(31,609)</b>	<b>23,798</b>
Income tax benefit			700	330	
<b>Net income (loss)</b>	<b>\$ (53,964)</b>	<b>\$ (40,042)</b>	<b>\$ (48,984)</b>	<b>\$ (31,279)</b>	<b>\$ 23,798</b>
Earnings (loss) per common share:					
Basic	\$ (1.70)	\$ (1.50)	\$ (1.86)	\$ (1.20)	\$ 1.18
Diluted	\$ (1.70)	\$ (1.50)	\$ (1.86)	\$ (1.20)	\$ 1.15
Weighted average number of common shares outstanding:					
Basic	31,711,264	26,620,278	26,321,398	26,096,515	20,236,743
Diluted	31,711,264	26,620,278	26,321,398	26,096,515	20,765,536

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

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	2012	2011	As of December 31, 2010	2009	2008
<b>Selected Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities, including long-term	\$ 326,635	\$ 115,937	\$ 100,959	\$ 130,737	\$ 126,772
Working capital	311,086	88,995	75,378	119,408	119,360
Total assets	335,660	124,490	124,566	157,318	160,618
Long-term debt due to Purdue entities, net of debt discount(1)		37,553			
Due to Millennium, less current portion(2)	6,252				
Accumulated deficit	(323,016)	(269,052)	(229,010)	(180,026)	(148,747)
Total stockholders' equity	310,205	15,433	49,484	90,312	103,121

- (1) In November 2011, we borrowed \$50 million under the line of credit agreement with Purdue and its independent associated entity, Purdue Pharma L.P., or PPLP. We reduced the long-term debt on our balance sheet with a debt discount. On September 7, 2012, upon completion of the sale and issuance of common stock to PPLP under the 2012 securities purchase agreement, the line of credit agreement with PPLP terminated in its entirety. See note 10 of the financial statements.
- (2) During the year ended December 31, 2012, we recorded \$14.4 million in research and development expense related to the fair value of a release payment of \$15 million, payable in installments, pursuant to the amended and restated agreement with Millennium. We paid \$1.7 million of this \$15 million release payment during the year ended December 31, 2012 and recorded \$6.5 million in due to Millennium, current and \$6.2 million in due to Millennium, noncurrent as we intend to pay these amounts by December 31, 2013 and December 31, 2014, respectively.

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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 an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines designed to address diseases with significant unmet need. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. Our programs focused on the inhibition of phosphoinositide-3-kinase and heat shock protein 90 are evidence of our innovative approach to drug discovery and development. We have worldwide development and commercialization rights to all of our development candidates and early discovery programs, subject to certain financial obligations to our current licensor and former development partners.

IPI-145, our lead product candidate, is a potent, oral inhibitor of Class I PI3K-delta and PI3K-gamma, which we are investigating in both hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the first PI3K-delta, gamma inhibitor in clinical development. The following is a summary of the clinical development of IPI-145 to date:

#### *Hematologic Malignancies*

We are conducting a Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies.

We are enrolling patients in five additional cohort expansions in the Phase 1 study to further evaluate the safety, pharmacokinetics and activity of IPI-145 in patients with the following hematologic malignancies:

Chronic lymphocytic leukemia, indolent non-Hodgkin lymphoma and mantle cell lymphoma

T-cell lymphomas

Aggressive B-cell lymphomas

Myeloid neoplasms

T-cell or B-cell acute lymphoblastic leukemia/lymphoma

We are planning to initiate at least two additional trials of IPI-145 in patients with hematologic malignancies in 2013.

#### *Inflammation*

We have completed a Phase 1, randomized, double-blind, placebo-controlled trial of IPI-145 in healthy adult subjects designed to support the development of IPI-145 in inflammatory diseases.

We are conducting a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in patients with mild, allergic asthma.

We are planning to initiate in the first half of 2013 a Phase 2, randomized, placebo-controlled study to evaluate the safety and activity of multiple doses of IPI-145 in patients with rheumatoid arthritis.



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In January 2013, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443. We expect to complete in the second half of 2013 nonclinical studies designed to enable the initiation of Phase 1 clinical development.

Our second clinical candidate, retaspimycin hydrochloride (HCl), is a novel, potent and selective inhibitor of heat shock protein 90 (Hsp90). We completed patient enrollment in a Phase 2, randomized, double-blind, placebo-controlled clinical trial evaluating retaspimycin HCl in combination with docetaxel, a chemotherapy, compared to placebo and docetaxel in 226 patients with second- or third-line non-small cell lung cancer (NSCLC), who are naive to docetaxel treatment and have a history of heavy smoking. We stratified patients in our Phase 2 trial by squamous cell carcinoma and adenocarcinoma based on results from our Phase 1b trial in which we observed partial responses in patients with squamous cell carcinoma. In addition, we are prospectively evaluating a novel biomarker that we believe may be predictive of response. We expect to report topline overall survival data from this trial in the first half of 2013.

We are also enrolling patients in a Phase 1b/2 trial to explore the safety and efficacy of retaspimycin HCl in combination with everolimus, an inhibitor of the mammalian target of rapamycin (mTOR), pathway, in NSCLC patients with a KRAS gene mutation. The objective of this Phase 1b/2 trial is to determine the recommended dose for the combination treatment and to evaluate the safety and clinical activity of retaspimycin HCl in combination with everolimus. We expect to provide an update from this Phase 1b/2 trial in the first half of 2013.

In addition to our clinical stage programs, we have multiple innovative projects in earlier stages of development. Through our internal discovery efforts, we also discovered IPI-940, a novel, orally available inhibitor of FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. We are currently seeking potential partnering opportunities for our FAAH program. In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our lead Hedgehog pathway inhibitor.

## **Strategic Alliances**

### ***Millennium***

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. We paid Intellikine a \$13.5 million up-front license fee. The entirety of this fee was included as research and development expense in the year ended December 31, 2010, although \$8.5 million of this fee was paid in January 2011. During the second half of 2011, we paid Intellikine \$4.0 million in milestone payments associated with the initiation of two Phase 1 studies of IPI-145, which we recorded as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In December 2012, we amended and restated our development and license agreement with Millennium.

Under the original agreement, we obtained worldwide development and commercialization rights to Millennium's portfolio of inhibitors of the delta and/or gamma isoforms of PI3K for all indications, and we conducted a collaborative research program with Millennium to identify compounds directed to PI3K-delta and/or PI3K-gamma which meet certain selectivity criteria, with such research collaboration under the original agreement set to expire in July 2013. Also under the original agreement, neither we nor Millennium were permitted to research, develop or commercialize products directed PI3K-delta and/or PI3K-gamma which meet certain selectivity criteria, other than the compounds subject to the collaboration, except that Millennium was permitted to research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

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Under the terms of the amended and restated agreement, we retained our worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications. We and Millennium will no longer conduct the collaborative research program and the restrictions on each party's ability to research, develop and commercialize products directed to the delta and/or gamma isoforms of PI3K that meet certain selectivity criteria have terminated, subject, in the case of Millennium, to the exclusive licenses granted to us under the amended and restated agreement.

Additionally, under the amended and restated agreement, Millennium waived the option it had under the original agreement to convert, upon payment of an option fee, its royalty interest in U.S. sales of PI3K products and its right to receive certain milestone payments with respect to such products into the right to share in 50% of profits and losses on U.S. development and commercialization of those PI3K products for which the first Phase 2 clinical trial, as defined in the original agreement, was conducted in an oncology indication, and to participate in up to 30% of the detailing effort for these products in the United States. In consideration of such waiver we have agreed to pay to Millennium \$15 million payable in installments. We have paid \$1.7 million of the \$15 million during the year ended December 31, 2012. Additionally, under the amended and restated agreement we have paid Millennium a \$5 million milestone payment associated with the initiation of our Phase 2a clinical trial of IPI-145 in patients with mild, allergic asthma. Under the terms of the original agreement, the initiation of the Phase 2a trial in asthma would not have required a milestone payment.

In addition to developing IPI-145, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443, and we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. During the year ended December 31, 2012, we paid Millennium a \$1.0 million milestone payment for the initiation of the first IND-enabling cGLP toxicology study of IPI-443. We are obligated to pay up to \$15 million in remaining 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. As a result of the amendment, such products may include products we license in from a third party. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from seven percent to 11 percent, which are the same royalty levels as those specified under the original agreement, upon successful commercialization of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction, and limits on the number of products, in certain circumstances.

The amended and restated agreement expires on the later of the expiration of certain patents and the expiration of the royalty payment terms for the products, 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. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium's reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days' prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days' prior written notice. The agreement also provides for customary reciprocal indemnification obligations of the parties.

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

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 termination agreements. The alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting FAAH. The

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2008 agreement with Mundipharma was focused on the development and commercialization outside of the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K, and product candidates arising out of our early discovery projects in all disease fields. Our Hsp90 program was expressly excluded from the alliance.

Under the terms of the 2012 termination agreements:

All intellectual property rights that we had previously licensed to Mundipharma and Purdue to develop and commercialize products under the previous strategic alliance agreements terminated, with the result that we have worldwide rights to all product candidates that had previously been covered by the strategic alliance.

We have no further obligation to provide research and development services to Mundipharma and Purdue as of July 17, 2012.

Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. During the year ended December 31, 2012, we received \$55 million in research and development funding. We recognized revenue for reimbursed research and development services we performed for Mundipharma and Purdue, including \$45 million in such revenue in the year ended December 31, 2012. We recognized \$88.5 million and \$67.0 million in such revenue, which included \$3.5 million and \$2.0 million, respectively, in revenue related to reimbursed research and development services for the transition of the FAAH program, in the years ended December 31, 2011 and 2010, respectively. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

We are obligated to pay Mundipharma and Purdue a four percent royalty in the aggregate (subject to reduction as described below), on worldwide net sales of products that were covered by the alliance until such time as they have recovered approximately \$260 million, representing the research and development funding paid to us for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a one percent royalty on net sales in the United States of products that were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products subject to the alliance that are subject to significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, no amounts have been accrued.

Royalties are payable under these agreements 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 royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

*Line of Credit Agreement*

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP, that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. The extension of the line of credit at an interest rate below our incremental borrowing rate represented the transfer of

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additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset on our balance sheet in 2008. The fair value of the loan commitment asset was determined using a discounted cash flow model of the differential between the terms and rates of the line of credit and market rates. We amortized the loan commitment asset to interest expense until we drew down the line of credit in November 2011. We recorded approximately \$1.6 million and \$1.7 million of related amortization expense in the years ended December 31, 2011 and 2010, respectively.

In November 2011, we borrowed \$50 million under this line of credit, which we recorded as long-term debt. The loan would have matured and was payable in full, including principal and any accrued interest, on April 1, 2019, which we referred to as the maturity date, and would have been subordinate to any senior indebtedness that we may have incurred. The loan bore interest at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and reset on the last business day of each month ending thereafter. At the time of the borrowing, the prime rate was 3.25%. Interest was compounded on each successive three-month anniversary following the date of borrowing. Upon drawing down the \$50 million under the line of credit agreement, we reclassified the loan commitment asset as a debt discount which reduced the debt on our balance sheet. The unamortized balance of the loan commitment asset was \$12.7 million as of the date of borrowing. We recorded interest expense on the net amount borrowed using the effective interest method. We recorded \$1.9 million and \$0.2 million of related interest expense in the years ended December 31, 2012 and 2011, respectively, using an effective interest rate of 7.29%.

On September 7, 2012, upon completion of the sale and issuance of common stock to PPLP under the 2012 securities purchase agreement described below, the line of credit agreement with PPLP terminated in its entirety and approximately \$51.0 million in principal and interest owed to PPLP under the line of credit agreement was extinguished.

*2008 Securities Purchase Agreement*

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a securities purchase agreement with Purdue and PPLP. Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of 6,000,000 shares of our common stock and warrants to purchase up to an aggregate of 6,000,000 shares of our common stock, for an aggregate purchase price of \$75 million. An equal number of securities were sold to each purchaser. As of December 31, 2012, all warrants that were issued in connection with the strategic alliance expired without having been exercised.

We recorded an aggregate of \$59.3 million in deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue, which consisted of the excess of the amount paid for the purchased shares over the closing market price on the day before the equity closings and the value of the loan commitment asset. We determined that the rights and licenses did not have stand-alone value, and we considered all of the obligations under the arrangement to be a single unit of accounting. There was no obligation for us to repay the \$59.3 million, and we had been recognizing the deferred revenue ratably over 14 years, which was our estimated period of performance under the arrangement through July 17, 2012. We recognized \$2.1 million, \$4.3 million and \$4.3 million in deferred revenue associated with grant of rights and licenses in the years ended December 31, 2012, 2011 and 2010, respectively. The unamortized balance as of July 17, 2012 was reversed and included in the calculation of the gain on termination.

*2012 Securities Purchase Agreement*

On July 17, 2012, in connection with the termination of the strategic alliance with Mundipharma and Purdue, we executed a securities purchase agreement with PPLP, which we refer to as the 2012 securities purchase agreement, under which we agreed to sell and issue 5,416,565 shares of our common stock to PPLP and two entities associated with PPLP, which we collectively refer to as the BRP entities, at a price of \$14.50 per share for an aggregate consideration of approximately \$78.5 million. The consideration was composed

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of extinguishment of approximately \$51.0 million in principal and interest owed to PPLP under the line of credit agreement and \$27.5 million in cash. We completed the sale and issuance on September 7, 2012 at which time the line of credit agreement with PPLP terminated in its entirety.

The 2012 securities purchase agreement also provides that, at any time during the period beginning January 1, 2013 and ending December 31, 2018, in the event we propose to make an underwritten offering of our common stock, subject to certain limitations, the Purdue entities will have piggyback registration rights, which require us, at the election of the Purdue entities, to use our reasonable best efforts to cause to be included in such underwritten offering, common stock then held by the Purdue entities representing up to 20% of the total estimated maximum dollar amount of our common stock proposed to be sold in such underwritten offering.

In addition, the BRP entities have agreed that during the period between July 17, 2012 and December 31, 2013, if requested by us and/or the managing underwriters, placement agents or initial purchasers for any offering of our stock proposed by us during such period, not to, among other things, offer, sell or otherwise transfer or dispose of, directly or indirectly, any common stock held by the BRP entities or to enter into any agreement that transfers, in whole or in part, any of the economic consequences of ownership of any common stock held by the BRP entities, during such period as may be requested by such managing underwriters, the placement agents or the initial purchasers, and to execute a lock-up agreement reflecting such restrictions, provided that all of our officers, directors and affiliates enter into similar agreements with equivalent terms.

The 2012 securities purchase agreement also terminated, as of July 17, 2012, all attendance rights to meetings of our board of directors held by the Purdue entities.

The BRP entities and each associated company holding shares of our common stock have agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017, and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting. However, with respect to any proposal to amend our corporate charter or approve certain extraordinary transactions, all shares of our common stock that are owned by those entities that were not issued pursuant to the 2012 securities purchase agreement will be voted in proportion to the manner in which all of our stockholders other than those entities vote in respect of such proposal, regardless of the recommendation of our board of directors.

*Accounting Impact of Alliance Termination, Debt Extinguishment and Sale and Issuance of Common Stock*

We recorded the following during the year ended December 31, 2012:

gain on termination of Purdue entities strategic alliance of \$46.6 million;

additional equity on our balance sheet of \$74.4 million;

extinguishment of \$39.5 million of debt on balance sheet;

elimination of \$54.0 million of deferred revenue on balance sheet; and

additional cash of \$27.5 million.

We considered the fact that certain elements of the arrangement discussed above closed before others, despite the fact that all of the elements were negotiated and signed concurrently in contemplation of one another. In particular, the strategic alliance with Mundipharma and Purdue was terminated on July 17, 2012, and therefore, there are no further deliverables required under those agreements. However, the equity offering and debt extinguishment did not close at that time because certain regulatory events outside of our control had to occur prior to the closing. As a result, we evaluated the termination of the strategic alliance separately from the financing transaction, including the extinguishment of debt and sale and issuance of stock. We recorded the gain on termination of the Mundipharma and Purdue strategic alliance for \$46.6 million which represented our past



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performance under the 2008 collaboration because we have no further obligation to provide research and development, and the financial risk associated with the research and development has been transferred to the Purdue entities. In particular, any payment of royalties to Mundipharma and Purdue are conditional on the future commercialization of our product candidates.

To establish the financial impact of the stock issuance and debt extinguishment, we determined both the fair value of the common stock we sold and issued and the debt and accrued interest extinguished. We consider Mundipharma and Purdue to be related parties for financial reporting purposes because of their equity ownership. Therefore, we recorded the difference between extinguishing the fair value of the debt and accrued interest, the sale and issuance of our common stock and receiving \$27.5 million in cash in additional paid-in capital.

## **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 milestone payments received from our collaboration partners. License fees were recognized as revenue ratably over the expected research and development period under our arrangement with Mundipharma and Purdue. Because our agreements with Mundipharma and Purdue also provided for funding for our research and development efforts, we recognized 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 potential future 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.

### ***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;

costs of purchasing laboratory supplies and materials;

costs of manufacturing product 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;

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

depreciation of equipment; and

allocated costs of facilities.



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

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

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

Interest 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 included amortization of the loan commitment asset from Purdue entities, net, from April 2009 through November 2011 when we drew down the full \$50 million loan available under the line of credit agreement. Interest expense also included accrued interest on the long-term debt, including amortization of the debt discount, through September 7, 2012 when the debt was extinguished.

Income from Massachusetts tax incentive award represents the pro-rata amount earned for an award we received for headcount growth.

### **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, and assumptions in the valuation of stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates. Differences between actual and estimated results have not been material and are adjusted in the period they become known. We believe that the following accounting policies and estimates are most critical to understanding and evaluating our reported financial results. Please refer to note 2 to our consolidated financial statements for a description of our significant accounting policies.

### ***Revenue Recognition***

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

Under our strategic alliance with Mundipharma and Purdue, we recognized revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which was the research and development term. We regularly considered whether events warranted a change in the estimated period of performance under an agreement. Such a change would have caused us to modify the period of time over which we recognized 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 recognized research and development funding as earned over

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the period of effort as related research and development costs are incurred in proportion to our forecasted total expenses as compared to the total expected research and development funding for the year. We recognized the impact of any change in forecasted total expenses or expected research and development funding as a change in accounting estimate and recorded the impact of that change on a prospective basis. On July 17, 2012, we mutually agreed with Mundipharma and Purdue to terminate our strategic alliance agreements.

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

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

the consideration relates solely to past performance, and

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

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

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

### ***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, respectively. We often rely on subjective judgments to determine the date on which certain services commence, the level of services performed on or before a given date, and the cost of such services. We make these judgments based upon the facts and circumstances known to us. Our estimates of expenses in future periods may be over- or under-accrued.

### ***Stock-Based Compensation***

We expense the fair value of employee stock options and other equity compensation. We use our judgment in determining the fair value of our equity instruments, including in selecting the inputs we use for the Black-Scholes valuation model. Equity instrument valuation models are by their nature highly subjective. Any

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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.

**Results of Operations**

The following table summarizes our results of operations for the years ended December 31, 2012, 2011 and 2010, in thousands, together with the change in each item as a percentage.

	2012	% Change	2011	% Change	2010
Revenue	\$ 47,114	(49)%	\$ 92,773	30%	\$ 71,331
Research and development expense	(118,595)	9%	(108,582)	9%	(99,232)
General and administrative expense	(27,882)	23%	(22,719)	8%	(21,070)
Gain on termination of Purdue entities alliance	46,555				
Interest expense	(1,908)	4%	(1,841)	(4)%	(1,910)
Interest and investment income	559	71%	327	(29)%	463
Income from Massachusetts incentive tax award	193				
Income from Therapeutic Discovery Grants				(100)%	734
Income tax benefit				(100)%	700
<i>Revenue</i>					

Our revenue during the year ended December 31, 2012 consisted of approximately:

\$45.0 million related to reimbursed research and development services we performed under our strategic alliance entered into with Mundipharma and Purdue in November 2008; and

\$2.1 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, 2011 consisted of approximately:

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

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

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

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

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

In the absence of any potential business development activities that generate revenue, we do not expect to recognize any revenue in 2013.

*Research and Development Expense*

Research and development expenses represented approximately 81% of our total operating expenses for the year ended December 31, 2012, 83% of our total operating expenses for the year ended December 31, 2011, and 82% of our total operating expenses for the year ended December 31, 2010.

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The increase in research and development expense for the year ended December 31, 2012 compared to the year ended December 31, 2011 was primarily attributable to:

\$14.4 million associated with the fair value of installment payments related to amended and restated agreement with Millennium; and

\$5.0 million associated with the achievement of a milestone for the initiation of a Phase 2a clinical trial of IPI-145 in patients with mild, allergic asthma and a \$1.0 million milestone for the initiation of the first IND-enabling cGLP toxicology study of IPI-443. These increases were partially offset by a decrease of \$6.2 million in pharmaceutical development expense due primarily to the discontinuation of company-sponsored development of saridegib and \$4.0 million in milestone payments associated with the initiation of two Phase 1 clinical trials in our PI3K program.

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

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

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

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, 2012. These expenses primarily relate to payroll and related expenses for personnel working on the programs, process development and manufacturing, preclinical toxicology studies, clinical trial costs and allocated costs of facilities. From August 2006 through December 2008, our Hsp90 inhibitor program was conducted in collaboration with MedImmune, a division of AstraZeneca plc, or MedImmune, and from August 2006 through November 2007, our Hedgehog pathway inhibitor program was conducted in collaboration with MedImmune. Under this collaboration, we shared research and development expenses equally with MedImmune. Pursuant to our cost-sharing arrangement, reimbursable amounts from MedImmune were credited to research and development expense, and the expenses for the Hsp90 inhibitor and Hedgehog pathway inhibitor programs below include credits of approximately \$34.4 million in years prior to 2009.

Program	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010	January 1, 2006 to December 31, 2012
	(in millions)			
PI3K Inhibitor(1)	\$ 48.8	\$ 23.5	\$ 18.0	\$ 90.3
Hsp90 chaperone inhibitor	21.3	15.2	13.9	124.0
Hedgehog pathway inhibitor	34.0	48.4	33.4	162.7
FAAH inhibitor		2.9	18.7	31.1

(1) Includes an upfront license fee of \$13.5 million in 2010, \$4.0 million in development milestones in 2011, as well as \$14.4 million recorded as fair value for the release payment for the amended and restated Millennium agreement and \$6.0 million in development milestones in 2012. We expect expenses related to our PI3K program to increase as we continue clinical development of IPI-145. We expect expenses related to our Hedgehog pathway inhibitor program to decrease significantly as a result of the discontinuation of company-sponsored development. We do not believe that the historical costs associated



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with our lead drug development programs are indicative of the future costs associated with these programs nor represent what any other future drug development program we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a product candidate and uncertainties related to cost estimates and our ability to obtain marketing approval for our product 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 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 product candidates. These risks include the uncertainty of:

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

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

clinical trial results;

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

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

the cost and timing of regulatory approvals;

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

the effect of competing technological and market developments.

*General and Administrative Expense*

The increase in general and administrative expense for the year ended December 31, 2012 as compared to the year ended December 31, 2011 was primarily attributable to:

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an increase of \$1.9 million in stock-based compensation expense;

an increase of \$1.7 million in consulting expenses, principally related to early commercial development; and

an increase of \$1.0 million in legal expenses primarily related to corporate development activities.

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

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

an increase of \$1.0 million in patent expenses.

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



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### *Gain on Termination of Purdue Entities Alliance*

The gain on termination of the Purdue entities alliance is non-recurring and due to the 2012 termination agreements.

### *Interest Expense*

Interest expense was comparable for the years ended December 31, 2012, 2011 and 2010. We expect interest expense in 2013 to be lower than in 2012 primarily due to the extinguishment of the long-term debt due to the Purdue entities on September 7, 2012.

### *Interest and Investment Income*

Interest and investment income increased in the year ended December 31, 2012 as compared to the year ended December 31, 2011 primarily as a result of higher average cash and investment balance. Interest and investment income decreased in the year ended December 31, 2011 as compared to the year ended December 31, 2010 primarily as a result of lower yields on our cash equivalents and available-for-sale securities.

### *Income from Massachusetts Tax Incentive Award*

During the year ended December 31, 2012, we recognized \$0.2 million as other income. We were awarded a tax grant from the Commonwealth of Massachusetts for approximately \$0.5 million for the year ended December 31, 2009, which is earned over a five year period based on headcount growth. We achieved the headcount growth required by the award for the first two years and therefore recognized a pro rata portion of the grant. As the amount received for the award is not related to our ordinary course of operations, we have recorded the amount as other income. As we did not achieve the headcount growth as of December 31, 2012, we have refunded in 2013 the remaining \$0.3 million to the Commonwealth of Massachusetts.

### *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 Tax Benefit*

During the year ended December 31, 2010, we recorded an income tax benefit of \$0.7 million because an uncertain tax position we took in a prior year was no longer subject to examination due to the expiration of the statute of limitations.

## **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, up-front license fees, expense reimbursement, milestones and cost sharing under our collaborations 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, 2012, 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.

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Our significant capital resources are as follows:

	December 31, 2012	December 31, 2011
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	\$ 326,635	\$ 115,937
Working capital	311,086	88,995

	Years ended December 31,		
	2012	2011	2010
	(in thousands)		
Cash (used in) provided by:			
Operating activities	\$ (80,135)	\$ (33,109)	\$ (26,585)
Investing activities	(61,998)	(13,688)	30,480
Capital expenditures (included in investing activities above)	(1,301)	(1,542)	(1,949)
Financing activities	293,678	50,577	235

**Cash Flows**

The principal use of cash in operating activities in all periods presented was related to our research and development programs. On July 17, 2012, we, Mundipharma, and Purdue mutually agreed to terminate our strategic alliance agreements, and as a result, Mundipharma discontinued all research and development funding thereafter. During the years ended December 31, 2012, 2011 and 2010, we received research and development funding from Mundipharma and Purdue totaling \$55 million, \$85 million and \$65 million, respectively. Our research and development costs exceeded the funding from Mundipharma and Purdue for the years ended December 31, 2011 and 2010 due primarily to investments we made in our Hedgehog and PI3K programs.

We expect our cash flow used in operating activities to increase in future periods as a result of the termination of the strategic alliance agreements with Mundipharma and Purdue. However, our cash flow used in operating activities in future periods may vary significantly due to various factors, including potential cash inflows from future collaboration agreements and potential cash outflows for licensing new programs from third parties.

Our cash flow used in operating activities for the year ended December 31, 2012 compared to the year ended December 31, 2011 increased primarily due to a decrease in research and development funding from Mundipharma and Purdue. Our cash used in operating activities for the year ended December 31, 2012 included a decrease in deferred revenue from the termination of the strategic alliance agreements. During the year ended December 31, 2012, we recorded \$14.4 million in research and development expense related to the fair value of a release payment of \$15 million, payable in installments, relating to the amended and restated agreement with Millennium. We paid \$1.7 million of this \$15 million release payment during the year ended December 31, 2012 and recorded \$12.7 million in Due to Millennium. During the year ended December 31, 2012, we paid Millennium \$1.0 million associated with the achievement of a milestone under the original agreement with Millennium and \$5.0 million associated with the achievement of a milestone under our amended and restated agreement with Millennium, which we recorded as research and development expense. During the year ended December 31, 2011, we paid Millennium \$4.0 million associated with the achievement of milestones under the original agreement, which we recorded as research and development expense. During the year ended December 31, 2010, we recorded \$13.5 million in research and development expense related to the up-front license fee for our PI3K program. During the year ended December 31, 2010, we paid \$5 million of this \$13.5 million fee and recorded the remaining \$8.5 million in accrued liabilities. We paid the remaining \$8.5 million license fee during the year ended December 31, 2011.

Our investing activities for the years ended December 31, 2012, 2011 and 2010 included the purchase of and proceeds from maturities and sales of available-for-sale securities and purchases of property and equipment. Our investing activities for the year ended December 31, 2012 included \$180.5 million in purchases of

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available-for-sale securities, proceeds of \$113.5 million from maturities of available-for-sale securities and proceeds of \$6.3 million from sales of available-for-sale securities. Capital expenditures for the year ended December 31, 2012 of \$1.3 million primarily consisted of laboratory equipment and software.

Our financing activities for the year ended December 31, 2012 included \$244.8 million of net proceeds from two public stock offerings, \$27.5 million of proceeds from issuance of common stock to PPLP as a result of termination of strategic agreements with Mundipharma and Purdue and \$21.4 million of proceeds from issuances of common stock from stock option exercises related to stock incentive plans. Our financing activities for the year ended December 31, 2011 includes borrowings of \$50.0 million on the line of credit made available to us by PPLP. On September 7, 2012, upon completion of the sale and issuance of common stock to PPLP under the 2012 securities purchase agreement, the line of credit agreement with PPLP terminated in its entirety.

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 are sufficient to fund our planned operations into 2015. We may, however, seek to raise additional funds before that date for other reasons, including if:

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

we advance our product candidates into clinical trials for more indications than we currently expect;

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

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

the cost of acquiring raw materials for, and of manufacturing, our product 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; or

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

Historically, we have relied on our strategic alliance with Mundipharma and Purdue for a significant portion of our research and development funding needs. Mundipharma and Purdue provided us approximately \$260 million in research and development funding during the term of our strategic alliance. Following the termination of the strategic alliance agreements with Mundipharma and Purdue on July 17, 2012, we no longer receive funding from Mundipharma or Purdue and must use other resources available to us to fund our research and development expenses. Our efforts to raise sufficient capital to replace the funding we previously received under the terminated strategic alliance agreements may not be successful.

During the year ended December 31, 2012, we received \$244.8 million of net proceeds from our public stock offerings. We may continue to 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. 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 product 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 candidate development programs or to scale back, suspend or terminate our business operations.

### *Organizational Restructuring*

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In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, and in July 2012, we restructured our strategic alliance agreements with Mundipharma and Purdue such that we are no longer entitled to research and development funding. As a result, we implemented work force reductions totaling 20% of

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our employee headcount as of December 31, 2011. Our work force reductions resulted in restructuring charges totaling \$2.6 million related to severance, benefits and related costs for employees and was recorded in research and development expenses and general and administrative expenses in the year ended December 31, 2012. We expect all payments to be complete by the third quarter of 2013, and we expect to realize cost savings from this restructuring activity during 2013.

**Contractual Obligations**

As of December 31, 2012, we had the following contractual obligations, excluding contingent milestone payments:

Contractual Obligations	Total	Payments Due by Period					2018 and beyond
		2013	2014	2015	2016	2017	
Software contract obligation	\$ 280	\$ 280	\$	\$	\$	\$	\$
Due to Millennium	13,334	6,667	6,667				
Operating lease obligations	14,420	4,627	4,715	4,677	401		
Total contractual cash obligations	\$ 28,034	\$ 11,574	\$ 11,382	\$ 4,677	\$ 401	\$	\$

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

**Off-Balance Sheet Arrangements**

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

**Inflation**

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

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

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

A hypothetical 100 basis point increase in interest rates would result in an approximate \$1 million decrease in the fair value of our investments as of December 31, 2012, as compared to an approximately \$0.8 million decrease as of December 31, 2011. 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, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, 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, 2012, 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 5, 2013 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 5, 2013

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

(in thousands, except share and per share amounts)

	December 31,	
	2012	2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 175,742	\$ 24,197
Available-for-sale securities	150,276	91,081
Unbilled accounts receivable from Purdue entities		218
Prepaid expenses and other current assets	3,731	2,485
<b>Total current assets</b>	<b>329,749</b>	<b>117,981</b>
Property and equipment, net	4,079	4,582
Long-term available-for-sale securities	617	659
Restricted cash	1,128	1,125
Other assets	87	143
<b>Total assets</b>	<b>\$ 335,660</b>	<b>\$ 124,490</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,148	\$ 5,952
Accrued expenses	10,059	18,819
Due to Millennium, current	6,456	
Deferred revenue from Purdue entities		4,215
<b>Total current liabilities</b>	<b>18,663</b>	<b>28,986</b>
Due to Millennium, less current portion	6,252	
Long-term debt due to Purdue entities, net of debt discount		37,553
Deferred revenue from Purdue entities, less current portion		42,147
Other liabilities	540	371
<b>Total liabilities</b>	<b>25,455</b>	<b>109,057</b>
Commitments and contingencies (note 9)		
<b>Stockholders' equity:</b>		
Preferred Stock, \$.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2012 and 2011		
Common Stock, \$.001 par value; 100,000,000 shares authorized, and 47,499,257 and 26,721,739 shares issued and outstanding, at December 31, 2012 and December 31, 2011, respectively		
Additional paid-in capital	48	27
Accumulated deficit	633,039	284,436
Accumulated other comprehensive income	(323,016)	(269,052)
	134	22
<b>Total stockholders' equity</b>	<b>310,205</b>	<b>15,433</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 335,660</b>	<b>\$ 124,490</b>





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

(in thousands, except share and per share amounts)

	Years Ended December 31,		
	2012	2011	2010
Collaborative research and development revenue from Purdue entities	\$ 47,114	\$ 92,773	\$ 71,331
Operating expenses:			
Research and development	118,595	108,582	99,232
General and administrative	27,882	22,719	21,070
Total operating expenses	146,477	131,301	120,302
Gain on termination of Purdue entities alliance	46,555		
Loss from operations	(52,808)	(38,528)	(48,971)
Other income (expense):			
Interest expense	(1,908)	(1,841)	(1,910)
Income from Massachusetts tax incentive award	193		
Income from Therapeutic Discovery Grants			734
Interest and investment income	559	327	463
Total other expense	(1,156)	(1,514)	(713)
Loss before income taxes	(53,964)	(40,042)	(49,684)
Income tax benefit			700
Net loss	\$ (53,964)	\$ (40,042)	\$ (48,984)
Basic and diluted loss per common share	\$ (1.70)	\$ (1.50)	\$ (1.86)
Basic and diluted weighted average number of common shares outstanding	31,711,264	26,620,278	26,321,398
Other comprehensive income (loss):			
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	\$ 112	\$ (32)	\$ 17
Comprehensive loss	\$ (53,852)	\$ (40,074)	\$ (48,967)

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

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

(in thousands)

	Years Ended December 31,		
	2012	2011	2010
<b>Operating activities</b>			
Net loss	\$ (53,964)	\$ (40,042)	\$ (48,984)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	1,643	2,099	2,184
Stock-based compensation including 401(k) match	7,811	5,441	7,883
Non-cash interest expense on long-term debt due to Purdue entities	1,908	102	
Amortization of loan commitment asset from Purdue entities		1,588	1,732
Net amortization of available-for-sale securities	1,653	915	1,496
Impairment of property and equipment	161		311
Other, net	46	72	80
Changes in operating assets and liabilities:			
Unbilled accounts receivable	218	(218)	
Prepaid expenses and other assets	(1,037)	356	599
Accounts payable, accrued expenses and other liabilities	(12,395)	1,359	11,762
Due to Millennium	12,708		
Deferred revenue from Purdue entities	(38,887)	(4,781)	(3,648)
Net cash used in operating activities	(80,135)	(33,109)	(26,585)
<b>Investing activities</b>			
Purchases of property and equipment	(1,301)	(1,542)	(1,949)
Purchases of available-for-sale securities	(180,498)	(150,588)	(201,095)
Proceeds from maturities of available-for-sale securities	113,520	137,153	226,284
Proceeds from sales of available-for-sale securities	6,281	1,289	7,240
Net cash (used in) provided by investing activities	(61,998)	(13,688)	30,480
<b>Financing activities</b>			
Borrowings of long-term debt from Purdue entities		50,000	
Proceeds from issuance of common stock related to stock offering, net	244,792		
Proceeds from issuance of common stock to Purdue entities	27,500		
Proceeds from issuances of common stock related to stock incentive plans	21,386	582	225
Other financing activities		(5)	10
Net cash provided by financing activities	293,678	50,577	235
Net increase in cash and cash equivalents	151,545	3,780	4,130
Cash and cash equivalents at beginning of period	24,197	20,417	16,287
Cash and cash equivalents at end of period	\$ 175,742	\$ 24,197	\$ 20,417
<b>Supplemental schedule of noncash investing and financing activities</b>			
Receivable for stock option exercises	\$ 200	\$	\$
Issuance of common stock to extinguish debt from Purdue entities	\$ 51,277	\$	\$

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



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

(in thousands, except share and per share amounts)

	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	\$ 270,275	\$ (180,026)	\$ 37	\$ 90,312
Exercise of stock options	85,406		225			225
Issuance of common stock to executive chair	100,000	1	588			589
Repurchase and retirement of common stock	(966)					
Restricted stock issued that vested in the year			30			30
Stock-based compensation expense			6,731			6,731
401(k) plan match issued in common stock	95,823		564			564
Unrealized loss on marketable securities					17	17
Net loss				(48,984)		(48,984)
Balance at December 31, 2010	26,519,217	\$ 27	\$ 278,413	\$ (229,010)	\$ 54	\$ 49,484
Exercise of stock options	114,815		582			582
Stock-based compensation expense			4,847			4,847
401(k) plan match issued in common stock	87,707		594			594
Unrealized loss on marketable securities					(32)	(32)
Net loss				(40,042)		(40,042)
Balance at December 31, 2011	26,721,739	\$ 27	\$ 284,436	\$ (269,052)	\$ 22	\$ 15,433

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

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

(in thousands, except share and per share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount				
Balance at December 31, 2011	26,721,739	\$ 27	\$ 284,436	\$ (269,052)	\$ 22	\$ 15,433
Exercise of stock options	2,632,097	3	21,583			21,586
Exercise of warrants	29,958					
Issuance of common stock in connection with public offering	12,646,461	13	244,779			244,792
Issuance of common stock to Purdue entities	5,416,565	5	74,430			74,435
Stock-based compensation expense			7,117			7,117
401(k) plan match issued in common stock	52,437		694			694
Unrealized loss on marketable securities					112	112
Net loss				(53,964)		(53,964)
Balance at December 31, 2012	47,499,257	\$ 48	\$ 633,039	\$ (323,016)	\$ 134	\$ 310,205

*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 an innovative drug discovery and development company seeking to discover, develop and deliver to patients best-in-class medicines designed to address diseases with significant unmet need. As used throughout these consolidated financial statements, the terms Infinity, we, us, and our refer to the business of Infinity Pharmaceuticals, Inc. and its wholly owned subsidiary.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

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

**Reclassifications**

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

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

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

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities at December 31, 2012 and 2011 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders' equity.

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

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

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

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

## **Concentration of Risk**

We have no significant off-balance sheet risk.

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

## **Segment Information**

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

All of our revenues to date have been generated under research collaboration agreements. Revenue associated with the amortization of the deferred revenue associated with the grant of rights and licenses to, and reimbursed research and development services provided for, Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, accounted for all of our revenue during the years ended December 31, 2012, 2011 and 2010. Payments due from Mundipharma and Purdue represented our entire unbilled accounts receivable balance at December 31, 2011. We consider Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes because of their equity ownership (see note 10).

## **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

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current operations. Amortization of leasehold improvements and capital leases are included in depreciation expense. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

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

**Impairment of Long-Lived Assets**

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

**Fair Value Measurements**

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

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

**Revenue Recognition**

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

Under our strategic alliance with Mundipharma and Purdue, we recognized revenues from non-refundable, up-front license fees on a straight-line basis over the contracted or estimated period of performance, which was the research and development term. We regularly considered whether events warrant a change in the estimated



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period of performance under an agreement. Such a change would have caused us to modify the period of time over which we recognized 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 recognized research and development funding as earned over the period of effort as related research and development costs are incurred in proportion to our forecasted total expenses as compared to the total expected research and development funding for the year. We recognized the impact of any change in forecasted total expenses or expected research and development funding as a change in accounting estimate and recorded the impact of that change on a prospective basis. On July 17, 2012, we mutually agreed with Mundipharma and Purdue to terminate our strategic alliance agreements. Further information regarding the terms and conditions of this termination is described below under note 10.

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

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

the consideration relates solely to past performance, and

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

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

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

## **Income Taxes**

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss and tax credit 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 of a change in tax rate on deferred taxes is recognized in income or loss in the period that includes the enactment date.

We use our judgment 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 net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of December 31, 2012 and 2011.

**Table of Contents****Basic and Diluted Net Loss per Common Share**

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

	At December 31,		
	2012	2011	2010
Stock options	5,574,527	6,985,460	6,087,491
Warrants	50,569	3,246,629	5,246,629
<b>Comprehensive Loss</b>			

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

**Stock-Based Compensation Expense**

For awards granted to employees and directors, 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 requisite service period on a straight-line basis. We record the expense of services rendered by non-employees based on the estimated fair value of the stock option using the Black-Scholes option-pricing model as of the respective vesting date. Further, we expense the fair value of non-employee stock options over the vesting term of the underlying stock options. We have no awards with market or performance conditions. We use the Black-Scholes valuation model in determining the fair value of equity awards.

**Research and Development Expense**

Research and development expense consists of expenses incurred in performing research and development activities, including salaries and benefits, overhead expenses including facilities expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. We also include as research and development expense up-front license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. We have been a party to collaboration agreements in which we are reimbursed for work performed on behalf of the collaborator, as well as one in which we reimbursed the collaborator for work it has performed. We record all appropriate expenses under our collaborations as research and development expense. If the arrangement provides for reimbursement of research and development expenses, as was the case with our alliance with Mundipharma and Purdue, we record the reimbursement as revenue. If the arrangement provides for us to reimburse the collaborator for research and development expenses or achieving a development milestone for which a payment is due, as was the case with our agreement with Intellikine, Inc., or Intellikine, we record the reimbursement or the achievement of the development milestone as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our phosphoinositide-3-kinase, or PI3K, program licensor as Millennium.

**Table of Contents****3. Stock-Based Compensation**

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

**2010 Stock Incentive Plan**

Our 2010 Stock Incentive Plan, or the 2010 Plan, was approved by our stockholders in May 2010. The 2010 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, or IRC, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based and cash-based awards. Up to 6,000,000 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, 2012, an aggregate of 2,593,605 shares of our common stock were reserved for issuance upon the exercise of outstanding awards and up to 3,579,345 shares of common stock may be issued pursuant to awards granted under the 2010 Plan.

**2000 Stock Incentive Plan**

Our 2000 Plan provided for the grant of stock options intended to qualify as incentive stock options under the IRC, nonstatutory stock options and restricted stock. As of December 31, 2012, an aggregate of 2,845,156 shares of our common stock were reserved for issuance upon the exercise of outstanding awards granted under our 2000 Plan. Our 2000 Plan was terminated upon approval of the 2010 Plan; therefore, no further grants may be made under the 2000 Plan.

**2001 Stock Incentive Plan**

In connection with the merger between Discovery Partners International, Inc., or DPI, and Infinity Pharmaceuticals, Inc., or IPI, in 2006, which we refer to as the DPI merger, we assumed awards that were granted under the Infinity Pharmaceuticals, Inc. Pre-Merger Stock Incentive Plan, or the 2001 Plan. The 2001 Plan provided for the grant of incentive stock options and nonstatutory stock options and restricted stock awards. Under the 2001 Plan, stock awards were granted to IPI's employees, officers, directors and consultants. Incentive stock options were granted at a price not less than fair value of the common stock on the date of grant. The board of directors of IPI determined the vesting of the awards. As of December 31, 2012, an aggregate of 135,766 shares of our common stock were reserved for issuance upon the exercise of outstanding assumed awards. The 2001 Plan was not assumed by us following the DPI merger; therefore, no further grants may be made under the 2001 Plan.

**Compensation Expense**

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

	2012	Year Ended December 31, 2011	2010
		(in thousands)	
Research and development	\$ 3,177	\$ 2,743	\$ 3,707
General and administrative	4,634	2,698	4,176

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As of December 31, 2012, we had approximately \$10.7 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options, which are expected to be recognized over a weighted-average period of 2.3 years.

**Valuation Assumptions**

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

	Year Ended December 31,		
	2012	2011	2010
Risk-free interest rate	1.1%	2.2%	2.6%
Expected annual dividend yield			
Expected stock price volatility	63.3%	58.2%	59.4%
Expected term of options	6.1 years	5.9 years	5.7 years

The valuation assumptions were determined as follows:

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

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

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

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

We stratify employees into two groups to evaluate exercise and post-vesting 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, 2012, 2011 and 2010, the weighted-average forfeiture rate was estimated to be 12%, 10% and 10%, respectively.

All options granted to employees during the years ended December 31, 2012, 2011 and 2010 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, 2012 is as follows:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2012	6,985,460	\$ 8.34		
Granted	1,706,363	10.42		

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Exercised	(2,632,097)		8.20		
Forfeited	(485,199)		8.85		
Outstanding at December 31, 2012	5,574,527	\$	9.00	6.9	\$ 144.9
Vested or expected to vest at December 31, 2012	5,294,842	\$	8.95	6.8	\$ 137.9
Exercisable at December 31, 2012	3,477,936	\$	9.00	5.8	\$ 90.4

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The weighted-average fair value per share of options granted during the years ended December 31, 2012, 2011 and 2010 were \$6.00, \$3.54 and \$3.58, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2012 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2012 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was \$34.1 million, \$0.4 million and \$0.3 million, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2012 was \$21.4 million.

All outstanding, unvested restricted stock became fully vested during the year ended December 31, 2010. The total fair value of the shares of restricted stock that vested during the year ended December 31, 2010 (measured on the date of vesting) was \$0.1 million.

No related income tax benefits were recorded during the years ended December 31, 2012, 2011 or 2010.

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

During the year ended December 31, 2012, two members of our board of directors retired, and we extended these directors' rights to exercise their vested stock options from 90 days following their retirement to two years following their retirement. In connection with these extensions, we recognized an additional \$0.3 million of stock-based compensation expense during the year ended December 31, 2012 with respect to the modification of these awards. In addition, during the year ended December 31, 2012, the chair of our board of directors resigned and entered into a three-year substantive consulting agreement to act as a strategic advisor. As a result of this transition, we recognized \$1.2 million of non-employee stock-based compensation expense in general and administrative expenses during the year ended December 31, 2012 with respect to the options that continue to vest. The fair value of the unvested options will be remeasured at each reporting date until the options have fully vested.

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 \$0.2 million 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 \$0.4 million in cash in recognition of services rendered. In connection with the modification of his incentive stock options and the grant of shares to him, we recognized an additional \$0.6 million in stock-based compensation expense during the year ended December 31, 2010.

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

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

	Cost	December 31, 2012		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
(in thousands)				
Cash and cash equivalents due in 90 days or less	\$ 175,742	\$	\$	\$ 175,742
Available-for-sale securities:				
Corporate obligations due in one year or less	88,644	53	(13)	88,684
Corporate obligations due in one to five years	16,291	8	(9)	16,290
Mortgage-backed securities due after ten years	547	70		617
U.S. government-sponsored enterprise obligations due in one year or less	38,779	22		38,801
U.S. government-sponsored enterprise obligations due in one to five years	6,498	3		6,501
Total available-for-sale securities	150,759	156	(22)	150,893
Total cash, cash equivalents and available-for-sale securities	\$ 326,501	\$ 156	\$ (22)	\$ 326,635

	Cost	December 31, 2011		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
(in thousands)				
Cash and cash equivalents due in 90 days or less	\$ 24,197	\$	\$	\$ 24,197
Available-for-sale securities:				
Corporate obligations due in one year or less	60,593	29	(50)	60,572
Corporate obligations due in one to five years	5,937	8	(3)	5,942
Mortgage-backed securities due after ten years	603	56		659
U.S. government-sponsored enterprise obligations due in one year or less	335			335
U.S. government-sponsored enterprise obligations due in one to five years	24,250	2	(20)	24,232
Total available-for-sale securities	91,718	95	(73)	91,740
Total cash, cash equivalents and available-for-sale securities	\$ 115,915	\$ 95	\$ (73)	\$ 115,937

We held 13 debt securities at December 31, 2012 that had been in an unrealized loss position for less than 12 months. The fair value on these securities was \$30.4 million. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these 13 securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost bases. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2012.

As of December 31, 2012, we held 17 financial institution and other corporate debt securities located in Switzerland Australia, the Netherlands, Japan and Canada with a fair value of \$64.0 million. Six of these securities, which were issued by Switzerland, Australia and Canada, had gross unrealized losses of \$14 thousand and fair value of \$19.0 million. These securities are short term in nature, with \$51.7 million scheduled to mature within 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2012.





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We had no material realized gains or losses on our available-for-sale securities for the years ended December 31, 2012, 2011 and 2010. There were no other-than-temporary impairments recognized for the years ended December 31, 2012, 2011 and 2010.

**5. Fair Value**

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, which we consider the highest level inputs, are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our own assumptions used to measure assets and liabilities at fair value. The classification of a financial asset or liability within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement. For our fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. We validate the prices provided by our third party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing our validation procedures, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2012 and 2011.

The following table provides the assets carried at fair value measured on a recurring basis as of December 31, 2012:

	Level 1	Level 2
	(in thousands)	
<i>Assets:</i>		
Cash and cash equivalents	\$ 174,991	\$ 751
Corporate obligations (including commercial paper)		104,974
Mortgage-backed securities		617
U.S. government-sponsored enterprise obligations		45,302
<b>Total</b>	<b>\$ 174,991</b>	<b>\$ 151,644</b>
<i>Liability:</i>		
Due to Millennium	\$	\$ 12,708
<b>Total</b>	<b>\$</b>	<b>\$ 12,708</b>

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

*Corporate Obligations:*

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

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

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

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*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.

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The amount due to Millennium related to a release payment of \$13.3 million is recorded at its fair value of \$12.7 million at December 31, 2012. The fair value was determined using a discounted cash flow model and based on an interest rate we would be charged for a similar loan as of December 31, 2012 (see note 10).

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

There have been no changes to the valuation methods during the year ended December 31, 2012. We evaluate transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between Level 1 and Level 2 during the year ended December 31, 2012. We had no available-for-sale securities that were classified as Level 3 at any point during the years ended December 31, 2012 or 2011.

**6. Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2012	2011
	(in thousands)	
Laboratory equipment	\$ 15,067	\$ 15,643
Computer hardware and software	7,033	6,634
Office equipment and furniture and fixtures	775	736
Leasehold improvements	4,574	4,279
	27,449	27,292
Less accumulated depreciation	(23,370)	(22,710)
	\$ 4,079	\$ 4,582

**7. Restricted Cash**

We held \$1.1 million in restricted cash as of December 31, 2012 and December 31, 2011. 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.

**8. Accrued Expenses**

Accrued expenses consisted of the following:

	December 31,	
	2012	2011
	(in thousands)	
Accrued compensation and benefits	\$ 5,555	\$ 6,287
Accrued drug manufacturing costs	1,288	4,888
Accrued clinical studies	1,234	2,977
Accrued preclinical studies	403	1,232
Other	1,579	3,435
Total accrued expenses	\$ 10,059	\$ 18,819

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We lease our office and laboratory space under two lease agreements. The term of our primary office and laboratory lease expires in January 2016, and may be terminated by us earlier under certain circumstances. We have the right to extend this lease for another five-year term on the same terms and conditions as the current lease by giving the landlord notice before the term of the lease expires. Under this lease, we have a tenant improvement allowance of up to \$0.7 million for the design and construction of fixed and permanent improvements until December 31, 2013. We have used \$0.3 million of the allowance as at December 31, 2012. Our secondary office lease expires in October 2014.

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

Years Ending December 31:	Facility Leases (in thousands)
2013	\$ 4,606
2014	4,706
2015	4,677
2016	401
Total minimum lease payments	\$ 14,390

Rent expense of \$4.8 million, \$4.7 million and \$4.7 million, before considering sublease income, was incurred during the years ended December 31, 2012, 2011 and 2010, respectively. Deferred rent is being amortized to rent expense over the life of the lease. During the years ended December 31, 2012, 2011 and 2010, we subleased a portion of our facility space for total sublease income of \$0.7 million each year. We record sublease payments as an offset to rental expense in our statement of operations. The sublease expires April 2013. Future minimum sublease income under noncancelable leases is expected to be \$0.2 million for the year ended December 31, 2013.

**10. Collaborations****Mundipharma and Purdue***Strategic Alliance Termination Agreements*

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 termination agreements. The alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting fatty acid amide hydrolase, or FAAH. The strategic alliance agreement with Mundipharma was focused on the development and commercialization outside of the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, phosphoinositide-3-kinase, or PI3K, and product candidates arising out of our early discovery projects in all disease fields. Our heat shock protein 90, or Hsp90, program was expressly excluded from the alliance.

Under the terms of the 2012 termination agreements:

All intellectual property rights that we had previously licensed to Mundipharma and Purdue to develop and commercialize products under the previous strategic alliance agreements terminated, with the result that we have worldwide rights to all product candidates that had previously been covered by the strategic alliance.

We have no further obligation to provide research and development services to Mundipharma and Purdue as of July 17, 2012.



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Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH. During the year ended December 31, 2012, we received \$55 million in research and development funding. We recognized revenue for reimbursed research and development services we performed for Mundipharma and Purdue. We recognized \$45 million in such revenue in the year ended December 31, 2012. We recognized \$88.5 million and \$67.0 million in such revenue, which included \$3.5 million and \$2.0 million, respectively, in revenue related to reimbursed research and development services for the transition of the FAAH program, in the years ended December 31, 2011 and 2010, respectively. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

We are obligated to pay Mundipharma and Purdue a four percent royalty in the aggregate, subject to reduction as described below, on worldwide net sales of products that were covered by the alliance until such time as they have recovered approximately \$260 million, representing the research and development funding paid to us for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a one percent royalty on net sales in the United States of products that were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products subject to the alliance that are subject to significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, no amounts have been accrued.

Royalties are payable under these agreements 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 royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

The 2012 termination agreements resulted in a gain on termination of Purdue entities alliance and a positive net income impact of \$46.6 million, or a decrease of \$1.47 in basic and diluted loss per share for the year ended December 31, 2012.

*Line of Credit Agreement*

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a line of credit agreement with Purdue and its independent associated company, Purdue Pharma L.P., or PPLP, that provided for the borrowing by us of one or more unsecured loans up to an aggregate maximum principal amount of \$50 million. In March 2009, Purdue assigned its interest under the line of credit agreement to PPLP. The extension of the line of credit at an interest rate below our incremental borrowing rate represented the transfer of additional value to us in the arrangement. As such, we recorded the fair value of the line of credit of \$17.3 million as a loan commitment asset on our balance sheet in 2008. The fair value of the loan commitment asset was determined using a discounted cash flow model of the differential between the terms and rates of the line of credit and market rates. We amortized the loan commitment asset to interest expense until we drew down the line of credit in November 2011. We recorded approximately \$1.6 million and \$1.7 million of related amortization expense in the years ended December 31, 2011 and 2010, respectively.

In November 2011, we borrowed \$50 million under this line of credit, which we recorded as long-term debt. The loan would have matured and was payable in full, including principal and any accrued interest, on April 1, 2019, which we referred to as the maturity date, and would have been subordinate to any senior indebtedness that

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we may have incurred. The loan bore interest at a fluctuating rate set at the prime rate on the business day prior to the funding of the loan and reset on the last business day of each month ending thereafter. At the time of the borrowing, the prime rate was 3.25%. Interest was compounded on each successive three-month anniversary following the date of borrowing. Upon drawing down the \$50 million under the line of credit agreement, we reclassified the loan commitment asset as a debt discount which reduced the debt on our balance sheet. The unamortized balance of the loan commitment asset was \$12.7 million as of the date of borrowing. We recorded interest expense on the net amount borrowed using the effective interest method. We recorded \$1.9 million and \$0.2 million of related interest expense in the years ended December 31, 2012 and 2011, respectively, using an effective interest rate of 7.29%.

On September 7, 2012, upon completion of the sale and issuance of common stock to PPLP under the 2012 securities purchase agreement described below, the line of credit agreement with PPLP terminated in its entirety.

*2008 Securities Purchase Agreement*

In connection with the previous strategic alliance with Mundipharma and Purdue, we also entered into a securities purchase agreement with Purdue and PPLP. Under the securities purchase agreement, we issued and sold in two separate closings an aggregate of 6,000,000 shares of our common stock and warrants to purchase up to an aggregate of 6,000,000 shares of our common stock, for an aggregate purchase price of \$75 million. An equal number of securities were sold to each purchaser. As of December 31, 2012, all warrants that were issued in connection with the strategic alliance expired without having been exercised.

We recorded an aggregate of \$59.3 million in deferred revenue associated with the grant of rights and licenses to Mundipharma and Purdue, which consisted of the excess of the amount paid for the purchased shares over the closing market price on the day before the equity closings and the value of the loan commitment asset. We determined that the rights and licenses did not have stand-alone value, and we considered all of the obligations under the arrangement to be a single unit of accounting. There was no obligation for us to repay the \$59.3 million, and we had been recognizing the deferred revenue ratably over 14 years, which was our estimated period of performance under the arrangement through July 17, 2012. We recognized \$2.1 million, \$4.3 million and \$4.3 million in deferred revenue associated with grant of rights and licenses in the years ended December 31, 2012, 2011 and 2010, respectively.

*2012 Securities Purchase Agreement*

On July 17, 2012, in connection with the termination of the strategic alliance with Mundipharma and Purdue, we executed a securities purchase agreement with PPLP, which we refer to as the 2012 securities purchase agreement, under which we agreed to sell and issue 5,416,565 shares of our common stock to PPLP and two entities associated with PPLP, which we collectively refer to as the BRP entities, at a price of \$14.50 per share for an aggregate consideration of approximately \$78.5 million. The consideration was composed of extinguishment of approximately \$51.0 million in principal and interest owed to PPLP under the line of credit agreement and \$27.5 million in cash. We completed the sale and issuance on September 7, 2012 at which time the line of credit agreement with PPLP terminated in its entirety.

The 2012 securities purchase agreement also provides that, at any time during the period beginning January 1, 2013 and ending December 31, 2018, in the event we propose to make an underwritten offering of our common stock, subject to certain limitations, the Purdue entities will have piggyback registration rights, which require us, at the election of the Purdue entities, to use our reasonable best efforts to cause to be included in such underwritten offering, common stock then held by the Purdue entities representing up to 20% of the total estimated maximum dollar amount of our common stock proposed to be sold in such underwritten offering.

In addition, the BRP entities have agreed that during the period between July 17, 2012 and December 31, 2013, if requested by us and/or the managing underwriters, placement agents or initial purchasers for any offering of our stock proposed by us during such period, not to, among other things, offer, sell or otherwise

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transfer or dispose of, directly or indirectly, any common stock held by the BRP entities or to enter into any agreement that transfers, in whole or in part, any of the economic consequences of ownership of any common stock held by the BRP entities, during such period as may be requested by such managing underwriters, the placement agents or the initial purchasers, and to execute a lock-up agreement reflecting such restrictions, provided that all of our officers, directors and affiliates enter into similar agreements with equivalent terms.

The 2012 securities purchase agreement also terminated, as of July 17, 2012, all attendance rights to meetings of our board of directors held by the Purdue entities.

The BRP entities and each associated company holding shares of our common stock have agreed to be present at each regular or special meeting of our stockholders held through September 6, 2017 and to vote all of their shares as recommended by our board of directors in the proxy materials mailed to our stockholders in connection with such meeting. However, with respect to any proposal to amend our corporate charter or approve certain extraordinary transactions, all shares of our common stock that are owned by those entities that were not issued pursuant to the 2012 securities purchase agreement will be voted in proportion to the manner in which all of our stockholders other than those entities vote in respect of such proposal, regardless of the recommendation of our board of directors.

### *Accounting Impact of Alliance Termination, Debt Extinguishment and Sale and Issuance of Common Stock*

We recorded the following during the year ended December 31, 2012:

gain on termination of Purdue entities strategic alliance of \$46.6 million;

additional equity on our balance sheet of \$74.4 million;

extinguishment of \$39.5 million of debt on balance sheet;

elimination of \$54.0 million of deferred revenue on balance sheet; and

additional cash of \$27.5 million.

We considered the fact that certain elements of the arrangement discussed above close before others, despite the fact that all of the elements were negotiated and signed concurrently in contemplation of one another. In particular, the strategic alliance with Mundipharma and Purdue was terminated on July 17, 2012, and therefore, there are no further deliverables required under those agreements. However, the equity offering and debt extinguishment did not close at that time because certain regulatory events outside of our control had to occur prior to the closing. As a result, we evaluated the termination of the strategic alliance separately from the financing transaction, including the extinguishment of debt and sale and issuance of stock. We recorded the gain on termination of the Mundipharma and Purdue strategic alliance for \$46.6 million which represented our past performance under the 2008 collaboration because we have no further obligation to provide research and development, and the financial risk associated with the research and development has been transferred to the Purdue entities. In particular, any payment of royalties to Mundipharma and Purdue are conditional on the future commercialization of our product candidates.

To establish the financial impact of the stock issuance and debt extinguishment, we determined both the fair value of the common stock we sold and issued and the debt and accrued interest extinguished. We consider Mundipharma and Purdue to be related parties for financial reporting purposes because of their equity ownership. Therefore, we recorded the difference between extinguishing the fair value of the debt and accrued interest, the sale and issuance of our common stock and receiving \$27.5 million in cash in additional paid-in capital.

### **Millennium**

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145. We paid Intellikine a \$13.5 million up-front license





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fee. The entirety of this fee was included as research and development expense in the year ended December 31, 2010, although \$8.5 million of this fee was paid in January 2011. During the second half of 2011, we paid Intellikine \$4.0 million in milestone payments associated with the initiation of two Phase 1 studies of IPI-145, which we recorded as research and development expense. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In December 2012, we amended and restated our development and license agreement with Millennium.

Under the original agreement, we obtained worldwide development and commercialization rights to Millennium's portfolio of inhibitors of the delta and/or gamma isoforms of PI3K for all indications, and we conducted a collaborative research program with Millennium to identify compounds directed to PI3K-delta and/or PI3K-gamma which meet certain selectivity criteria, with such research collaboration under the original agreement set to expire in July 2013. Also under the original agreement, neither we nor Millennium were permitted to research, develop or commercialize products directed to PI3K-delta and/or PI3K-gamma which meet certain selectivity criteria, other than the compounds subject to the collaboration, except that Millennium was permitted to research, develop or commercialize such products that it was researching, developing or commercializing on its own or with a third party prior to its acquisition of Intellikine.

Under the terms of the amended and restated agreement, we retained our worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications. We and Millennium will no longer conduct the collaborative research program and the restrictions on each party's ability to research, develop and commercialize products directed to the delta and/or gamma isoforms of PI3K that meet certain selectivity criteria have terminated, subject, in the case of Millennium, to the exclusive licenses granted to us under the amended and restated agreement.

Additionally, under the amended and restated agreement, Millennium waived the option it had under the original agreement to convert, upon payment of an option fee, its royalty interest in U.S. sales of PI3K products and its right to receive certain milestone payments with respect to such products into the right to share in 50% of profits and losses on U.S. development and commercialization of those PI3K products for which the first Phase 2 clinical trial, as defined in the original agreement, conducted in an oncology indication, and to participate in up to 30% of the detailing effort for these products in the United States. In consideration of such waiver we have agreed to pay to Millennium \$15 million, payable in installments. During the year ended December 31, 2012, we paid \$1.7 million of the \$15 million, and we recorded the \$15 million release payment at its fair value of \$14.4 million in research and development expenses. The fair value was determined using a discounted cash flow model and based on an interest rate we would be charged for a similar loan as of December 31, 2012. The remaining amount is payable in two equal payments, which we expect to pay in 2013 and 2014, and which we recorded as short-term and long-term liabilities at their fair values of \$6.5 million and \$6.2 million, respectively. The discount amount of \$0.6 million will be amortized over the payment term. Additionally, under the amended and restated agreement we paid Millennium a \$5 million milestone payment associated with the initiation of our Phase 2a clinical trial of IPI-145 in patients with mild, allergic asthma.

In addition to developing IPI-145, we announced our second potent, oral PI3K-delta,gamma inhibitor, IPI-443, and we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. During the year ended December 31, 2012, we paid to Millennium a \$1.0 million milestone payment related to the initiation of the first IND-enabling cGLP toxicology study. We are obligated to pay up to \$15 million in remaining 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. As a result of the amendment, such products may include products we license in from a third party. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from seven percent to 11 percent, which are the same royalty levels as those specified under the original agreement, upon successful commercialization of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction, and limits on the number of products, in certain circumstances.

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The amended and restated agreement expires on the later of the expiration of certain patents and the expiration of the royalty payment terms for the products, 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. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium's reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days prior written notice. The agreement also provides for customary reciprocal indemnification obligations of the parties.

**11. Income Taxes**

We had no income tax expense or benefit for the years ended December 31, 2012 and 2011. Our income tax benefit of \$0.7 million for the year ended December 31, 2010 primarily consisted of U.S. federal taxes.

Our income tax benefit for the years ended December 31, 2012, 2011 and 2010 differed from the expected U.S. federal statutory income tax benefit as set forth below:

	2012	2011 (in thousands)	2010
Expected federal tax benefit	\$ (18,348)	\$ (13,609)	\$ (16,893)
Permanent differences	(4,685)	1,295	909
State taxes, net of the deferred federal benefit	(2,849)	(2,180)	(2,869)
Tax credits	(589)	(1,931)	562
Effect of change in state tax rate on deferred tax assets and deferred tax liabilities		61	425
Expired state net operating loss		1,424	1,895
Change in tax reserves			(700)
Adjustments to deferred tax assets and deferred tax liabilities	3,371	745	
Change in valuation allowance	23,066	14,160	15,946
Other	34	35	25
<b>Income tax benefit</b>	<b>\$</b>	<b>\$</b>	<b>\$ (700)</b>

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

	Year Ended December 31,	
	2012	2011
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 89,998	\$ 56,587
Tax credits	16,233	15,644
Deferred revenue		18,211
Intangible assets	14,270	4,895
Accrued expenses	1,442	2,043
Stock-based compensation	7,015	7,430
Other	752	729
Valuation allowance	(129,710)	(105,539)
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>



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We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2012, 2011 and 2010 because management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately \$24.2 million during the year ended December 31, 2012 primarily as a result of increases in unbenefitted deferred tax assets such as tax losses and credits and intangible assets. The valuation allowance increased by approximately \$14.2 million during the year ended December 31, 2011 primarily as a result of increases in unbenefitted deferred tax assets such as tax losses, credits and intangible assets. The valuation allowance increased by approximately \$16.0 million 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.

Subject to the limitations described below, at December 31, 2012, we had cumulative net operating loss carryforwards of approximately \$263.2 million and \$152.0 million available to reduce federal and state taxable income, which expire through 2032, and have begun to expire and expire through 2032, respectively. In addition, we have cumulative federal and state tax credit carryforwards of \$12.6 million and \$5.6 million, respectively, available to reduce federal and state income taxes which expire through 2032 and 2027, respectively. The net operating loss carryforwards include approximately \$22.1 million 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 have and 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, 2012.

A reconciliation of the allowance for uncertain tax positions for the years ended December 31, 2012, 2011 and 2010 is as follows:

	2012	2011	2010
	(in millions)		
Balance at January 1	\$	\$	\$ 0.6
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			(0.6)
Balance at December 31	\$	\$	\$

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 2009, although carryforward attributes that were generated prior to tax year 2009 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.

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**12. Stockholders Equity**

**Common Stock Offerings**

In August 2012, we completed an underwritten public offering of 6,095,000 shares of common stock, which were sold at a price of \$14.50 per share. This offering resulted in \$82.8 million of net proceeds. In December 2012, we completed an underwritten public offering of 6,551,461 shares of common stock, which were sold at a price of \$26.33 per share. This offering resulted in \$162.0 million of net proceeds. Related legal and accounting fees for both offerings were recorded as an offset to additional paid-in capital.

**Warrants**

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

In July 2002, IPI issued warrants to purchase shares of convertible preferred stock, which subsequently in the DPI merger became warrants to purchase shares of common stock in the DPI merger, in conjunction with the entry into 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 were recorded in other non-current assets and have been fully amortized over the lease period as rent expense.

Warrants described above to purchase 246,629 shares of our common stock were outstanding at December 31, 2011 and 2010. At December 31, 2012, warrants to purchase 50,569 shares of our common stock were outstanding, and all of these outstanding warrants were exercised in January 2013 at \$13.35 per share.

**13. Income from Therapeutic Discovery Grants**

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

**14. Income from Massachusetts Tax Incentive Award**

During the year ended December 31, 2012, we recognized \$0.2 million as other income due to the Massachusetts tax incentive award. We were awarded a tax grant from the Commonwealth of Massachusetts of approximately \$0.5 million for the year ended December 31, 2009, which is earned over a five year period based on headcount growth. We achieved the headcount growth required by the award for the first two years and therefore recognized a pro rata portion of the grant. As the amount received for the award is not related to our ordinary course of operations, we have recorded the amount as other income. As we did not achieve the headcount growth as of December 31, 2012, we have refunded in 2013 the remaining \$0.3 million to the Commonwealth of Massachusetts.

**15. Restructuring Activities**

In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our Hedgehog pathway inhibitor, after a planned futility analysis of interim data from our Phase 2, double-blind, randomized, placebo-controlled study evaluating saridegib in patients with metastatic or locally advanced, inoperable chondrosarcoma showed that treatment with saridegib was similar to placebo and, therefore, the trial would not

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meet its primary endpoint. Following this analysis, we accelerated our review of data from 12 evaluable patients enrolled in our exploratory Phase 2 clinical trial of saridegib in patients with myelofibrosis, which showed that the level of clinical activity observed in these patients did not satisfy our pre-specified criteria for expansion of the trial. We will continue to incur costs associated with the discontinuation of company-sponsored development of saridegib, but we do not expect these costs to be significant beyond 2012. We reallocated remaining resources to other potential development programs and product portfolio efforts and reduced our work force. We incurred a restructuring expense of \$1.5 million during the year ended December 31, 2012. In July 2012, we agreed with Mundipharma and Purdue to terminate our strategic alliance agreements with the result that Mundipharma would have no further obligation to provide research and development funding to us (see note 10), and therefore we undertook a subsequent workforce reduction. During the year ended December 31, 2012, we incurred a restructuring expense of \$1.1 million related to this reduction.

As a result of both of these work force reductions, we reduced our employee headcount by approximately 20% compared to our employee headcount as of December 31, 2011. The following table summarizes the impact of the work force reductions on operating expenses and payments for the year ended December 31, 2012 and the current liability remaining on the balance sheet as of December 31, 2012, in thousands:

	<b>Charges Incurred During the Year Ended December 31, 2012</b>	<b>Amounts Paid Through December 31, 2012</b>	<b>Amounts Accrued at December 31, 2012</b>
Employee severance, benefits and related costs for work force reductions	\$ 2,583	\$ (2,191)	\$ 392

We have recorded all associated restructuring expenses associated with the work force reductions as research and development and general and administrative expenses on the statement of operations and comprehensive income (loss). We expect all payments to be complete by the third quarter of 2013.

**16. Defined Contribution Benefit Plan**

We sponsor a 401(k) retirement plan in which substantially all of our full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. During the years ended December 31, 2012, 2011 and 2010, we matched 50% of the first six percent of participant contributions with shares of our common stock. Our matching contributions during the years ended December 31, 2012, 2011 and 2010 were \$0.7 million, \$0.6 million and \$0.6 million, respectively.

**Table of Contents****17. Quarterly Financial Information (unaudited)**

	Quarter Ended March 31, 2012	Quarter Ended June 30, 2012	Quarter Ended September 30, 2012	Quarter Ended December 31, 2012
(In Thousands, Except Shares and Per Share Amounts)				
Collaborative research and development revenue from Purdue entities	\$ 25,202	\$ 21,912	\$	\$
Operating expenses:				
Research and development	28,551	28,533	21,495	40,016
General and administrative	6,812	7,666	6,294	7,110
Total operating expenses	35,363	36,199	27,789	47,126
Gain on termination of Purdue entities alliance			46,555	
Income (loss) from operations	(10,161)	(14,287)	18,766	(47,126)
Other (expense) income:				
Interest expense	(681)	(694)	(533)	
Income from Massachusetts tax incentive award		193		
Interest and investment income	120	127	170	142
Total other expense	(561)	(374)	(363)	142
Net income (loss)	\$ (10,722)	\$ (14,661)	\$ 18,403	\$ (46,984)
Earnings (loss) per common share:				
Basic	\$ (0.40)	\$ (0.54)	\$ (0.57)	\$ (1.15)
Diluted	\$ (0.40)	\$ (0.54)	\$ (0.52)	\$ (1.15)
Weighted average number of common shares outstanding:				
Basic	26,776,856	27,061,435	32,039,866	40,855,124
Diluted	26,776,856	27,061,435	35,173,223	40,855,124



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

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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, 2012. 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, 2012, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our management including our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

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

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

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

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

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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 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, 2012. 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, 2012, 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, 2012, 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, 2012, 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, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2012 of Infinity Pharmaceuticals, Inc. and our report dated March 5, 2013 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

March 5, 2013

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

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal year ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

Not applicable.

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**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 Conduct and Ethics appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 11, 2013 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 Compensation of Executive Officers appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 11, 2013 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 June 11, 2013 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 June 11, 2013 are incorporated herein by reference.

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

The section titled Audit Fees appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 11, 2013 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>	60
<u>Consolidated Balance Sheets at December 31, 2012 and 2011</u>	61
<u>Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010</u>	62
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010</u>	63
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010</u>	64
<u>Notes to Consolidated Financial Statements</u>	66

**(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 5, 2013

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

*President & Chief Executive Officer*

*(Principal Executive 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.

Signature	Title	Date
/s/ ADELENE Q. PERKINS  <b>Adelene Q. Perkins</b>	President, Chief Executive Officer; Chair of the Board of Directors  <i>(Principal Executive Officer)</i>	March 5, 2013
/s/ LAWRENCE E. BLOCH, M.D., J.D. <b>Lawrence E. Bloch, M.D., J.D.</b>	Executive Vice President, Chief Financial Officer and Chief Business Officer; Secretary and Treasurer  <i>(Principal Financial Officer)</i>	March 5, 2013
/s/ CHRISTOPHER M. LINDBLOM <b>Christopher M. Lindblom</b>	Vice President, Accounting and Financial Planning; Assistant Treasurer <i>(Principal Accounting Officer)</i>	March 5, 2013
/s/ MARTIN BABLER <b>Martin Babler</b>	Director	March 5, 2013
/s/ ANTHONY B. EVNIN, PH.D. <b>Anthony B. Evnin, Ph.D.</b>	Director	March 5, 2013
/s/ GWEN A. FYFE, M.D. <b>Gwen A. Fyfe, M.D.</b>	Director	March 4, 2013
/s/ ERIC S. LANDER, PH.D. <b>Eric S. Lander, Ph.D.</b>	Director	March 4, 2013
/s/ PATRICK P. LEE <b>Patrick P. Lee</b>	Director	March 4, 2013
/s/ THOMAS J. LYNCH, JR., M.D. <b>Thomas J. Lynch, Jr., M.D.</b>	Director	March 1, 2013
/s/ NORMAN C. SELBY <b>Norman C. Selby</b>	Director	March 4, 2013
/s/ IAN F. SMITH <b>Ian F. Smith</b>	Director	March 5, 2013

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

Director

March 5, 2013



**Table of Contents****EXHIBIT INDEX**

<b>Exhibit</b>	<b>Description</b>
3.1	Restated Certificate of Incorporation of the Registrant. Previously filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
3.2	Amended and Restated Bylaws of the Registrant. Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 17, 2009 (File No. 000-31141) and incorporated herein by reference.
4.1	Form of Common Stock Certificate. Previously filed as Exhibit 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 000-31141) and incorporated herein by reference.
10.1	Securities Purchase Agreement, dated as of July 17, 2012, between the Registrant, Purdue Pharma L.P., Beacon Company and Rosebay Medical Company L.P. Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 19, 2012 (File No. 000-31141) and incorporated herein by reference.
10.2	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between the Registrant and Mundipharma International Corporation Limited. Previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on July 19, 2012 (File No. 000-31141) and incorporated herein by reference.
10.3	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between the Registrant and Purdue Pharmaceutical Products L.P. Previously filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on July 19, 2012 (File No. 000-31141) and incorporated herein by reference.
10.4	Amended and Restated Development and License Agreement, dated as of December 24, 2012, by and between the Registrant and Intellikine, LLC. Filed herewith.
10.5	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.
10.6	Fifth Amendment to Lease dated July 8, 2011 between the Registrant and ARE-770/784/790 Memorial Drive LLC. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 filed on August 9, 2011 (File No. 000-31141) and incorporated herein by reference.
10.7	Sixth Amendment to Lease dated July 8, 2012 between the Registrant and ARE-770/784/790 Memorial Drive LLC. Previously filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 7, 2012 (File No. 000-31141) and incorporated herein by reference.
10.8	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.

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<b>Exhibit</b>	<b>Description</b>
10.9	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.
10.10	Fourth Amendment to Sublease dated December 19, 2012 between IDI and Hydra, together with Consent to Fourth Amendment to Sublease dated December 28, 2012 by ARE-770/784/790 Memorial Drive LLC, IDI and Hydra. Filed herewith.
10.11*	Offer Letter between the Registrant and Lawrence E. Bloch, M.D., J.D. dated May 15, 2012. Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 25, 2012 (File No. 000-31141) and incorporated herein by reference.
10.12*	Offer Letter between IDI and Julian Adams dated as of August 19, 2003. Previously filed as Exhibit 10.10 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.13*	Amendment to Offer Letter between IDI and Julian Adams dated as of October 25, 2007. Previously filed as Exhibit 99.4 to the Registrant's Current Report on Form 8-K filed on October 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.14*	Offer Letter between IDI and Adelene Perkins dated as of February 6, 2002. Previously filed as Exhibit 10.11 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.15*	Amendment to Offer Letter between IDI and Adelene Perkins dated as of October 25, 2007. Previously filed as Exhibit 99.5 to the Registrant's Current Report on Form 8-K filed on October 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.16	Pre-Merger Stock Incentive Plan. Previously filed as Exhibit 10.18 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.17*	Form of Incentive Stock Agreement entered into with each of the officers identified on the schedule thereto. Previously filed as Exhibit 10.25 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.18*	Form of Nonstatutory Stock Option Agreement entered into with each of the officers identified on the schedule thereto. Previously filed as Exhibit 10.27 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.19	2000 Stock Incentive Plan. Previously filed as Exhibit 10.59 to the Registrant's Registration Statement on Form S-1 filed on May 9, 2000 (File No. 333-36638) and incorporated herein by reference.
10.20	Amendment No. 1 to 2000 Stock Incentive Plan; Amendment No. 2 to 2000 Stock Incentive Plan; Amendment No. 3 to 2000 Stock Incentive Plan. Previously filed as Exhibit 10.32 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.21	Amendment No. 4 to 2000 Stock Incentive Plan. Previously filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 000-31141) and incorporated herein by reference.
10.22	Amendment No. 5 to 2000 Stock Incentive Plan. Previously filed as Exhibit 99.4 to the Registrant's Registration Statement on Form S-8 filed on May 23, 2008 (File No. 333-151135) and incorporated herein by reference.

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<b>Exhibit</b>	<b>Description</b>
10.23	Form of Incentive Stock Option Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.33 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.24	Form of Nonstatutory Stock Option Agreement under 2000 Stock Incentive Plan. Previously filed as Exhibit 10.34 to the Registrant's Current Report on Form 8-K filed on September 18, 2006 (File No. 000-31141) and incorporated herein by reference.
10.25	2010 Stock Incentive Plan. Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 28, 2010 (File No. 333-31141) and incorporated herein by reference.
10.26	Form of Incentive Stock Option Agreement under 2010 Stock Incentive Plan. Previously filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on May 28, 2010 (File No. 333-31141) and incorporated herein by reference.
10.27	Form of Nonstatutory Stock Option Agreement under 2010 Stock Incentive Plan. Previously filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on May 28, 2010 (File No. 333-31141) and incorporated herein by reference.
10.28	Amendment No. 1 to 2010 Stock Incentive Plan. Previously filed as Exhibit 99.2 to the Registrant's Current Report on Form 8-K filed on December 14, 2010 (File No. 333-31141) and incorporated herein by reference.
10.29	Amendment No. 2 to 2010 Stock Incentive Plan. Previously filed as Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed on May 18, 2012 (File No. 333-31141) and incorporated herein by reference.
21.1	Subsidiaries of the Registrant. Filed herewith.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. Filed herewith.
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.
31.2	Certification of 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 officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32.2	Statement of 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.
101	The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Cash Flows, (iv) the Consolidated Statements of Stockholders' Equity, and (v) Notes to Consolidated Financial Statements.

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