INFINITY PHARMACEUTICALS, INC.
Form 10-K
February 25, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2013

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

For the transition period from to

Commission file number: 000-31141

INFINITY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	33-0655706
(State or other jurisdiction of incorporation or organization)	(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	NASDAQ Global Select Market
(Title of each class)	(Name of each exchange on which listed)

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

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 x

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 x 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 x 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. x

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 x	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 x

The aggregate market value of voting Common Stock held by non-affiliates of the registrant as of June 28, 2013 was $756,105,453 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 14, 2014: 48,281,015

Documents incorporated by reference:

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2014 in connection with our 2014 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 2014, 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 biopharmaceutical company dedicated to discovering, developing and delivering best-in-class medicines to people with difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. 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 delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which we are investigating in both hematologic malignancies and inflammatory diseases. The PI3Ks are a family of enzymes involved in multiple cellular functions, including cell proliferation and survival, cell differentiation, cell migration and immunity. The PI3K-delta and PI3K-gamma isoforms are preferentially expressed in white blood cells, where they have distinct and mostly non-overlapping roles in immune cell development and function. Targeting PI3K-delta and PI3K-gamma may provide multiple opportunities to develop differentiated therapies for the treatment of hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the most advanced PI3K-delta,gamma inhibitor in clinical development. The following is a summary of the clinical development of IPI-145 and 2014 goals:

Hematologic Malignancies

We have launched DUETTS™, a worldwide investigation of IPI-145 in blood cancers. As part of the DUETTS™ program, we are conducting DYNAMO™, a Phase 2, open-label, single arm study evaluating the safety and efficacy of IPI-145 dosed at 25mg BID in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL, including follicular lymphoma (or FL), marginal zone lymphoma and small lymphocytic lymphoma (or SLL), whose disease is refractory to radioimmunotherapy or both rituximab and chemotherapy. The FDA has granted orphan drug designation to IPI-145 for the potential treatment of FL, the most common subtype of iNHL.

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Also under the DUETTS™ program, we are also conducting DUO™, a randomized, monotherapy Phase 3 study of IPI-145 in approximately 300 patients with relapsed/refractory chronic lymphocytic leukemia, or CLL.

We are also conducting an ongoing 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. The dose escalation portion of the trial is complete, with the maximum tolerated dose defined as 75 mg twice daily, or BID. We are continuing to evaluate IPI-145 across two 25mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and mantle cell lymphoma, MCL, and treatment-naïve CLL in high-risk patients (those patients who are over age 65 or who have one of two genomic alterations known as a 17p deletion or a p53 mutation). Additionally, we are continuing to evaluate IPI-145 across five 75mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and MCL; T-cell lymphomas; aggressive B-cell lymphomas; myeloid neoplasms; and T-cell or B-cell acute lymphoblastic leukemia/lymphoma.

In 2014, we intend to initiate DYNAMO+R, a Phase 3 study of IPI-145 dosed at 25 mg BID in combination with rituximab in patients with relapsed/refractory iNHL, as well as a Phase 2 study of IPI-145 in treatment-naïve patients with iNHL. We also expect to initiate at least one additional clinical trial in patients with hematologic malignancies in 2014.

Inflammation and Autoimmune Diseases

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 and autoimmune diseases.

We are conducting a Phase 2, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and pharmacokinetics of IPI-145 in patients with rheumatoid arthritis, or RA, which we refer to as the ASPIRA trial. We intend to report topline data from this study in 2014.

We are also conducting a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in patients with mild, allergic asthma. We intend to report topline data from this study in 2014.

We are also developing our second PI3K product candidate, a potent, oral inhibitor of PI3K-delta and gamma which we refer to as IPI-443. The nonclinical studies of IPI-443 required for Phase 1 development have been completed, and the data from the two Phase 2 studies of IPI-145 in inflammatory and autoimmune diseases will guide the next steps for the development of IPI-443.

In September 2013 we announced topline data from our Phase 2 study evaluating retaspimycin hydrochloride, or HCl, a novel, potent and selective inhibitor of heat shock protein 90, or Hsp90, in combination with docetaxel, a chemotherapy, in 226 patients with second or third-line non-small cell lung cancer, or NSCLC, who are naïve to docetaxel treatment and have a history of heavy smoking. In this randomized, double-blind, placebo-controlled study, retaspimycin HCl did not meet its pre-specified efficacy endpoints for demonstrating an improvement in overall survival in the total patient population or in patients with squamous cell carcinoma, despite observing partial responses in patients with squamous cell carcinoma during the Phase 1b testing. Additionally, the combination of retaspimycin HCl plus docetaxel did not show a treatment benefit in patient populations defined by pre-specified biomarkers, including KRAS, p53 and plasma levels of Hsp90-alpha. We expect to present final data in a peer-reviewed setting after all analyses are complete.

We completed enrollment of the final cohort of patients in our separate, exploratory study of retaspimycin HCl in combination with everolimus (an mTOR inhibitor) in NSCLC patients with a KRAS mutation. Completing enrollment has concluded our development of retaspimycin HCl, and we will not initiate any new trials with retaspimycin HCl.

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Recent Development

Facility Agreement

On February 24, 2014, or Effective Date, we entered into a Facility Agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which Deerfield agreed to loan to us up to $100,000,000, subject to the terms and conditions set forth in the Facility Agreement. Under the Facility Agreement, we may draw down on the facility in $25,000,000 increments at any time during the 12 months following the Effective Date. Our ability to draw down under the Facility Agreement is subject to various customary conditions, including the entry into a Guaranty and Security Agreement, or Guaranty, with Deerfield and Infinity Discovery, Inc., or IDI, our a wholly-owned subsidiary, pursuant to which, as security for the repayment of our obligations under the Facility Agreement, IDI will guaranty all of our obligations under the Facility Agreement and, to secure the obligations under the Facility Agreement and the Guaranty, both we and IDI will grant to Deerfield a security interest in substantially all of our assets including intellectual property.

Any amounts drawn under the Facility Agreement accrue interest at a rate of 7.95% per annum, payable quarterly in arrears beginning on June 1, 2014, provided that, during the first five interest payment dates of any draw under the Facility Agreement, we may elect to pay all or a portion of such accrued interest by adding it to the principal amount outstanding. All such accrued interest will, regardless of which draw it applies to, be payable on the last business day of the sixth calendar quarter following the date of the first draw. We have the right to terminate the Facility Agreement and/or to prepay amounts owed under the Facility Agreement at any time, provided that, to the extent that any amount was drawn less than three years before such early termination or prepayment, we will be required to pay an additional amount equal to three years of interest less the amount of interest previously paid. We will be required to repay Deerfield one-third of the total principal amount drawn under the Facility Agreement on each of the third, fourth and fifth anniversaries of the first draw, however the final payment must be made by December 15, 2019. On February 27, 2015, or upon the earlier termination or acceleration of the facility, we are required to pay a fee equal to 3% of the then undrawn portion of the $100,000,000 commitment.

Deerfield will have the right to accelerate payment of the facility in the event that we consummate a major transaction, which is generally defined as a change in control, a sale of all or substantially all of our assets, a tender or exchange offer for our common stock, a liquidation, bankruptcy, insolvency, dissolution or wind up, a delisting and/or the common stock ceases to be registered under the Securities Exchange Act of 1934, or the Exchange Act.

Any amounts drawn under the Facility Agreement may become immediately due and payable upon (i) customary events of default, as defined in the Facility Agreement, or (ii) the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination, as described above.

Principal and interest under the Facility may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion.

The Facility Agreement contains various representations and warranties, and affirmative and negative covenants, customary for financings of this type, provided that the negative covenants are not applicable until the first draw under the Facility Agreement.

Warrants

In connection with the execution of the Facility Agreement, we issued to Deerfield warrants to purchase an aggregate of 1,000,000 shares of common stock at an exercise price of $13.83 per share, or the Initial Warrants. As noted above, pursuant to the Facility Agreement, we have the right to request from Deerfield one or more

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cash disbursements in the minimum amount of $25,000,000 per disbursement, which disbursements shall be accompanied by the issuance to Deerfield of warrants to purchase an aggregate number of shares of common stock equal to (A) a quotient derived by dividing (x) the aggregate amount of such disbursement by (y) the volume weighted average closing price per share of the common stock during the 20 trading days following Deerfield s receipt of the applicable draw notice, or the 20-Day VWAP, multiplied by (B) 50%, or the Draw Warrants. We refer to the Initial Warrants and the Draw Warrants individually as a Warrant or together as the Warrants. The exercise price of the Draw Warrants will be the applicable 20-Day VWAP for each disbursement. The number of shares of common stock into which a Warrant is exercisable and the exercise price of any Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

Each Warrant issued under the Facility Agreement expires on the seventh anniversary of its issuance. Subject to certain exceptions, the Warrants and the Facility Agreement contain certain limitations such that we may not issue shares of common stock to Deerfield pursuant to the Warrants or the Facility Agreement if such issuance would result in Deerfield beneficially owning in excess of 9.985% of the total number of shares of our common stock of then issued and outstanding.

The holder of a Warrant may exercise the Warrant either for cash or on a cashless basis. In connection with certain major transactions, the holder may have the option to receive, upon exercise of the Warrant in whole or in part, either cash or a number of shares of common stock equal to the Black-Scholes value of the Warrant, as defined in the Warrant.

Registration Rights Agreement

In connection with the entry into the Facility Agreement and issuance of the Initial Warrants, we entered into a Registration Rights Agreement with Deerfield dated February 24, 2014. Pursuant to the terms of the Registration Rights Agreement, we have agreed to file a registration statement on Form S-3 with the SEC on or prior to 30 days from the Effective Date, to register for resale the shares of common stock issuable upon the exercise of the Initial Warrants. Additionally, pursuant to the terms of the Registration Rights Agreement, we have agreed to file one or more additional registration statements with the SEC to register for resale the shares of common stock issuable upon the exercise of the applicable Draw Warrants, on or prior to 30 days after issuance of each of the Draw Warrants.

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, 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

Historically, our product development programs have arisen 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 relevant 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 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 our PI3K programs.

IPI-145, 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 Millennium. We also have multiple 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 candidate 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.

Our product development programs as of February 1, 2014 are illustrated in the following chart:

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PI3K Inhibitor Program

The phosphoinositide-3-kinases, or PI3Ks, are key cellular signaling proteins that act as a central node for relaying signals from cell surface receptors to modulate downstream biochemical events. The PI3K-delta and PI3K-gamma isoforms are preferentially expressed in white blood cells, 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 most advanced 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 CLL, Hodgkin lymphoma and non-Hodgkin lymphoma, or NHL. It is estimated that there will be approximately 130,000 newly diagnosed incident cases of NHL in the seven major pharmaceutical markets (France, Germany, Italy, Japan, Spain, UK and US) in 2014. The distribution of NHL subtypes differs by country. In the United States and major European countries, diffuse large B-cell lymphoma, or DLBCL, accounts for the majority of NHL cases ranging from 40-43 percent, while CLL accounts for 25-33 percent and FL for 17-22 percent. MCL is the rarest subtype, accounting for 5-6 percent of cases. Even with advances in treatment options for these diseases, the clinical outlook still remains poor for patients. A significant proportion of patients relapses following treatment and become refractory to current agents, representing a significant unmet medical need.

Our 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 is ongoing (ClinicalTrials.gov Identifier NCT01476657). Data from this study, presented in December 2013 at the Annual Meeting of the American Society for Hematology, or ASH, and in January 2014 at the 6th Annual T-Cell Lymphoma Forum, showed that IPI-145 is clinically active in CLL, iNHL, T-Cell lymphoma and other hematologic malignancies.

Indolent Non-Hodgkin Lymphoma

IPI-145 is clinically active in patients with iNHL, with a 73 percent overall response rate, or ORR, (11 of 15 evaluable patients) and a 20 percent complete response rate (3 of 15 patients). Eight patients (53 percent) remain progression-free for over one year. IPI-145 was generally well tolerated, and the majority of side effects were low-grade, asymptomatic and transient. The most common ³ Grade 3 side effects were increases in ALT or AST (two liver enzymes) (38 percent), neutropenia (31 percent) and diarrhea (13 percent).

We have initiated DYNAMO, a Phase 2, open-label, single arm study evaluating the safety and efficacy of IPI-145 dosed at 25mg BID in approximately 120 patients with iNHL, including FL, marginal zone lymphoma and SLL, whose disease is refractory to radioimmunotherapy or both rituximab and chemotherapy. The FDA has granted orphan drug designation to IPI-145 for the potential treatment of FL, the most common subtype of iNHL. We intend to initiate DYNAMO+R, a Phase 3 study in combination with rituximab in patients with relapsed/refractory iNHL in 2014, as well as initiate a Phase 2 study in treatment-naïve patients with iNHL.

Chronic Lymphocytic Leukemia

IPI-145 is clinically active in patients with relapsed/refractory CLL, with a nodal response rate of 89 percent and an overall response rate of 48 percent as defined by criteria established by the International Workshop on Chronic Lymphocytic Leukemia, or IWCLL criteria, including one complete response and 12 partial responses, among patients receiving IPI-145 at doses £ 25 mg BID. Onset of activity was rapid, with the majority of

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responses occurring in less than two months. Among 12 patients evaluable with 17p deletions or p53 mutations who received IPI-145 at doses £ 25 mg BID, there were six partial responses, five patients with stable disease and one disease progression due to Richter transformation, an aggressive disease. Patients with CLL with 17p deletions or p53 mutations generally have a poor response to chemotherapy and worse prognosis. Preliminary data in treatment-naïve patients showed a decrease in the size of lymph nodes, in all six patients. Three of these six patients had nodal responses, a different way of measuring of clinical activity, including nodal responses in two patients with p53 mutations.

Data showed that IPI-145 was generally well tolerated, with a safety profile consistent with co-morbidities seen in patients with advanced hematologic malignancies. The majority of side effects were low-grade and/or asymptomatic. The most common ³ Grade 3 side effects in patients with relapsed/refractory CLL were neutropenia (30 percent), anemia (12 percent), diarrhea (6 percent) and increases in ALT or AST (6 percent). Fewer side effects were observed in treatment-naïve patients, which is consistent with the co-morbidities of patients with less advanced disease.

We are conducting DUO ™, a Phase 3 monotherapy study designed to evaluate the safety and efficacy of IPI-145 in patients with relapsed/refractory CLL. This randomized study is designed to evaluate the safety and efficacy of IPI-145 dosed at 25 mg BID compared to ofatumumab in approximately 300 patients with relapsed or refractory CLL. The primary endpoint of the study is progression-free survival. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to IPI-145 for the potential treatment of CLL and SLL. We are also continuing to evaluate patients from our Phase 1 study with relapsed or refractory CLL and patients with CLL over the age of 65 or have a 17p deletion or p53 mutation and are treatment naïve.

T-Cell Lymphoma and Other Lymphomas

IPI-145 is clinically active in advanced T-cell lymphomas. Treatment with IPI-145 in patients with T-cell lymphomas led to an overall response rate of 38 percent (10 of 26 patients), including one complete response and nine partial responses. Among the 11 patients with peripheral T-cell lymphoma, or PTCL, evaluable for activity, IPI-145 led to one complete response and five partial responses (ORR of 55 percent). Among the 15 patients with cutaneous T-cell lymphoma, or CTCL, evaluable for activity, IPI-145 led to four partial responses (ORR of 27 percent). Stable disease was observed in seven patients with CTCL. The onset of activity was rapid, with a median time to response of 1.9 months (range: 1.5 2.7) for patients with PTCL and 2.4 months (range: 1.7 3.8) for patients with CTCL. The median number of treatment cycles for the 13 patients with PTCL was 2.2 (range 0.5-8) and the median number of treatment cycles for the 17 patients with CTCL was 3.1 (range: 0.4-11).

IPI-145 was generally well tolerated in this patient population with the majority of T-cell lymphoma patients (20 of 30) receiving 75 mg BID IPI-145. The most common Grade 3 side effects were increases in ALT or AST (10 of 30 patients, 33 percent), rash (4 of 30 patients, 13 percent) and fatigue (3 of 30 patients, 10 percent). One patient (3%) had grade 4 ALT or AST increases.

Additionally, early clinical data in patients with aggressive non-Hodgkin lymphoma, or aNHL, and T-cell acute lymphoblastic leukemia, or T-ALL, were reported, with reductions in adenopathy, or decrease in the size of lymph nodes, observed in patients with DLBCL and Richter transformation, an aggressive disease, as well as a partial response in one patient with transformed FL. Translational data showed that IPI-145 effects key signaling molecules in the tumor microenvironment, providing a potential mechanistic rationale for the clinical activity of IPI-145 observed in patients with iNHL and CLL.

An investigator-sponsored Phase 1b, open-label study of IPI-145 in patients with B-cell NHL, CLL and T-cell lymphoma in combination with rituximab (a monoclonal antibody therapy), bendamustine (a chemotherapy) or both rituximab and bendamustine is also open for enrollment (NCT01871675).

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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, RA and asthma, affect large sections of the population with an estimated annual number of prevalent cases in the seven major markets in 2013 of 5.3 million and 76.5 million, respectively. Symptoms of RA include painful swelling and stiffness of the joints and surrounding tissues, while asthma is characterized by inflammation in the lungs leading to wheezing, shortness of breath, chest tightness and coughing. 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.

Within inflammatory diseases, IPI-145 is currently being evaluated in two Phase 2 trials. The first trial, which we refer to as the ASPIRA trial, is a Phase 2, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and pharmacokinetics of IPI-145 in patients with RA. The study is expected to enroll approximately 316 adults with moderate-to-severe RA and is designed to examine three dose levels of IPI-145 given twice daily for 12 weeks in combination with methotrexate compared to treatment with methotrexate alone. The primary efficacy endpoint of the study is the American College of Rheumatology 20 response rate, or ACR20, which is defined as the proportion of people who achieve at least a 20 percent improvement in ACR response criteria. The second is a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in patients with mild, allergic asthma. Endpoints of this multi-dose, two-way crossover study include safety, pharmacokinetics and FEV1, a measure of lung function. We expect to provide an update on this trial in 2014.

Pipeline Expansion

We are also developing our second PI3K product candidate, a potent, oral inhibitor of PI3K-delta and gamma which we refer to as IPI-443. The nonclinical studies of IPI-443 required for Phase 1 development are complete, and the data from the two Phase 2 studies of IPI-145 in inflammatory and autoimmune diseases will guide the next steps for the development of IPI-443.

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 discovered IPI-940, a novel, orally available inhibitor of fatty acid amide hydrolase, or FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response and may have applicability in a broad range of painful or inflammatory conditions. We are currently seeking potential partnering opportunities for our FAAH program.

Strategic Alliances

Since our inception, strategic alliances have been integral to our growth. These alliances have provided access to breakthrough science, significant research support and funding and innovative drug development programs, all intended to help us realize the full potential of our product pipeline. Since our inception, all of our revenue has been derived from our strategic alliances, and all of our revenue during 2012 and 2011 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, 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 and we paid Intellikine a $13.5 million up-front license

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fee. 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 terms of the amended and restated agreement, we retained worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement. Additionally, under the amended and restated agreement, Millennium waived certain commercial rights and, in consideration of such waiver, we agreed to pay to Millennium $15 million, payable in installments.

In addition to developing IPI-145, we are seeking to develop our second potent, oral PI3K-delta,gamma inhibitor product candidate, 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 to Millennium up to $5 million in remaining success-based milestone payments for the development of two distinct product candidates and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Millennium a $10 million milestone payment in connection with the initiation of our Phase 3 study of IPI-145 in patients with relapsed or refractory CLL. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from 7 percent to 11 percent 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

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 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, PI3K and product candidates arising out of our early discovery projects in all disease fields. Our Hsp90 program was expressly excluded from the alliance.

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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 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.

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 percent. 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 percent of the amounts otherwise payable during the applicable royalty payment period.

Intellectual Property

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

We have five issued or allowed U.S. patents covering IPI-145 and/or other molecules related to our PI3K program, which expire on various dates between 2029 and 2031, excluding any patent term extension. In addition, we have approximately 170 patents and patent applications pending worldwide related to our PI3K program. Any patents that may issue from our pending patent applications would expire between 2029 and 2034, 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, and we intend to continue to file patent applications to protect such technology and compounds 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.

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Competition

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

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 in the clinical stage of development of compounds targeting the delta and/or gamma isoforms of PI3K:

- Gilead Sciences, Inc., which we believe is conducting multiple late stage clinical trials of idelalisib and is conducting a Phase 1b clinical trial of GS-9820;
- Amgen, Inc., which we believe is conducting a Phase 1 clinical trial of AMG-319;
- TG Therapeutics, Inc., which we believe is conducting a Phase 1 clinical trial of TGR-1202;
- Rhizen Pharmaceuticals S.A., which we believe is conducting a Phase 1 clinical trial of RP-6530; and
- GlaxoSmithKline, which we believe has completed Phase 1 clinical trials of GSK-2269557.

In addition, many companies are developing product candidates directed to disease targets such as Bruton s Tyrosine Kinase (or BTK), Janus Kinase (or JAK), Spleen Tyrosine Kinase (or Syk) and B-cell lymphoma 2 (or Bcl-2) 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 has received approval with the U.S. Food and Drug Administration, or FDA, of ibrutinib, a BTK inhibitor, for the treatment of people with MCL or CLL and is conducting multiple late stage clinical studies of ibrutinib in additional hematologic malignancies;

Incyte Corporation which has received FDA approval of ruxolitinib, a JAK inhibitor, in patients with intermediate or high-risk myelofibrosis;

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Rigel Pharmaceuticals, Inc. which has completed a Phase 2 clinical trial of fostamatinib, a Syk inhibitor, in patients with immune thrombocytopenic purpura; and

AbbVie, Inc., which we believe is conducting multiple Phase 1 clinical trials of ABT-199, a Bcl-2 inhibitor, in hematologic malignancies.

Research and Development

As of February 1, 2014, our research and development group consisted of 151 employees, of whom over 34 percent hold Ph.D. or M.D. degrees and an additional 25 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, 2013, 2012 and 2011 was approximately $99.8 million, $118.6 million and $108.6 million, respectively. Reimbursement for our strategic collaborator-sponsored research and development expenses for the years ended December 31, 2013, 2012 and 2011 totaled approximately $0, $45.0 million, and $88.5 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 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 for commercial sale and/or shipment in the United States, we must comply with the requirements of the Federal Food, Drug and Cosmetic Act (FFD&C Act), which generally involves the following:

preclinical laboratory and animal tests performed in compliance with the FDA s Good Laboratory Practices, or GLP, regulations;

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

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

conduct of 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 marketing approval process requires substantial time, effort and financial resources. 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 GLP. 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 an exemption from the FFD&C Act that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and 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 NDA. 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 product candidates. 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 clinical site proposing to conduct the clinical trial must review and approve each study protocol, and study subjects must provide informed consent. During clinical studies the FDA requires the submission of serious adverse event reports and other periodic reports.

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 with the disease being investigated 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 a larger number of patients at geographically dispersed clinical study sites.

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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.

The NDA process. If clinical trials are successful, the next step in the drug development 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 act, or PDUFA, in effect at that time. Current timing commitments under PDUFA vary depending on whether an NDA qualifies for a priority or standard review. FDA acceptance of an NDA for review regardless of the review classification does not guarantee that an application will be approved or even acted upon by any specific deadline. The review process can be significantly extended by FDA due to 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 commitment studies, commonly referred to as Phase 4 trials, to monitor the safety and/or 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 plans. The FDA has broad post-marketing 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.

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With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug s approved labeling (known as off-label use), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties. Although physicians may prescribe FDA-approved products 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 product candidates. 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/ethics committee (EC) approval of interventional clinical trials. Most European regulators also require the submission of serious 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 granting 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 orphan 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 5 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

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the FDA may not approve any other applications to market the same drug (sameness defined as same active moiety) for the same indication, except in very limited circumstances, for seven years. In the European Union, the period of product exclusivity is ten years.

Orphan Drug exclusivity, however, also could block the approval of one of our products in the United States for seven years for an Orphan Drug indication if a competitor obtains approval of the same drug, as defined by the FDA, for such Orphan Drug indication or if our product candidate is determined to be contained within the competitor s product for the same indication or disease. We intend to seek Orphan Drug status for our product candidates as appropriate, but even if an Orphan Drug designation is granted it 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 1, 2014, we had 180 full-time employees, 151 of whom were engaged in research and development and 29 of whom were engaged in general business management, administration and finance. Over 57 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.

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Executive Officers

The following table lists the positions, names and ages of our executive officers as of February 15, 2014:

Name	Age	Position
Adelene Q. Perkins	54	President and Chief Executive Officer
Julian Adams, Ph.D.	59	President of Research & Development
Lawrence E. Bloch, M.D., J.D.	48	Executive Vice President, Chief Financial Officer and Chief Business Officer
Vito J. Palombella, Ph.D.	51	Chief Scientific Officer
David A. Roth, M.D.	51	Chief Medical Officer

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 Financial Officer and Chief Business 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 & Woman 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.

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

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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-kB regulation. Dr. Palombella received a B.S. in Microbiology from Rutgers University and an 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.

David A. Roth, M.D., has served as our Chief Medical Officer since January 2014. In this role, he provides strategic leadership for our clinical development activities, including responsibility for the company s medical affairs, pharmacovigilance and clinical operations functions. Prior to his role as Chief Medical Officer, Dr. Roth served as our Senior Vice President of Clinical Development and Medical Affairs from the time he joined Infinity in September 2013. Prior to joining Infinity, Dr. Roth was with Pfizer Inc. and Wyeth Pharmaceuticals, publicly traded pharmaceutical companies, from 2003 to 2013 where he contributed to the successful regulatory approval of several products, including Bosulif® (bosutinib), a dual Src/Abl tyrosine kinase inhibitor for the treatment of chronic myelogenous leukemia; Xyntha® and ReFacto AF® for the treatment of hemophilia A; and BeneFIX® for the treatment of hemophilia B. Dr. Roth also led the early development of palbociclib, a CDK 4/6 inhibitor, to Phase 3 evaluation in women with ER positive advanced breast cancer. Among other leadership positions, Dr. Roth served as Vice President and Head of the Early Development, Oncology Business Unit at Pfizer from 2009 to 2013. While at Wyeth, he held the role of Assistant Vice President, Clinical Research & Development and Global Therapeutic Area Director of Hematology from 2007 until Pfizer s acquisition of Wyeth in 2009. During his tenure at Pfizer and Wyeth, Dr. Roth also co-chaired Pfizer s oncology research and development board and served on several oncology and hematology R&D leadership teams and governance committees. Prior to joining the pharmaceutical industry, Dr. Roth s experience included over 10 years in research and clinical practice as an academic hematologist, and he served on the full time faculty at Harvard Medical School and Beth Israel Deaconess Medical Center in Boston. Dr. Roth received his B.S. from the Massachusetts Institute of Technology and his M.D. from Harvard Medical School in the Harvard-M.I.T. Division of Health Sciences and Technology, where he remains on the Affiliated Faculty.

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.

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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 retaspimycin hydrochloride in combination with docetaxel in patients with non-small cell lung cancer, which did not yield results consistent with results obtained from an earlier Phase 1b 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 not observed in early clinical trials may be seen for the first time in later studies, or adverse events observed in a small number of patients in early 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, 2013, we had an accumulated deficit of $449.8 million. We expect to continue to spend significant resources to fund the research and development of IPI-145 and our other product candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

Our 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

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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 without limitation 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 previous 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 to satisfy our need for additional funds by drawing down funds under the debt Facility Agreement we entered into with affiliates of Deerfield Management Company, L.P., or Deerfield, in February 2014. Under the Facility Agreement, Deerfield agreed to loan to us up to $100 million subject to the terms and conditions of the Facility Agreement. Our ability to draw down under the Facility Agreement is subject to various customary conditions, however, there is no assurance that we will be able to satisfy these conditions and draw down any funds. If we draw down under the Facility Agreement, we will be required to grant to Deerfield a security interest in substantially all of our assets including intellectual property, issue additional warrants to Deerfield, and repay any amounts borrowed together with interest accruing at a rate of 7.95% per annum no later than December 15, 2019. Any amounts drawn under the Facility Agreement may become immediately due and payable upon customary events of default or the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination. Principal and interest under the Facility may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion. There is no assurance that the conditions to our ability to repay the loan in shares of our common stock would be satisfied at the time that any outstanding principal and interest under the loan is due, in which case we would be obligated to repay the loan in cash, or that events permitting acceleration of the loan will not occur, in which event we would be required to repay any outstanding principal and interest sooner than anticipated.

We may also 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 as would be the case if we decided to draw down under the Facility Agreement with Deerfield. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us

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to relinquish or encumber rights to some of our technologies or product candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our product development programs 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 into, and expect to enter into 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 our 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, launch,

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market and sell new drugs. In some cases, we will not be involved in some or all of 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.

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 that Gilead Sciences, Inc., Amgen Inc., Rhizen Pharmaceuticals S.A, TG Therapeutics, Inc., and GlaxoSmithKline, are conducting clinical trials of drugs that target the delta and/or gamma isoforms of phosphoinositide-3-kinase, or PI3K, which is the target of IPI-145; and
- many companies are developing product candidates directed to disease targets such as Bruton s Tyrosine Kinase (or BTK), Janus Kinase (or JAK), Spleen Tyrosine Kinase (or Syk) and B-cell lymphoma 2 (or Bcl-2) 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, including Pharmacyclics, Inc., Incyte Corporation, Rigel Pharmaceuticals, Inc., and AbbVie, Inc.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have, and may be better equipped to discover, develop, manufacture and commercialize product candidates than we are;

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

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product candidates that have been approved, such as ibrutinib, a BTK inhibitor being developed and commercialized by Pharmacyclics, Inc. for the treatment of people with mantle cell lymphoma or chronic lymphocytic leukemia, 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 encounter difficulties in managing organizational change, which could adversely affect our operations.

Our ability to effectively manage changes to our organization, including organizational growth, 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, products, product candidates and technologies could adversely affect our business and our stock price.

We may acquire additional businesses, products, product candidates, or technologies that complement or augment our existing business. We may not be able to integrate any acquired business, product, product candidate or technology successfully or operate any acquired business profitably. Integrating any newly acquired business, product, product candidate, or technology 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, products, product candidates, or technologies which may result in, among other things, dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire businesses, products, product candidates and technologies 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.

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

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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, 2013, we had approximately $214 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 prioritizes 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 and have, in the past, exercised such rights. 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 it could adversely impact our financial results and available cash and 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 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.

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Risks Related to the Development and Commercialization of Our Product 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 Food and Drug Administration, or 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 IPI-145, the lead compound in our PI3K inhibitor program, in all phases of clinical development and we anticipate initiating multiple additional trials of IPI-145 in 2014. If any of these trials or other trials of our product candidates are successful, we may need to conduct further clinical trials and will need to 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 constraints on the manner in which we may market the product and curtailing 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, 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:

- unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;

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- 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, comparator drugs 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.

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, including eligibility criteria for the trial;

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

- the commitment of clinical investigators to identify eligible patients; and

- competing studies or trials.

Additionally, the availability of safe and effective treatments for the relevant disease being studied may impact patient enrollment in our clinical trials. For example, Pharmacyclics, Inc. has received approval to manufacture and market, ibrutinib, a BTK inhibitor for the treatment of CLL, an indication in which we are currently evaluating IPI-145 in a Phase 3 clinical trial.

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 authorities 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.

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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.

There has been limited success to date industry-wide in developing companion diagnostics. To be successful in developing a companion diagnostic, 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 obligations 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.

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.

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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.

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.

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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 products;
- lower demonstrated clinical safety or efficacy, or less convenient route of administration, compared to competitive products;
- 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 products marketed by others;
- the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;
- the lack of 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, cGMPs, 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.

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

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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 future products, or we may be required to sell our future products at prices that are below our expectations.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of our future products in determining whether, and at what level, to approve reimbursement for our future 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 future products 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 future products will be reimbursed to a smaller set than we believe our future products are effective in treating.

In some foreign countries, particularly Canada and European Union member states, 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 or is 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.

Healthcare reform measures could hinder or prevent our future products 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.

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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 percent 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;

- 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

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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

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 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.

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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 their methods of 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 became 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 for 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 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.

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In addition, we rely on intellectual property assignment agreements with our strategic alliance partners, vendors, employees, consultants, clinical investigators, 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. 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, while we cannot predict the outcome of any 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

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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 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

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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;
- 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, including but not limited to litigation to enforce or defend any of our intellectual property rights or to defend product liability claims;
- the failure of any of our product candidates, if approved, to achieve commercial success;
- 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;

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.

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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 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.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law statute, which generally prohibits a person who owns in excess of 15 percent of our outstanding voting stock from engaging in a transaction with us for a period of three years after the date on which such person acquired in excess of 15 percent of our outstanding voting common stock, unless the transaction is approved by our board of directors and holders of at least two-thirds of our outstanding voting stock, excluding shares held by such person. The prohibition against such transactions does not apply if, among other things, prior to the time that such person became an interested stockholder, our board of directors approved the transaction in which such person acquired 15 percent or more of our outstanding voting stock. 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, based on the number of shares of our common stock outstanding on December 31, 2013, our executive officers, directors, their respective affiliates, and stockholders holding 5 percent or more of our common stock, owned in the aggregate approximately 56 percent 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 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.

Item 1B. Unresolved Staff Comments

None.

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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 expired 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.

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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.

	2013		2012	
	High	Low	High	Low
First quarter	$ 50.51	$ 32.13	$ 12.40	$ 5.50
Second quarter	50.40	16.07	14.15	11.02
Third quarter	23.68	15.45	24.00	13.45
Fourth quarter	18.35	11.57	35.32	17.21

Holders

As of February 1, 2014, there were 56 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, 2008 through December 31, 2013 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, 2008, 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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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,				
	2013	2012	2011	2010	2009
Statement of Operations Data:					
Collaborative research and development revenue from Purdue entities	$	$ 47,114	$ 92,773	$ 71,331	$ 50,765
Operating expenses:					
Research and development	99,760	118,595	108,582	99,232	77,857
General and administrative	27,916	27,882	22,719	21,070	19,456
Total operating expenses	127,676	146,477	131,301	120,302	97,313
Gain on termination of Purdue entities alliance		46,555			
Loss from operations	(127,676)	(52,808)	(38,528)	(48,971)	(46,548)
Interest income (expense), net	896	(1,349)	(1,514)	(1,447)	744
Income from NIH reimbursement					1,745
Income from residual funding after reacquisition of Hsp90 program					12,450
Income from Therapeutic Discovery Grants				734	
Income from Massachusetts tax incentive award		193			
Loss before income taxes	(126,780)	(53,964)	(40,042)	(49,684)	(31,609)
Income tax benefit				700	330
Net loss	$ (126,780)	$ (53,964)	$ (40,042)	$ (48,984)	$ (31,279)
Loss per common share:					
Basic	$ (2.64)	$ (1.70)	$ (1.50)	$ (1.86)	$ (1.20)
Diluted	$ (2.64)	$ (1.70)	$ (1.50)	$ (1.86)	$ (1.20)
Weighted average number of common shares outstanding:					
Basic	47,936,001	31,711,264	26,620,278	26,321,398	26,096,515
Diluted	47,936,001	31,711,264	26,620,278	26,321,398	26,096,515

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	As of December 31,				
	2013	2012	2011	2010	2009
Selected Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities, including long-term	$ 214,468	$ 326,635	$ 115,937	$ 100,959	$ 130,737
Working capital	202,735	311,086	88,995	75,378	119,408
Total assets	230,710	335,660	124,490	124,566	157,318
Long-term debt due to Purdue entities, net of debt discount(1)			37,553		
Due to Millennium, less current portion(2)	6,456	6,252			
Accumulated deficit	(449,796)	(323,016)	(269,052)	(229,010)	(180,026)
Total stockholders equity	201,275	310,205	15,433	49,484	90,312

(1) In November 2011, we borrowed $50 million under a 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 11 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 the remaining balance as a liability. As of December 31, 2013, we have a balance of $6.7 million in Due to Millennium, current and $6.5 million in Due to Millennium, noncurrent.

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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 biopharmaceutical company dedicated to discovering, developing and delivering best-in-class medicines to patients with difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. 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.

Research and Development Programs

PI3 Kinase Inhibitor Program

Phosphoinositide-3-kinases, or the PI3Ks, are a family of enzymes involved in multiple cellular functions, including cell proliferation and survival, cell differentiation, cell migration and immunity. The PI3K-delta and PI3K-gamma isoforms are preferentially expressed in white blood cells, where they have distinct and mostly non-overlapping roles in immune cell development and function. Targeting PI3K-delta and PI3K-gamma may provide multiple opportunities to develop differentiated therapies for the treatment of hematologic malignancies and inflammatory diseases. IPI-145, our lead product candidate, is a potent, oral inhibitor of Class I PI3K-delta and PI3K-gamma, or a PI3K delta,gamma inhibitor, which we are investigating in both hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the most advanced PI3K-delta,gamma inhibitor in clinical development.

We have launched DUETTS™, a worldwide investigation of IPI-145 in blood cancers. As part of the DUETTS™ program, we are conducting DYNAMO™, a Phase 2, open-label, single arm study evaluating the safety and efficacy of IPI-145 dosed at 25mg twice daily, or BID, in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL, including FL, marginal zone lymphoma and SLL, whose disease is refractory to radioimmunotherapy or both rituximab and chemotherapy. Patients enrolled in the study must have progressed within six months of receiving their last therapy. The primary endpoint of the study is response rate according to the International Working Group Criteria. The U.S. Food and Drug Administration, or FDA, has granted orphan drug designation to IPI-145 for the potential treatment of follicular lymphoma, or, FL, the most common subtype of iNHL. We intend to expand the DUETTS™ program in 2014 with the initiation of DYNAMO+R, a Phase 3 study of IPI-145 in combination with rituximab in patients with relapsed/refractory iNHL, as well as a Phase 2 study in treatment-naïve patients with iNHL and at least one additional clinical study in patients with hematologic malignancies.

Additionally, under the DUETTS™ program we are also enrolling patients in DUO™, a Phase 3 study of IPI-145 in patients with chronic lymphocytic lymphoma, or CLL. This randomized study is designed to evaluate the safety and efficacy of IPI-145 dosed at 25 mg BID compared to ofatumumab in approximately 300 patients with relapsed or refractory CLL. The primary endpoint of the study is progression-free survival. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to IPI-145 for the potential treatment of CLL and SLL.

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These trials are supported by data from our ongoing 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. The dose-escalation portion of the trial is complete, with the maximum tolerated dose defined at 75 mg BID. We are continuing to evaluate IPI-145 across two 25mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and mantle cell lymphoma, or MCL, and treatment-naïve CLL in high-risk patients (those patients who are over age 65 or have either of two genetic abnormalities known as a 17p deletion or p53 mutation). Additionally, we are continuing to evaluate IPI-145 across five 75mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and MCL; T-cell lymphomas; aggressive B-cell lymphomas; myeloid neoplasms; and T-cell or B-cell acute lymphoblastic leukemia/lymphoma. Data from this study, presented in December 2013 at the Annual Meeting of the American Society for Hematology, or ASH, and in January 2014 at the 6th Annual T-Cell Lymphoma Forum, showed that IPI-145 is clinically active in CLL, iNHL, T-Cell lymphoma, as well as other hematologic malignancies.

An investigator-sponsored Phase 1b, open-label study of IPI-145 in patients with B-cell NHL, CLL and T-cell lymphoma in combination with rituximab (a monoclonal antibody therapy), bendamustine (a chemotherapy) or both rituximab and bendamustine is also open for enrollment (NCT01871675).

Inflammatory and Autoimmune Diseases

Within inflammatory diseases, IPI-145 is currently being evaluated in two Phase 2 trials. The first, which we refer to as the ASPIRA trial, is a Phase 2, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and pharmacokinetics of IPI-145 in patients with rheumatoid arthritis (RA). The study is expected to enroll approximately 316 adults with moderate-to-severe RA and is designed to examine three dose levels of IPI-145 given twice daily for 12 weeks in combination with methotrexate compared to treatment with methotrexate alone. The primary efficacy endpoint of the study is the American College of Rheumatology 20, or ACR20, response rate, which is defined as the proportion of people who achieve at least a 20 percent improvement in ACR response criteria. The second trial is a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in patients with mild, allergic asthma. Endpoints of this multi-dose, two-way crossover study include safety, pharmacokinetics and FEV1, a measure of lung function. We expect to provide an update on this trial by the end of 2013.

PI3K Pipeline Expansion

We are also developing our second PI3K product candidate, a potent, oral inhibitor of PI3K-delta and gamma which we refer to as IPI-443. The nonclinical studies of IPI-443 required for Phase 1 development have been completed, and the data from the two Phase 2 studies of IPI-145 in inflammatory and autoimmune diseases will guide the next steps for the development of IPI-443.

Other Programs

In September 2013 we announced topline data from our Phase 2 study evaluating retaspimycin hydrochloride (HCl), a novel, potent and selective inhibitor of heat shock protein 90 (Hsp90), in combination with docetaxel, a chemotherapy, in 226 patients with second or third-line non-small cell lung cancer (NSCLC) who are naïve to docetaxel treatment and have a history of heavy smoking. In this randomized, double-blind, placebo-controlled study, retaspimycin HCl did not meet its pre-specified efficacy endpoints for demonstrating an improvement in overall survival in the total patient population or in patients with squamous cell carcinoma, despite observing partial responses in patients with squamous cell carcinoma during the Phase 1b testing. Additionally, the combination of retaspimycin HCl plus docetaxel did not show a treatment benefit in patient populations defined by pre-specified biomarkers, including KRAS, p53 and plasma levels of Hsp90-alpha. We expect to present final data in a peer-reviewed setting after all analysis are complete.

We also announced in September that we will complete enrollment of the final cohort of patients in our separate, exploratory study of retaspimycin HCl in combination with everolimus (an mTOR inhibitor) in NSCLC patients with a KRAS mutation by the end of 2013. This enrollment will conclude our development of retaspimycin HCl, and we will not initiate any new trials with retaspimycin HCl.

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In addition to our clinical stage programs, we have multiple innovative projects in earlier stages of development. Through our internal discovery efforts, we discovered IPI-940, a novel, orally available inhibitor of fatty acid amide hydrolase, or FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response, and may have applicability in a broad range of painful or inflammatory conditions. We are currently seeking potential partnering opportunities for our FAAH program.

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 and we paid Intellikine a $13.5 million up-front license fee. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, 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 terms of the amended and restated agreement, we retained worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement. Additionally, under the amended and restated agreement, Millennium waived certain commercial rights and, in consideration of such waiver, we agreed to pay to Millennium $15 million, payable in installments.

In addition to developing IPI-145, we are seeking to develop our second potent, oral PI3K-delta,gamma inhibitor product candidate, 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 to Millennium up to $5 million in remaining success-based milestone payments for the development of two distinct product candidates and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Millennium a $10 million milestone payment in connection with the initiation of our Phase 3 study of IPI-145 in patients with relapsed or refractory CLL. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from 7 percent to 11 percent 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

Strategic Alliance Termination Agreements

On July 17, 2012, we terminated our strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or 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 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, 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. We recognized $45 million in such revenue in the year ended December 31, 2012. We recognized $88.5 million in such revenue, which included $3.5 million in revenue related to reimbursed research and development services for the transition of the FAAH program, in the year ended December 31, 2011. 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, which products 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 percent. 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

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any such reductions capped at 50 percent 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. 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 percent.

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.

2012 Securities Purchase Agreement; 2013 Offering

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 a 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 terminated, as of July 17, 2012, all attendance rights to meetings of our board of directors held by the Purdue entities.

On April 16, 2013, the BRP entities, through two selling stockholders, sold 11,416,565 shares in an underwritten public offering at a price of $40 per share, representing their entire holdings in our common stock. In connection with the public offering and sale of their common stock, we entered into an agreement with the BRP entities, pursuant to which the 2012 securities purchase agreement, as amended in connection with the offering, terminated in its entirety.

Recent Development

Facility Agreement

On February 24, 2014, or Effective Date, we entered into a Facility Agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which Deerfield agreed to loan to us up to $100,000,000, subject to the terms and conditions set forth in the Facility Agreement. Under the Facility Agreement, we may draw down on the facility in $25,000,000 increments at any time during the 12 months following the Effective Date. Our ability to draw down under the Facility Agreement is subject to various customary conditions, including the entry into a Guaranty and Security Agreement, or Guaranty, with Deerfield and Infinity Discovery, Inc., or IDI, our a wholly-owned subsidiary, pursuant to which, as security for the repayment of our obligations under the Facility Agreement, IDI will guaranty all of our obligations under the Facility Agreement and, to secure the obligations under the Facility Agreement and the Guaranty, both we and IDI will grant to Deerfield a security interest in substantially all of our assets including intellectual property.

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Any amounts drawn under the Facility Agreement accrue interest at a rate of 7.95% per annum, payable quarterly in arrears beginning on June 1, 2014, provided that, during the first five interest payment dates of any draw under the Facility Agreement, we may elect to pay all or a portion of such accrued interest by adding it to the principal amount outstanding. All such accrued interest will, regardless of which draw it applies to, be payable on the last business day of the sixth calendar quarter following the date of the first draw. We have the right to terminate the Facility Agreement and/or to prepay amounts owed under the Facility Agreement at any time, provided that, to the extent that any amount was drawn less than three years before such early termination or prepayment, we will be required to pay an additional amount equal to three years of interest less the amount of interest previously paid. We will be required to repay Deerfield one-third of the total principal amount drawn under the Facility Agreement on each of the third, fourth and fifth anniversaries of the first draw, however the final payment must be made by December 15, 2019. On February 27, 2015, or upon the earlier termination or acceleration of the facility, we are required to pay a fee equal to 3% of the then undrawn portion of the $100,000,000 commitment.

Deerfield will have the right to accelerate payment of the facility in the event that we consummate a major transaction, which is generally defined as a change in control, a sale of all or substantially all of our assets, a tender or exchange offer for our common stock, a liquidation, bankruptcy, insolvency, dissolution or wind up, a delisting and/or the common stock ceases to be registered under the Securities Exchange Act of 1934, or the Exchange Act.

Any amounts drawn under the Facility Agreement may become immediately due and payable upon (i) customary events of default, as defined in the Facility Agreement, or (ii) the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination, as described above.

Principal and interest under the Facility may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion.

The Facility Agreement contains various representations and warranties, and affirmative and negative covenants, customary for financings of this type, provided that the negative covenants are not applicable until the first draw under the Facility Agreement.

Warrants

In connection with the execution of the Facility Agreement, we issued to Deerfield warrants to purchase an aggregate of 1,000,000 shares of common stock at an exercise price of $13.83 per share, or the Initial Warrants. As noted above, pursuant to the Facility Agreement, we have the right to request from Deerfield one or more cash disbursements in the minimum amount of $25,000,000 per disbursement, which disbursements shall be accompanied by the issuance to Deerfield of warrants to purchase an aggregate number of shares of common stock equal to (A) a quotient derived by dividing (x) the aggregate amount of such disbursement by (y) the volume weighted average closing price per share of the common stock during the 20 trading days following Deerfield s receipt of the applicable draw notice, or the 20-Day VWAP, multiplied by (B) 50%, or the Draw Warrants. We refer to the Initial Warrants and the Draw Warrants individually as a Warrant or together as the Warrants. The exercise price of the Draw Warrants will be the applicable 20-Day VWAP for each disbursement. The number of shares of common stock into which a Warrant is exercisable and the exercise price of any Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

Each Warrant issued under the Facility Agreement expires on the seventh anniversary of its issuance. Subject to certain exceptions, the Warrants and the Facility Agreement contain certain limitations such that we may not issue shares of common stock to Deerfield pursuant to the Warrants or the Facility Agreement if such issuance would result in Deerfield beneficially owning in excess of 9.985% of the total number of shares of our common stock of then issued and outstanding.

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The holder of a Warrant may exercise the Warrant either for cash or on a cashless basis. In connection with certain major transactions, the holder may have the option to receive, upon exercise of the Warrant in whole or in part, either cash or a number of shares of common stock equal to the Black-Scholes value of the Warrant, as defined in the Warrant.

Registration Rights Agreement

In connection with the entry into the Facility Agreement and issuance of the Initial Warrants, we entered into a Registration Rights Agreement with Deerfield dated February 24, 2014. Pursuant to the terms of the Registration Rights Agreement, we have agreed to file a registration statement on Form S-3 with the SEC on or prior to 30 days from the Effective Date, to register for resale the shares of common stock issuable upon the exercise of the Initial Warrants. Additionally, pursuant to the terms of the Registration Rights Agreement, we have agreed to file one or more additional registration statements with the SEC to register for resale the shares of common stock issuable upon the exercise of the applicable Draw Warrants, on or prior to 30 days after issuance of each of the Draw Warrants.

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, as well as 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 and development 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.

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 included in this report for a description of our significant accounting policies.

Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved and/or royalties on product sales. We recognize revenue 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 previous 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 have, in turn, resulted in changes in our quarterly and annual results. We recognized research and development

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funding as earned over the period of effort as related research and development costs were 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 in note 11 to our consolidated financial statements included in this report.

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 under- or over-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 under- or over-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, 2013, 2012 and 2011, in thousands, together with the change in each item as a percentage.

	2013	% Change	2012	% Change	2011
Revenue	$	(100)%	$ 47,114	(49)%	$ 92,773
Research and development expense	(99,760)	(16)%	(118,595)	9%	(108,582)
General and administrative expense	(27,916)	0%	(27,882)	23%	(22,719)
Gain on termination of Purdue entities alliance		(100)%	46,555		
Interest expense		(100)%	(1,908)	4%	(1,841)
Interest and investment income	896	60%	559	71%	327
Income from Massachusetts incentive tax award		(100)%	193		

Revenue

We did not recognize revenue during the year ended December 31, 2013 as our strategic alliance with Mundipharma and Purdue terminated in 2012.

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

- $45 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.

In the absence of any potential business development activities that generate revenue, we do not expect to recognize any revenue in 2014.

Research and Development Expense

Research and development expenses represented approximately 78 percent of our total operating expenses for the year ended December 31, 2013, 81 percent of our total operating expenses for the year ended December 31, 2012, and 83 percent of our total operating expenses for the year ended December 31, 2011.

The decrease in research and development expense for the year ended December 31, 2013 compared to the year ended December 31, 2012 was primarily attributable to:

$25.8 million lower clinical expenses, including clinical manufacturing expenses, primarily due to the discontinuation of company-sponsored development of saridegib, as well as conclusion of our development of retaspimycin HCl.

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$14.4 million incurred in 2012 associated with the fair value of installment payments related to amended and restated agreement with Millennium; and

$5 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 decreases were partially offset by an increase of $28.1 million in clinical expenses, including clinical manufacturing expenses, related to increased clinical development activities of IPI-145.

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 incurred in 2012 associated with the fair value of installment payments related to amended and restated agreement with Millennium; and

$5 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 million in milestone payments associated with the initiation of two Phase 1 clinical trials in our PI3K program.

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, 2013. 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; 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, 2013	Year Ended December 31, 2012	Year Ended December 31, 2011	January 1, 2006 to December 31, 2013
			(in millions)	
PI3K Inhibitor(1)	$ 71.7	$ 48.8	$ 23.5	$ 162.0
Hsp90 inhibitor	12.1	21.3	15.2	136.1
Hedgehog pathway inhibitor	1.2	34.0	48.4	164.0

(1) Includes an upfront license fee of $13.5 million in 2010, $4 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 million in development milestones in 2012.

We expect expenses related to our PI3K programs to increase as we continue clinical development of IPI-145. We expect expenses related to our Hsp90 program to decrease significantly as we conclude development of retaspimycin HCl. We expect to incur minimal expenses related to our Hedgehog pathway inhibitor programs as a result of the discontinuation of company-sponsored development. We do not believe that the historical costs associated with our lead drug development programs are indicative of the future costs associated with these

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programs, nor represent what any other future drug development programs 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 our 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

General and administrative expense is comparable for the years ended December 31, 2013 and 2012.

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:

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.

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

There was no interest expense in the year ended December 31, 2013 as compared to the years ended December 31, 2012 and 2011 due to the extinguishment of the long-term debt due to the Purdue entities on September 7, 2012.

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Interest and Investment Income

Interest and investment income increased in the year ended December 31, 2013 as compared to the year ended December 31, 2012 primarily as a result of higher yields and higher average cash and investment balances. 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 balances.

Income from Massachusetts Tax Incentive Award

During the year ended December 31, 2012, we recognized $0.2 million as other income, which related to a tax grant we were awarded in 2009 from the Commonwealth of Massachusetts. The total award was approximately $0.5 million and was earned over a five year period based on our achieving certain headcount growth levels each year. We achieved the required headcount growth levels for the first two years and therefore recognized a pro rata portion of the grant in the year ended December 31, 2012. However, we did not meet the required headcount level in the third year and were required to repay the remaining $0.3 million to the Commonwealth of Massachusetts in 2013.

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, 2013, is less than six months. Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our significant capital resources are as follows:

	December 31, 2013	December 31, 2012
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	$ 214,468	$ 326,635
Working capital	202,735	311,086

	Years ended December 31,		
	2013	2012	2011
		(in thousands)	
Cash (used in) provided by:			
Operating activities	$ (113,907)	$ (80,135)	$ (33,109)
Investing activities	606	(61,998)	(13,688)
Capital expenditures (included in investing activities above)	(1,754)	(1,301)	(1,542)
Financing activities	5,673	293,678	50,577

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 and 2011, we received research and development funding from Mundipharma and Purdue totaling $55 million and $85 million, respectively. Our research and development costs exceeded the funding from Mundipharma and Purdue for the year ended December 31, 2011 due primarily

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to investments we made in our Hedgehog and PI3K programs. 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. We cannot be certain whether and when we may enter into any such collaboration agreements or in-licenses.

Our cash flow used in operating activities for the year ended December 31, 2013 compared to the year ended December 31, 2012 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, 2013 included a prepayment of approximately $8 million related to purchases of comparator drugs to be used for our clinical trials. 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 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 million associated with the achievement of milestones under the original agreement, which we recorded as research and development expense.

Our investing activities for the years ended December 31, 2013, 2012 and 2011 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, 2013 included $249.8 million in purchases of available-for-sale securities, proceeds of $251.1 million from maturities of available-for-sale securities and proceeds of $1.0 million from sales of available-for-sale securities. Capital expenditures for the year ended December 31, 2013 of $1.8 million primarily consisted of laboratory equipment and software.

Our financing activities for the year ended December 31, 2013 included $5.3 million of proceeds from issuances of common stock from stock option exercises related to stock incentive plans and $0.4 million of proceeds from issuances of common stock related to our employee stock purchase plan. 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 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. In the absence of changes to our current operating plans, we will need to raise additional funds by that date. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectations, if we 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, without limitation, 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;

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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 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.

We have received $244.8 million of net proceeds from our public stock offerings since the termination of the strategic alliance agreements with Mundipharma and Purdue. 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, if 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 development programs or to scale back, suspend or terminate our business operations.

Organizational Restructuring

In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our Hedgehog pathway inhibitor, 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 percent of 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. All payments have been made in 2013.

Contractual Obligations

As of December 31, 2013, we had the following contractual obligations, excluding contingent milestone payments:

		Payments Due by Period (in thousands)			
Contractual Obligations	**Total**	**2014**	**2015**	**2016**	**2017 and beyond**
Due to Millennium	$ 13,334	$ 6,667	$ 6,667	$	$
Operating lease obligations	9,793	4,715	4,677	401	
Software contract obligations	696	363	333		
Total contractual cash obligations	$ 23,823	$ 11,745	$ 11,677	$ 401	$

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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. In February 2014, we paid to Millennium a $10 million milestone payment in connection with the initiation of our Phase 3 study of IPI-145 in patients with relapsed or refractory CLL.

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 $0.8 million decrease in the fair value of our investments as of December 31, 2013, as compared to an approximately $1.0 million decrease as of December 31, 2012. 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, 2013 and 2012, 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, 2013. 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, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, 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), Infinity Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) and our report dated February 25, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 25, 2014

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INFINITY PHARMACEUTICALS, INC.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 68,114	$ 175,742
Available-for-sale securities	145,772	150,276
Prepaid expenses and other current assets	11,055	3,731
Total current assets	224,941	329,749
Property and equipment, net	4,010	4,079
Long-term available-for-sale securities	582	617
Restricted cash	1,130	1,128
Other assets	47	87
Total assets	$ 230,710	$ 335,660
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 6,375	$ 2,148
Accrued expenses	9,164	10,059
Due to Millennium, current	6,667	6,456
Total current liabilities	22,206	18,663
Due to Millennium, less current portion	6,456	6,252
Other liabilities	773	540
Total liabilities	29,435	25,455
Commitments and contingencies (note 10)		
Stockholders equity:		
Preferred Stock, $.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2013 and 2012		
Common Stock, $.001 par value; 100,000,000 shares authorized, and 48,227,838 and 47,499,257 shares issued and outstanding, at December 31, 2013 and December 31, 2012, respectively	48	48
Additional paid-in capital	650,867	633,039
Accumulated deficit	(449,796)	(323,016)
Accumulated other comprehensive income	156	134
Total stockholders equity	201,275	310,205
Total liabilities and stockholders equity	$ 230,710	$ 335,660

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

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INFINITY PHARMACEUTICALS, INC.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Years Ended December 31,		
	2013	2012	2011
Collaborative research and development revenue from Purdue entities	$	$ 47,114	$ 92,773
Operating expenses:			
Research and development	99,760	118,595	108,582
General and administrative	27,916	27,882	22,719
Total operating expenses	127,676	146,477	131,301
Gain on termination of Purdue entities alliance		46,555	
Loss from operations	(127,676)	(52,808)	(38,528)
Other income (expense):			
Interest expense		(1,908)	(1,841)
Income from Massachusetts tax incentive award		193	
Investment and other income	896	559	327
Total other income (expense)	896	(1,156)	(1,514)
Loss before income taxes	(126,780)	(53,964)	(40,042)
Income tax benefit			
Net loss	$ (126,780)	$ (53,964)	$ (40,042)
Basic and diluted loss per common share	$ (2.64)	$ (1.70)	$ (1.50)
Basic and diluted weighted average number of common shares outstanding	47,936,001	31,711,264	26,620,278
Other comprehensive income (loss):			
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	$ 22	$ 112	$ (32)
Comprehensive loss	$ (126,758)	$ (53,852)	$ (40,074)

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

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INFINITY PHARMACEUTICALS, INC.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2013	**2012**	**2011**
Operating activities			
Net loss	$ (126,780)	$ (53,964)	$ (40,042)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,823	1,643	2,099
Stock-based compensation including 401(k) match	12,155	7,811	5,441
Non-cash interest expense on long-term debt due to Purdue entities		1,908	102
Non-cash interest expense on Due to Millennium amount	415		
Amortization of loan commitment asset from Purdue entities			1,588
Net amortization of premium/discount on available-for-sale securities	2,201	1,653	915
Impairment of property and equipment		161	
Other, net	(2)	46	72
Changes in operating assets and liabilities:			
Unbilled accounts receivable		218	(218)
Prepaid expenses and other assets	(7,284)	(1,037)	356
Accounts payable, accrued expenses and other liabilities	3,565	(12,395)	1,359
Due to Millennium		12,708	
Deferred revenue from Purdue entities		(38,887)	(4,781)
Net cash used in operating activities	(113,907)	(80,135)	(33,109)
Investing activities			
Purchases of property and equipment	(1,754)	(1,301)	(1,542)
Purchases of available-for-sale securities	(249,764)	(180,498)	(150,588)
Proceeds from maturities of available-for-sale securities	251,093	113,520	137,153
Proceeds from sales of available-for-sale securities	1,031	6,281	1,289
Net cash provided by (used in) investing activities	606	(61,998)	(13,688)
Financing activities			
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	5,299	21,386	582
Proceeds from issuances of common stock related to employee stock purchase plan	374		
Other financing activities			(5)
Net cash provided by financing activities	5,673	293,678	50,577
Net increase (decrease) in cash and cash equivalents	(107,628)	151,545	3,780
Cash and cash equivalents at beginning of period	175,742	24,197	20,417
Cash and cash equivalents at end of period	$ 68,114	$ 175,742	$ 24,197
Supplemental schedule of noncash investing and financing activities			
Receivable for stock option exercises	$ 152	$ 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.

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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, 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
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 gain 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.

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, 2012	47,499,257	$ 48	$ 633,039	$ (323,016)	$ 134	$ 310,205
Exercise of stock options	634,420		5,299			5,299
Exercise of warrants	32,248					
Stock-based compensation expense			11,495			11,495
401(k) plan match issued in common stock	30,010		660			660
Issuance of common stock related to employee stock purchase plan	31,903		374			374
Unrealized gain on marketable securities					22	22
Net loss				(126,780)		(126,780)
Balance at December 31, 2013	48,227,838	$ 48	$ 650,867	$ (449,796)	$ 156	$ 201,275

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 biopharmaceutical company seeking to discover, develop and deliver to patients best-in-class medicines designed to address difficult-to-treat diseases. As used throughout these audited, consolidated financial statements, the terms Infinity, we, us, and our refer to the business of Infinity Pharmaceuticals, Inc. and its wholly owned subsidiaries.

2. Summary of Significant Accounting Policies

Basis of Presentation

These consolidated financial statements include the accounts of Infinity and its wholly owned subsidiaries. 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.

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 obligations 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 corporate obligations, 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, 2013 and 2012 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 in investment income interest and dividends on securities classified as available-for-sale.

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).

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

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 to, 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 and 2011. We did not record any revenue in the year ended December 31, 2013 due to the termination of our strategic alliance with Mundipharma and Purdue on July 17, 2012, (see note 11).

We considered Mundipharma, Purdue and their respective associated entities to be related parties for financial reporting purposes prior to April 2013 because of their equity ownership in us (see note 11).

Property and Equipment

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

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

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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 7 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 (see note 11).

Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements. The terms of these research collaboration agreements may include payment to us of non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved and/or royalties on product sales. We recognize revenue 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.

We did not recognize any revenue for the year ended December 31, 2013 as our strategic alliance with Mundipharma and Purdue was mutually terminated on July 17, 2012 (see note 11). We did not enter into any new research collaboration agreements in 2013 that resulted in revenue to be recognized.

Under our previous 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 these agreements. 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 have, in turn, resulted 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 were 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.

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At the inception of an 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.

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, 2013 and 2012.

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

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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,		
	2013	2012	2011
Stock options	6,083,318	5,574,527	6,985,460
Warrants		50,569	3,246,629

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) is comprised of unrealized holding gains and losses arising during the period on available-for-sale securities that are not other-than-temporarily impaired. During the year ended December 31, 2013, there were no reclassifications out of accumulated other comprehensive income (loss).

Stock-Based Compensation Expense

For awards granted to employees and directors, including our Employee Stock Purchase Plan, or ESPP, 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 as of the respective vesting date. We use the Black-Scholes valuation model in determining the fair value of all equity awards. We have no awards with market or performance conditions.

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. Nonrefundable advance payments for comparator drugs that will be used for future research and development activities are deferred and capitalized and recognized as expense when the drugs are delivered. 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.

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 percent of the shares underlying the award at the end of the first year of service with the remaining 75 percent 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.

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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, 2013, an aggregate of 3,494,836 shares of our common stock were reserved for issuance upon the exercise of outstanding awards and up to 2,436,134 shares of common stock may be issued pursuant to awards granted under the 2010 Plan.

2000 Stock Incentive Plan

The 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, 2013, an aggregate of 2,519,372 shares of our common stock were reserved for issuance upon the exercise of outstanding awards granted under the 2000 Plan. The 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, 2013, an aggregate of 69,110 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.

2013 Employee Stock Purchase Plan

Our 2013 ESPP permits eligible employees to purchase shares of our common stock at a discount and consists of consecutive, overlapping 24-month offering periods, each consisting of four six-month purchase periods. On the first day of each offering period, each employee who is enrolled in the ESPP will automatically receive an option to purchase up to a whole number of shares of our common stock. The purchase price of each of the shares purchased in a given purchase period will be 85 percent of the closing price of a share of our common stock on the first day of the offering period or the last day of the purchase period, whichever is lower. During 2013, 31,903 shares of common stock were purchased for total proceeds of $0.4 million.

Compensation Expense

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

	Year Ended December 31,		
	2013	2012	2011
	(in thousands)		
Research and development	$ 6,213	$ 3,177	$ 2,743
General and administrative	5,942	4,634	2,698

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As of December 31, 2013, we had approximately $19.9 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested options and awards under our ESPP, which are expected to be recognized over a weighted-average period of 2.7 years.

Valuation Assumptions

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

	Year Ended December 31,		
	2013	2012	2011
Risk-free interest rate	1.1%	1.1%	2.2%
Expected annual dividend yield			
Expected stock price volatility	64.6%	63.3%	58.2%
Expected term of options	5.4 years	6.1 years	5.9 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 implied and 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, 2013, 2012 and 2011, the weighted-average forfeiture rate was estimated to be 13 percent, 12 percent and 10 percent, respectively.

All options granted to employees during the years ended December 31, 2013, 2012 and 2011 were granted with exercise prices equal to the fair market value of our common stock on the date of grant. We consider the closing price of our common stock as reported on the NASDAQ Global Select Market to be the fair market value.

A summary of our stock option activity for the year ended December 31, 2013 is as follows:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2013	5,574,527	$ 9.00		

Granted	1,412,894		32.57			
Exercised	(634,420)		8.36			
Forfeited	(269,683)		20.27			
Outstanding at December 31, 2013	6,083,318	$	14.04	6.6	$	23.8
Vested or expected to vest at December 31, 2013	5,809,122	$	13.60	6.5	$	23.3
Exercisable at December 31, 2013	4,112,636	$	10.79	5.7	$	18.9

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The weighted-average fair value per share of options granted during the years ended December 31, 2013, 2012 and 2011 was $18.07, $6.00 and $3.54, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2013 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2013 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2013, 2012 and 2011 was $16.0 million, $34.1 million and $0.4 million, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2013 was $5.3 million.

No related income tax benefits were recorded during the years ended December 31, 2013, 2012 or 2011.

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. We recognized $0.7 million of non-employee stock-based compensation expense in general and administrative expenses during the year ended December 31, 2013 with respect to the remeasurement and continued vesting of these options.

4. Cash, Cash Equivalents and Available-for-Sale Securities

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

	December 31, 2013			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Cash and cash equivalents due in 90 days or less	$ 68,114	$	$	$ 68,114
Available-for-sale securities:				
Corporate obligations due in one year or less	103,889	18	(16)	103,891
Corporate obligations due in one to five years	13,513	32		13,545
Mortgage-backed securities due after ten years	478	104		582
U.S. government-sponsored enterprise obligations due in one year or less	24,144	13		24,157
U.S. government-sponsored enterprise obligations due in one to five years	4,174	5		4,179
Total available-for-sale securities	146,198	172	(16)	146,354
Total cash, cash equivalents and available-for-sale securities	$ 214,312	$ 172	$ (16)	$ 214,468

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	December 31, 2012			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(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

We held 15 debt securities at December 31, 2013 that had been in an unrealized loss position for less than 12 months. The fair value on these securities was $50.7 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 15 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, 2013.

As of December 31, 2013, we held securities of 15 financial institutions and other corporate debt securities located in the Netherlands, the United Kingdom, Australia, Switzerland, Canada, Japan and France with a fair value of $64.5 million. These securities are short term in nature, with $59.3 million scheduled to mature within 12 months. Eight of these securities had gross unrealized losses of approximately $10 thousand and fair value of $20.2 million. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2013.

We had no material realized gains or losses on our available-for-sale securities for the years ended December 31, 2013, 2012 and 2011. There were no other-than-temporary impairments recognized for the years ended December 31, 2013, 2012 and 2011.

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, 2013 and 2012.

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The following table provides the assets carried at fair value measured on a recurring basis as of December 31, 2013:

	Level 1	Level 2
	(in thousands)	
Assets:		
Cash and cash equivalents	$ 68,114	$
Corporate obligations (including commercial paper)		117,436
Mortgage-backed securities		582
U.S. government-sponsored enterprise obligations		28,336
Total	$ 68,114	$ 146,354

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 the three month Treasury bill published on last business day of the month.

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

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

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

The amount due to Millennium is recorded at its carrying value at December 31, 2013. The fair value of the amount due to Millennium, a Level 2 measurement, was approximately $13.3 million as of December 31, 2013 and 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, 2013 (see note 11).

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, 2013. 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, 2013. We had no available-for-sale securities that were classified as Level 3 at any point during the years ended December 31, 2013 or 2012.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2013	2012
	(in thousands)	
Comparator drug prepaid	$ 8,008	$
Prepaid expenses	2,044	2,701
Other current assets	1,003	1,030
Total prepaid expenses and other current assets	$ 11,055	$ 3,731

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7. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2013	2012
	(in thousands)	
Laboratory equipment	$ 14,958	$ 15,067
Computer hardware and software	6,488	7,033
Office equipment and furniture and fixtures	872	775
Leasehold improvements	4,982	4,574
	27,300	27,449
Less accumulated depreciation	(23,290)	(23,370)
	$ 4,010	$ 4,079

During the year ended December 31, 2013, we capitalized approximately $0.4 million of costs associated with internally developed software. Depreciation expense associated with this software was $49 thousand during 2013.

8. Restricted Cash

We held $1.1 million in restricted cash as of December 31, 2013 and December 31, 2012. The balances are held on deposit with a bank to collateralize a standby letter of credit in the name of our facility lessor in accordance with our facility lease agreement.

9. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2013	2012
	(in thousands)	
Accrued compensation and benefits	$ 1,839	$ 5,555
Accrued drug manufacturing costs	991	1,288
Accrued clinical studies	4,009	1,234
Accrued preclinical studies	303	403
Other	2,022	1,579
Total accrued expenses	$ 9,164	$ 10,059

10. Commitments and Contingencies

We lease our office and laboratory space under two lease agreements. The term of our primary office and laboratory lease expires in January 2016, and may be terminated by us 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 all of the allowance as of December 31, 2013. Our secondary office lease expires in October 2014.

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

	Facility Leases (in thousands)
Years Ending December 31:	
2014	$ 4,706
2015	4,677
2016	401
Total minimum lease payments	$ 9,784

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

11. Collaborations

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, and we paid Intellikine a $13.5 million up-front license fee. 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 terms of the amended and restated agreement, we retained worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement. Additionally, under the amended and restated agreement, Millennium waived certain commercial rights and, in consideration of such waiver, we 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 remaining amount is payable in two equal payments due in January 2014 and January 2015, which we recorded as short-term and long-term liabilities Due to Millennium on our balance sheet.

In addition to developing IPI-145, we are seeking to develop our second potent, oral PI3K-delta,gamma inhibitor product candidate, 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 to Millennium up to $5 million in remaining success-based milestone payments for the development of two distinct product candidates, and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Millennium a $10 million milestone payment in connection with the initiation of our Phase 3 study of IPI-145 in patients with relapsed or refractory CLL. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from 7 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.

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.

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 in such revenue, which included $3.5 million in revenue related to reimbursed research and development services for the transition of the FAAH program, in the year ended December 31, 2011. 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

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were previously subject to the strategic alliance. All payments are contingent upon the successful commercialization of products subject to the alliance, which products 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 percent. 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 percent 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 of related amortization expense in the year ended December 31, 2011.

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 percent. 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 percent. 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

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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 $0, $2.1 million and $4.3 million in deferred revenue associated with grant of rights and licenses in the years ended December 31, 2013, 2012 and 2011, 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 a 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 terminated, as of July 17, 2012, all attendance rights to meetings of our board of directors held by the Purdue entities.

On April 16, 2013, the BRP entities, through two selling stockholders, sold 11,416,565 shares in an underwritten public offering at a price of $40 per share, representing their entire holdings in our common stock. In connection with the public offering and sale of their common stock, we entered into an agreement with the BRP entities, pursuant to which the 2012 securities purchase agreement, as amended in connection with the offering, terminated in its entirety. Following the closing of the offering, the BRP entities no longer owned any shares of our common stock at such time, and, as such, are no longer related parties.

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

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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.

12. Income Taxes

We had no income tax expense or benefit for the years ended December 31, 2013, 2012 and 2011.

Our income tax benefit for the years ended December 31, 2013, 2012 and 2011 differed from the expected U.S. federal statutory income tax benefit as set forth below:

	2013	2012	2011
		(in thousands)	
Expected federal tax benefit	$ (43,105)	$ (18,348)	$ (13,609)
Permanent differences	2,681	(4,685)	1,295
State taxes, net of the deferred federal benefit	(6,694)	(2,849)	(2,180)
Tax credits	(11,534)	(589)	(1,931)
Effect of change in state tax rate on deferred tax assets and deferred tax liabilities			61
Expired state net operating loss			1,424
Adjustments to deferred tax assets and deferred tax liabilities	129	3,371	745
Change in valuation allowance	58,461	23,066	14,160
Other	62	34	35
Income tax benefit	$	$	$

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

	Year Ended December 31,	
	2013	2012
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 136,879	