INFINITY PHARMACEUTICALS, INC.
Form 10-K
February 24, 2015
Table of Contents

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, 2014

¨ **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 x No ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No 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 30, 2014 was $605,578,255 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 18, 2015: 48,920,286

Documents incorporated by reference:

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2015 in connection with our 2015 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

TABLE OF CONTENTS

Table of Contents

Forward-Looking Information

The following discussion of our financial condition and results of operations contained in this Annual Report on Form 10-K 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, the possible achievement of discovery and development goals and milestones in 2015, our future discovery and development efforts, our collaborations, and our future operating results and financial position, includes forward-looking statements that involve risks and uncertainties. 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, or FDA, 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. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in Part I, Item 1A, Risk 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. 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 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 for potential applications in oncology. Our most advanced product candidate is duvelisib, also known as IPI-145, an oral, dual-inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which is currently being evaluated for the treatment of hematologic malignancies. We believe that duvelisib is the only inhibitor of PI3K-delta and gamma being investigated in Phase 3 clinical trials. In addition to duvelisib, we seek to expand our pipeline through a dedicated internal discovery research program and licensing of potential new product candidates or technologies discovered by third parties. The following is a summary of the clinical development of duvelisib and 2015 goals:

We are conducting DUETTS™ (**Duv**elisib **T**rials in Hema**t**ologic Malignancie**s**), a worldwide investigation of duvelisib 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 duvelisib dosed at 25 mg twice daily, or BID, in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL, including follicular lymphoma, 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 duvelisib for the potential treatment of follicular lymphoma, the most common subtype of iNHL;

Table of Contents

DYNAMO+R, a Phase 3 randomized, placebo-controlled study evaluating duvelisib dosed at 25 mg BID in combination with rituximab, a monoclonal antibody treatment, compared to placebo plus rituximab in approximately 400 patients with previously treated follicular lymphoma;

DUO™, a Phase 3 randomized, monotherapy study evaluating duvelisib dosed at 25 mg BID compared to ofatumumab, a monoclonal antibody treatment, in approximately 300 patients with relapsed or refractory chronic lymphocytic leukemia, or CLL;

A Phase 1b trial of duvelisib in combination with obinutuzumab, a monoclonal antibody treatment, in CLL patients whose disease has progressed following treatment with a Bruton s tyrosine kinase, or BTK, inhibitor; and

A Phase 1b/2 clinical study of duvelisib in combination with obinutuzumab or rituximab in patients with previously untreated follicular lymphoma.

We are also conducting an ongoing Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of duvelisib in patients with advanced hematologic malignancies. The dose escalation portion of the trial is complete, with the maximum tolerated dose defined as 75 mg BID.

In 2015, we intend to:

complete enrollment of DYNAMO during the first half of 2015;

report topline data from DYNAMO during the second half of 2015;

complete enrollment of DUO during the second half of 2015;

initiate the first clinical study evaluating duvelisib in combination with venetoclax (or ABT-199), a B-cell lymphoma 2 (or BCL-2) inhibitor being developed by AbbVie Inc. (or AbbVie); and

initiate two additional clinical studies investigating duvelisib in iNHL.

We are pursuing duvelisib in oncology through a strategic collaboration with AbbVie. For information regarding our collaboration, please see below under the heading *AbbVie* in the section entitled Strategic Alliances.

In 2014, we completed two Phase 2 studies of duvelisib in inflammation and concluded our investigation of duvelisib in this therapeutic area. The first, a randomized, double-blind, placebo-controlled crossover study of patients with mild, allergic asthma, was designed to evaluate the activity and safety of duvelisib in 50 patients following an allergen inhalation challenge. Patients were randomized to receive treatment with placebo followed by duvelisib or duvelisib followed by placebo in a two-period cross-over design, with duvelisib administered at either 1 mg BID or 5 mg BID for 14 days, or 25 mg BID for five days. We reported topline data from this study in October 2014 which showed that the study primary endpoint of significantly improving the maximum early-phase or late-phase asthmatic response as measured by FEV_1 (a standard lung function test that measures the amount of air that can be exhaled in one second) was not met at any of the doses tested. Clinical improvement in the late-phase response was observed at the 25 mg BID dose ($p = 0.052$) and multiple pre-specified secondary efficacy endpoints were positive at the 25 mg BID dose, including an improvement in FEV_1 area under the curve over the entire assessment period ($p = 0.013$) and a decrease in patients sensitivity to methacholine treatment, a measure of airway hyper-reactivity ($p = 0.036$). Additionally, the 5 mg BID and 25 mg BID doses of duvelisib significantly decreased serum levels of key mediators of airway inflammation.

The second study, a Phase 2, double-blind, randomized, placebo-controlled study, was designed to evaluate the efficacy, safety and pharmacokinetics of duvelisib dosed at either 0.5 mg, 1.0 mg or 5.0 mg BID for 12 weeks on background methotrexate compared to treatment with placebo plus methotrexate. The study evaluated 322 adults with active moderate-to-severe rheumatoid arthritis receiving a stable dose of methotrexate. The primary efficacy endpoint of the study was ACR20 response rate at 12 weeks, which is defined as the proportion of

Table of Contents

patients who achieve at least a 20% improvement in American College of Rheumatology, or ACR, response criteria after 12 weeks of study treatment. Topline data reported from this study in January 2015 demonstrated that the primary efficacy endpoint of the study was not met at any of the doses tested. Based on the results from these studies, we will not proceed with further clinical development of duvelisib or IPI-443, our second oral inhibitor of PI3K-delta and gamma, in inflammatory diseases, and we expect that any further development of IPI-443 in inflammatory diseases would be conducted through out-licensing or partnering efforts.

In August 2014, we licensed rights to our fatty acid amide hydrolase, or FAAH program, to FAAH Pharma Inc., or FAAH Pharma, a company pursuing the clinical development of IPI-940 to investigate its potential to treat neuropathic pain. We received a 23% ownership in FAAH Pharma in exchange for the license. FAAH Pharma receives funding from TVM Life Science Ventures VII, L.P., or TVM, through potential milestone payments.

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

Product Development Pipeline

Historically, our product development programs have arisen from a combination of internally developed programs and strategic licensing arrangements. We focus on targets that have the potential to fundamentally change 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.

Duvelisib, 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, acting through its Millennium business unit. We refer to our PI3K program licensor as Takeda. We also have multiple innovative projects in earlier stages of development and actively evaluate potential licenses and collaborations regarding new product candidates and technologies discovered by third parties.

Table of Contents

Our product development programs as of February 1, 2015 are illustrated in the following chart:

PI3 Kinase Inhibitor Program in Hematologic Malignancies

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. Our lead product candidate, duvelisib, is an oral, dual inhibitor of PI3K-delta and PI3K-gamma, which we believe is the only inhibitor of PI3K-delta and gamma being investigated in Phase 3 clinical trials.

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 132,000 newly diagnosed cases of NHL in the seven major pharmaceutical markets (United States, France, Germany, Italy, Japan, Spain, and United Kingdom) in 2015. 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 37-43%, while CLL accounts for 25-33% and follicular lymphoma for 17-22%. Even with advances in treatment options for these diseases, the clinical outlook for patients still remains poor. A significant proportion of patients relapses following treatment and becomes refractory to current agents, representing a significant unmet medical need.

To address this need, we are conducting DUETTS, a worldwide investigation of duvelisib in blood cancers. The initiation of the DUETTS trials, discussed below in detail, is supported by data from our ongoing Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of duvelisib 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 duvelisib across two 25 mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and mantle cell lymphoma, or MCL, and treatment-naïve CLL in high-risk patients defined as patients over age 65 or having either of two genetic abnormalities known as a 17p deletion or p53 mutation. Additionally, we are continuing to evaluate duvelisib across five 75 mg 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 2014 at the Annual Meeting of the American Society for Hematology, or ASH, and in January 2015 at the 7th Annual T-Cell Lymphoma Forum, showed that duvelisib is clinically active in CLL, iNHL, and T-cell lymphoma, as well as other hematologic malignancies.

Table of Contents

Indolent Non-Hodgkin Lymphoma

Data from our Phase 1 study has demonstrated that duvelisib administered at 25 mg BID is clinically active in patients with iNHL, with a 72% (13 of 18 evaluable patients) overall response rate and a 33% (6 of 18 evaluable patients) complete response rate. Among patients with follicular lymphoma, the overall response rate was 69% (9 of 13 evaluable patients), including a 38% complete response rate (5 of 13 evaluable patients). The median progression free survival and median overall survival have not yet been reached, with 69% progression-free and 89% overall survival at 24 months. Duvelisib was generally well tolerated, and the majority of side effects were low-grade, asymptomatic and transient. The majority of adverse events were Grade 1 or 2, reversible and/or clinically manageable. At the 25 mg BID dose, the most common Grade 3 side effects were increases in alanine aminotransferase, or ALT, or aspartate aminotransferase, or AST, (32%), diarrhea (16%), neutropenia and pneumonia (11% each). Grade 4 neutropenia was 11% (2 patients), Grade 4 ALT or AST increase was 5% (1 patient) and Grade 4 pneumonia was 5% (1 patient).

As Part of the DUETTS program, we are conducting DYNAMO, a Phase 2, open-label, single arm study evaluating the safety and efficacy of duvelisib dosed at 25 mg BID in approximately 120 patients with iNHL, including follicular lymphoma, 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 DYNAMO study is designed with the potential to support accelerated approval of duvelisib in patients with follicular lymphoma, the most common subtype of iNHL, assuming we are able to generate positive safety and efficacy data from the study and on the condition that we conduct a confirmatory study. Additionally, the FDA has granted orphan drug designation to duvelisib for the potential treatment of follicular lymphoma. We expect to complete patient enrollment in DYNAMO in the first half and report topline data in the second half of 2015. The availability of accelerated approval is dependent on a number of factors including whether duvelisib has demonstrated a meaningful benefit over available therapies. For a further discussion of the FDA s accelerated approval pathway, and certain risks related to our ability to seek accelerated approval for duvelisib, see Government Regulation Review and Approval of Drugs in the United States and Risk Factors Risks Related to the Development and Commercialization of Our Product Candidates elsewhere in this report.

We have expanded the DUETTS program in follicular lymphoma with the initiation of two new trials. The first, DYNAMO+R, is a Phase 3 randomized, placebo-controlled study evaluating duvelisib dosed at 25 mg BID in combination with rituximab compared to placebo plus rituximab in approximately 400 patients with previously treated follicular lymphoma and is designed to serve as our confirmatory study in the event we are able to receive accelerated approval of duvelisib for the treatment of patients with follicular lymphoma based on the results of our DYNAMO study. The second is a Phase 1b/2 clinical study of duvelisib in combination with obinutuzumab or rituximab in patients with previously untreated follicular lymphoma.

Chronic Lymphocytic Leukemia

Data from our Phase 1 study demonstrates that duvelisib administered at 25 mg BID is clinically active in patients with relapsed/refractory CLL, with a 57% overall response rate (17 of 30 evaluable patients), including one complete response. The median progression free survival and median overall survival in the 31 patients who received the 25 mg BID dose have not yet been reached with a median time on treatment of 7.6 months (range: 0.9 months 34.1 months). The majority of side effects were Grade 1-2, reversible and/or clinically manageable. Across all doses evaluated in the study (N = 55), the most common Grade 3 side effects were pneumonia (24%), neutropenia (18%) and anemia (16%). Grade 4 pneumonia was 2% (1 patient), Grade 4 neutropenia was 24% (13 patients) and Grade 4 anemia was 2% (1 patient).

Also as part of the DUETTS program, we are enrolling patients in DUO, a Phase 3 study of duvelisib in patients with CLL. This randomized study is designed to evaluate the safety and efficacy of duvelisib dosed at 25 mg BID compared to ofatumumab in approximately 300 patients with relapsed or refractory CLL. The primary

Table of Contents

endpoint of the study is progression-free survival. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to duvelisib for the potential treatment of CLL and SLL. We expect to complete enrollment of DUO in the second half of 2015. We have further expanded the DUETTS program in CLL with the initiation of a Phase 1b trial of duvelisib in combination with obinutuzumab in CLL patients whose disease has progressed following treatment with a BTK inhibitor. This study is supported by Phase 1 data of duvelisib in six CLL patients previously treated with ibrutinib, a BTK inhibitor. Early clinical activity was observed, with partial responses in one CLL patient and stable disease in five CLL patients. The safety profile of duvelisib in these patients appeared consistent with the safety profile observed in other patients with advanced hematologic malignancies treated with duvelisib in the Phase 1 study.

T-Cell Lymphoma and Other Lymphomas

Duvelisib is clinically active in advanced T-cell lymphomas. Treatment with duvelisib in heavily pre-treated patients with relapsed/refractory T-cell lymphoma led to an overall response rate of 42% (14 of 33 patients evaluable for response), including two complete responses and twelve partial responses. Among the 15 patients with peripheral T-cell lymphoma, or PTCL, who were evaluable for response, duvelisib led to two complete responses and six partial responses, for an overall response rate of 53%. Among the 18 patients with cutaneous T-cell lymphoma, or CTCL, evaluable for response, duvelisib led to six partial responses, for an overall response rate of 33%. Stable disease was observed in one patient with PTCL and six patients with CTCL. The Grade 3 side effects in patients with T-cell lymphoma included increases in ALT or AST (31%, 11 patients), rash (17%, 6 patients) and pneumonia (14%, 5 patients). Two patients (6%) had Grade 4 ALT or AST increases and one patient (3%) had Grade 4 pneumonia. The majority of patients (27 of 35) received duvelisib dosed at 75 mg BID.

Additionally, early clinical data in patients with aggressive non-Hodgkin lymphoma and T-cell acute lymphoblastic leukemia, have been 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 follicular lymphoma.

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.

AbbVie

On September 2, 2014, we entered into a collaboration and license agreement with AbbVie, which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we will collaborate with AbbVie to develop and commercialize products containing duvelisib, which we refer to as Duvelisib Products, in oncology indications. Under the terms of the AbbVie Agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture Duvelisib Products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. We and AbbVie retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie Agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

Under the AbbVie Agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for Duvelisib Products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock.

We and AbbVie share oversight of development and have each agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We have primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and

Table of Contents

AbbVie has responsibility for the conduct of certain contemplated combination clinical studies, which we refer to as the AbbVie Studies. We have the responsibility to manufacture Duvelisib Products until we transition manufacturing responsibility to AbbVie, which we expect to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we are responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million after which we will share Duvelisib Product development and manufacturing costs equally with AbbVie. The development and manufacturing costs of the AbbVie Studies will be shared equally.

We and AbbVie share operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Specifically, we have the primary responsibility for advertising, distribution, and booking sales, and we share certain other commercialization functions with AbbVie. Assuming regulatory approval, we and AbbVie are obligated to each provide half of the sales representative effort to promote Duvelisib Products in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States.

AbbVie has paid us a non-refundable $275 million upfront payment and has agreed to pay us up to $530 million in potential future milestone payments comprised of $130 million associated with the completion of enrollment of either DYNAMO or DUO, which we expect to occur in 2015, up to $275 million associated with the achievement of specified regulatory filing and approval milestones, and up to $125 million associated with the achievement of specified commercialization milestones. Under the terms of the AbbVie Agreement, we and AbbVie will equally share commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for sales of Duvelisib Products in the United States, as well as sharing equally the existing U.S. milestone payment obligations to Takeda. Additionally, AbbVie has agreed to pay us tiered royalties on net sales of Duvelisib Products outside the United States ranging from 23.5% to 30.5%, depending on annual net sales of Duvelisib Products by AbbVie, its affiliates and its sublicensees. We are responsible for the existing royalty obligations to Mundipharma and Purdue outside the United States and to Takeda worldwide, and AbbVie has agreed to reimburse us for our existing Duvelisib Product milestone payment obligations to Takeda outside the United States. The tiered royalty from AbbVie is subject to a reduction of 4% at each tier if our royalties to Mundipharma and Purdue are reduced according to the terms of our agreements with Mundipharma and Purdue. This tiered royalty can further be reduced based on specified factors, including patent expiry, generic entry, and royalties paid to third parties with blocking intellectual property. These royalties are payable on a product-by-product and country-by-country basis until AbbVie ceases selling the product in the country.

Subject to limited exceptions, we have agreed that we and our affiliates will not commercialize, or assist others in commercializing, in oncology indications any product that is a PI3K delta, gamma inhibitor that meets certain agreed-to criteria, other than Duvelisib Products, and AbbVie has agreed to similar restrictions. Registration-directed clinical trials and commercialization of Duvelisib Products for uses outside of oncology indications would require our and AbbVie s mutual consent.

The AbbVie Agreement will remain in effect until all development, manufacturing and commercialization of Duvelisib Products cease, unless terminated earlier. Either we or AbbVie may terminate the AbbVie Agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the AbbVie Agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances. However, we may terminate the AbbVie Agreement only on a country-by-country basis in the event AbbVie is not using diligent efforts to obtain regulatory approval or to commercialize Duvelisib Products in a country outside the United States. AbbVie may also terminate the AbbVie Agreement for convenience after a specified notice period. In the event there is a material uncured breach by either us or AbbVie of development or commercialization obligations, the non-breaching party may also have the right to assume and conduct such applicable development or commercialization obligations. If AbbVie or any of its affiliates or sublicensees

Table of Contents

challenges the patents we have licensed to AbbVie, we can terminate the AbbVie Agreement if the challenge is not withdrawn after a specified notice period.

If the AbbVie Agreement is terminated, we would receive all rights to the regulatory filings related to duvelisib upon our request, our license to AbbVie would terminate, and AbbVie would grant us a perpetual, irrevocable license to develop, manufacture and commercialize products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates. This license would be royalty free, unless the AbbVie Agreement is terminated for material breach, in which case, depending on the breaching party and the timing of the material breach, a royalty rate may be payable by us ranging from a low single-digit percentage to a low double-digit percentage of net sales, and, in some cases, subject to a payment cap.

If the AbbVie Agreement is terminated, there are certain wind-down obligations to ensure a smooth transition of the responsibilities of the parties.

Takeda

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 duvelisib, and we paid Intellikine a $13.5 million upfront license fee. In January 2012, Intellikine was acquired by Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Takeda. In December 2012, we amended and restated our development and license agreement with Takeda.

Under the terms of the amended and restated agreement, we retained worldwide development rights and, in exchange for an agreement to pay Takeda $15 million in installments, we regained commercialization rights for products arising from the agreement for all therapeutic indications and are solely responsible for research conducted under the agreement.

In addition to developing duvelisib, we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. We are obligated to pay to Takeda up to $5 million in remaining success-based milestone payments for the development a second product candidate and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Takeda a $10 million milestone payment in connection with the initiation of our Phase 3 study of duvelisib in patients with relapsed or refractory CLL. In addition, we are obligated to pay Takeda tiered royalties on worldwide net sales ranging from 7% to 11% 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 of the royalties, and, in certain circumstances, limits on the number of products subject to a royalty obligation. 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. Takeda 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 Takeda, demonstrate to Takeda s reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Takeda 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.

On July 29, 2014, we entered into an amendment to our amended and restated development and license agreement with Takeda. Under the terms of the amendment, we paid to Takeda a one-time upfront payment of $5 million in exchange for the option to terminate our royalty obligations to Takeda under the amended and restated development and license agreement solely with respect to worldwide net sales in oncology indications of

Table of Contents

products containing or comprised of duvelisib. The option may be exercised by payment to Takeda of a fee of $52.5 million on or before March 31, 2015. If the option is not exercised, our royalty obligations to Takeda will remain unchanged.

Mundipharma and Purdue

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and we entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 Termination Agreements. The strategic 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 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.

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 resulting in the return to us of 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 strategic alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each strategic alliance program other than FAAH. 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 4% 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 1% 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 that were subject to the alliance, which products require significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, no amounts have been accrued.

Royalties are payable under these agreements until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third-party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

Deerfield

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which, Deerfield agreed to loan us up to $100 million, subject to the terms and conditions set forth in the facility agreement. On September 22, 2014, we amended the facility agreement with Deerfield such that the maximum principal amount that we may draw down is reduced to $50 million. We refer to

9

Table of Contents

the facility agreement with Deerfield, as amended, as the Facility Agreement. Under the terms of the Facility Agreement, we had the right to draw down on the Facility Agreement in $25 million minimum disbursements at any time during a pre-specified draw period. The draw period has expired without us having drawn down on the Facility Agreement. On February 27, 2015, or upon the earlier termination of the facility, we are required to pay a fee equal to $1.5 million representing 3% of the total amount remaining undrawn under the facility. 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. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock. The warrants expire on the seventh anniversary of their issuance and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it exceeding 9.985% of the total number of shares of common stock then issued and outstanding.

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 thirteen issued or allowed U.S. patents covering duvelisib and/or other molecules related to our PI3K programs, which expire on various dates between 2029 and 2033, excluding any patent term extension. In addition, we have approximately 200 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 2035, 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.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in the 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.

Table of Contents

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

- Gilead Sciences, Inc., or Gilead, has received approval from the FDA of idelalisib for the treatment of people with CLL, SLL, or follicular lymphoma, and which we believe is conducting a Phase 1b clinical trial of GS-9820;
- Bayer AG, which we believe is conducting a Phase 2 and a Phase 3 clinical trial of copanlisib;
- Acerta Pharma BV, which we believe is conducting a Phase 1 clinical trial of ACP 319;
- TG Therapeutics, Inc., which we believe is conducting a Phase 1 clinical trial of TGR-1202; and
- Rhizen Pharmaceuticals S.A., which we believe is conducting a Phase 1 clinical trial of RP-6530.

In addition, many companies are developing product candidates directed to disease targets such as BTK, BCL-2, Janus Kinase (or JAK), Spleen Tyrosine Kinase (or Syk), B-lymphocyte antigen CD-19, and programmed death 1/ligand 1 (or PD-1/PD-L1) in the fields of hematology-oncology, including in the specific diseases for which we are currently developing duvelisib, or for which we may develop duvelisib or other PI3K inhibitors in the future. Such companies include:

- Pharmacyclics, Inc., through its collaboration with Janssen Biotech, which has received approval from the 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;
- AbbVie, which we believe is conducting a Phase 3 and multiple Phase 1 and Phase 2 clinical trials of ABT-199, a BCL-2 inhibitor, in hematologic malignancies;
- Celgene Corporation, which has received FDA approval of lenalidomide, an immunomodulator, for the treatment of people with multiple myeloma, MCL, and myelodyplastic syndromes, and is conducting late stage clinical studies of lenalidomide in additional hematologic malignancies; we also believe that Celgene is conducting a Phase 1 clinical trial of CC-292, a BTK inhibitor, in patients with CLL;
- Gilead Sciences, Inc./Ono Pharmaceutical Group, which we believe is conducting Phase 1 clinical trials of ONO-4059, a BTK inhibitor, in patients with NHL and CLL;

Acerta Pharma BV, which we believe is conducting a Phase 1 clinical trial of ACP-196 in patients with CLL;

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

Novartis AG, which we believe is conducting a Phase 1/2 trial of CTL-019, which targets CD-19, in a trial that includes iNHL and CLL and ALL patients;

MorphoSys, which we believe is conducting Phase 2 clinical trials of MOR208, a B-lymphocyte antigen CD-19 inhibitor, in patients with NHL, CLL, and ALL; and

Bristol-Myers Squibb Company, Roche Group and its subsidiary Genentech, and AstraZeneca PLC, each of which we believe is conducting Phase 1 clinical trials of anti-PD-1 or anti-PD-L1 antibodies, in patients with hematologic malignancies.

Table of Contents

Research and Development

As of February 1, 2015, our research and development group consisted of 162 employees, of whom 30% hold Ph.D. or M.D. degrees and an additional 27% 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, 2014, 2013 and 2012 was approximately $143.6 million, $99.8 million and $118.6 million, respectively. Reimbursement for our strategic collaborator-sponsored research and development expenses under our previous alliance with Mundipharma and Purdue for the year ended December 31, 2012 totaled approximately $45.0 million. 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. Under the AbbVie agreement, we will transition the responsibility to manufacture Duvelisib Products to AbbVie as promptly as is practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we are responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million, after which we will share Duvelisib Product development and manufacturing costs equally with AbbVie. The development and manufacturing costs of the AbbVie Studies will be shared equally. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States. 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. In order to commercialize any drugs if and when they are approved for sale, we will need to, and beginning in 2015 we intend to, develop the necessary marketing, sales and distribution capabilities. Under the AbbVie agreement, we and AbbVie share operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States, while AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products outside of the United States.

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. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. 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.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a

Table of Contents

variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which allows human clinical trials to begin unless the FDA objects within 30 days;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application, or NDA;
- satisfactory review of the NDA by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product s identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post-approval studies required by the FDA.

Preclinical testing. Preclinical tests may 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 FDCA 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. Following commencement of a clinical trial under an IND, the FDA may place a clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical

Table of Contents

hold is a delay or suspension of only part of the clinical work requested under the IND. During clinical studies the FDA requires the submission of serious adverse event reports and other periodic reports. The IND application process may be extremely costly and substantially delay development of product candidates.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

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 and, if possible, to gain an early indication of its effectiveness. These studies may be conducted in healthy volunteers or patients with the disease being studied.

Phase 2: The product candidate is administered to 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: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

These are commonly referred to as pivotal studies. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites in late-stage clinical trials to assure compliance with GCP and the integrity of the clinical data submitted.

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.

Specifically, upon submission of an NDA, the FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA s receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for priority review products are meant to be

Table of Contents

reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. . 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 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 s Decision on an NDA

On the basis of the FDA s evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product s NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA s time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as breakthrough therapies. A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and

Table of Contents

preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case- by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA s goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor s agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug s clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Table of Contents

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United

17

Table of Contents

States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product will be entitled to orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

FDA Regulation of Companion Diagnostics

If safe and effective use of a therapeutic product depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of the diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. The FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic simultaneously with approval of the drug.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee, which exceeds $250,000 for most PMAs. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer s facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA s evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant s agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer s manufacturing processes and those of its suppliers are required to comply with the applicable

Table of Contents

portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

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 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.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the

Table of Contents

federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and

analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

As a result, the marketability of any product which receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has increased and will continue to increase the

Table of Contents

pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Regulatory Matters

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, 2015, we had 195 full-time employees, 162 of whom were engaged in research and development and 33 of whom were engaged in general business management, administration and finance. Approximately 56% 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.

Executive Officers

The following table lists the positions, names and ages of our executive officers as of February 1, 2015:

Name	Age	Position
Adelene Q. Perkins	55	President and Chief Executive Officer
Julian Adams, Ph.D.	60	President of Research & Development
Lawrence E. Bloch, M.D., J.D.	49	Executive Vice President, Chief Financial Officer and Chief Business Officer
Vito J. Palombella, Ph.D.	52	Executive Vice President, Chief Scientific Officer
David A. Roth, M.D.	52	Executive Vice President, 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.

Table of Contents

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 bortezomib, also known as 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 Executive Vice President, 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, 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 Executive Vice President and Chief Scientific Officer since May 2010. He is responsible for our drug discovery and preclinical development activities. Prior to his role as Chief Scientific Officer, Dr. Palombella was Vice President, Drug Discovery from September 2006 to May 2010 and Vice President, Biology of IPI from January 2004 to September 2006. Prior to joining Infinity, Dr. Palombella was Director of Molecular Biology and Protein Chemistry at Syntonix Pharmaceuticals where he was responsible for improving and expanding its core Fc receptor-mediated drug delivery technology. Before joining Syntonix, Dr. Palombella was Senior Director of Cell and Molecular Biology at Millennium Pharmaceuticals, which he joined through its acquisition of LeukoSite, at which he held the same title, in 1999. Prior to its acquisition by LeukoSite, Dr. Palombella held a number of positions at ProScript, Inc. between 1994 and 1999. While at ProScript, LeukoSite and Millennium, Dr. Palombella was involved in the discovery and development of bortezomib, also known as Velcade®, 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 Executive Vice President and 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 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

Table of Contents

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.

Table of Contents

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, 2014, we had an accumulated deficit of $467 million. We expect to continue to spend significant resources to fund the research and development of duvelisib 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. In addition, in connection with seeking and possibly obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. 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 additional funds to support our planned operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectation, if we acquire a third party, or if we acquire or license rights to additional product candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including without limitation if:

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

Table of Contents

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;

the cost or quantity required of comparator drugs used in clinical studies increases;

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.

We may seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, or at all. In addition, the terms of such financings may result in, among other things, dilution for stockholders or the incurrence of indebtedness that may impact our ability to make capital expenditures or incur additional debt. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us to relinquish or encumber rights to some of our technologies or product candidates, and we may not be 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 our strategic alliance with AbbVie, or any future alliance we may enter into, is unsuccessful, our operations may be negatively impacted.

We have a strategic collaboration with AbbVie Inc., or AbbVie, to research, develop and jointly commercialize products containing or comprised of duvelisib, which we refer to as Duvelisib Products, in oncology indications. We refer to this agreement as the AbbVie Agreement. Pursuant to the AbbVie Agreement, AbbVie has committed to providing substantial funding, as well as significant capabilities in development, marketing and sales. However, we may not be able to maintain our alliance with AbbVie or any other future alliance partner if, for example, development or approval of duvelisib or other product candidates is delayed or sales of Duvelisib Products or other products are disappointing. Further, AbbVie may be the only alliance we are able to successfully execute, making us overly dependent on the success of duvelisib in oncology indications and therefore particularly vulnerable if duvelisib or the alliance with AbbVie fails, as discussed in the next risk factor.

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.

The success of a strategic alliance, whether with AbbVie or any future partner, is largely dependent on the resources, efforts, technology and skills brought to such alliance by such partner. The benefits of such alliances will be reduced or eliminated if any such partner does not devote sufficient time and resources to its alliance arrangements with us, without which we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if such partner were to breach or terminate its arrangements with us or fail to maintain the financial resources necessary to continue financing its portion of development, manufacturing, and commercialization costs, as applicable, we may not have the financial resources or capabilities necessary to continue development and commercialization of the product candidate on our own. Consequently, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated, and we may find it difficult to attract a new alliance partner for such product

25

Table of Contents

candidate. Disputes and difficulties in these types of relationships are common, often due to priorities changing over time, conflicting priorities or conflicting interests. Merger and acquisition activity may exacerbate these conflicts.

As is the case with our strategic collaboration with AbbVie, much of the potential revenue from alliances consists of payments contingent upon the achievement of specified milestones and 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, 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. Under the AbbVie Agreement, for instance, we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. AbbVie or any future alliance partner may fail to develop or effectively commercialize duvelisib or future drug products if 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 AbbVie or 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.

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.

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,

Table of Contents

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; Pfizer, Inc.; and Johnson & Johnson. 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.

We are also aware of a number of companies developing product candidates or selling products directed to the same biological targets that our own product candidates are designed to inhibit. Specifically:

- we believe that Gilead Sciences, Inc., or Gilead; Bayer AG; Acerta Pharma BV; Rhizen Pharmaceuticals S.A.; and TG Therapeutics, Inc.; 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 duvelisib; and

- many companies are developing product candidates or selling products directed to disease targets such as Bruton s Tyrosine Kinase (or BTK), B-cell lymphoma 2 (or BCL-2), Janus Kinase (or JAK), Spleen Tyrosine Kinase (or Syk), B-lymphocyte antigen CD-19, and programmed death 1/ligand 1 (or PD-1/PD-L1) in the fields of hematology-oncology, including in the specific diseases for which we are currently developing duvelisib, or for which we may develop duvelisib or other PI3K inhibitors in the future, including: Pharmacyclics, Inc. through its collaboration with Janssen Biotech; AbbVie, Inc.; Celgene Corporation; Gilead Sciences, Inc./Ono Pharmaceutical Group; Acerta Pharma BV; Incyte Corporation; MorphoSys; Roche Group and its subsidiary Genentech; Bristol-Myers Squibb Company; Novartis AG; and AstraZeneca PLC.

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

- product candidates that have been approved by the FDA, 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 CLL), and idelalisib, a compound targeting the delta isoform of PI3K, being developed and commercialized by Gilead Sciences, Inc. for the treatment of people with CLL, 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 organizational changes and growth, depends upon the continual improvement of our processes and procedures and the preservation of our corporate culture. Under the AbbVie Agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for the Duvelisib Products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock. Any future alliance may also require implementation of a similarly

27

Table of Contents

complex governing structure. We may not be able to implement improvements in an efficient or timely manner or to 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 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, 2014, we had approximately $333 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.

Table of Contents

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 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 require us to restate prior period revenue.

If we are not able to maintain effective internal control 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 control 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 control in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

Risks Related to the Development and Commercialization of Our 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 U.S. 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 duvelisib, the lead compound in our PI3K inhibitor program, in all phases of clinical development, and we anticipate initiating multiple additional trials of duvelisib in 2015. 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.

Table of Contents

We may not receive expedited or priority review, or accelerated approval, for any of our product candidates, and receipt of expedited or priority review may not lead to a faster development or regulatory review or approval process.

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. For example, the DYNAMO study is designed with the potential to support accelerated approval of duvelisib for treatment of patients with follicular lymphoma, assuming we are able to generate positive safety and efficacy data from the study and on the condition that we conduct a confirmatory study. The availability of accelerated approval is dependent on a number of factors including whether duvelisib has demonstrated a meaningful benefit over available therapies. We cannot guarantee that duvelisib will qualify for accelerated approval. In particular, we are aware that Gilead has received accelerated approval for idelalisib, its product candidate to treat follicular lymphoma. If Gilead is able to complete its confirmatory study and receive full approval to market idelalisib for the treatment of follicular lymphoma faster than anticipated, our efforts to seek accelerated approval for duvelisib for the treatment of follicular lymphoma may be materially adversely affected. Moreover, even if we are able to receive accelerated approval for duvelisib the FDA may upon review of data from DYNAMO+R later decide that duvelisib no longer meets the conditions for approval resulting in revocation of approval.

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;
- 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.

Table of Contents

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 duvelisib in a Phase 3 clinical trial, and Gilead has received accelerated approval to manufacture and market idelalisib for the treatment of follicular lymphoma, an indication for which we are currently evaluating duvelisib in our DYNAMO and DYNAMO+R Studies.

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.

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. For example, we have designed our DYNAMO study with the potential to support accelerated approval of duvelisib for the treatment of follicular lymphoma, an indication for which Gilead has

Table of Contents

received accelerated approval to manufacture and market idelalisib. If we experience delays in the conduct of our DYNAMO study, or Gilead is able to complete its confirmatory study and receive full approval to market idelalisib for the treatment of follicular lymphoma faster than anticipated, our efforts to seek accelerated approval for duvelisib for the treatment of follicular lymphoma may be materially adversely affected.

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 noncompliance were to occur, our efforts to obtain regulatory approval for and to commercialize our product candidates may be delayed.

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

Our product candidates require precise, high quality manufacturing. The third-party manufacturers on which we rely may not be able to comply with the FDA s current good manufacturing practices, or cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of our product

Table of Contents

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 may not be able to successfully transition responsibilities for the manufacturing of Duvelisib Products to AbbVie.

We may be unsuccessful in transferring the responsibility to manufacture Duvelisib Products to AbbVie. The transition process may be more complicated, time consuming and expensive than originally intended, which may negatively affect the supply of Duvelisib Products. Should the strategic collaboration with AbbVie terminate, the process of transitioning manufacturing back to us may be time consuming and expensive, and we may become unable to maintain an adequate supply of Duvelisib Products worldwide.

We currently have limited marketing, sales and distribution experience and capabilities and are dependent upon AbbVie to commercialize Duvelisib Products outside the United States.

We and AbbVie share the obligations to commercialize Duvelisib Products in oncology in the United States, and AbbVie has the sole obligation to commercialize Duvelisib Products in oncology outside the United States. To successfully commercialize Duvelisib Products, we will need to, and we intend to, establish adequate marketing, sales and distribution capabilities for commercialization in the United States. Failure to establish these capabilities, whether due to insufficient resources or some other cause, will limit or potentially halt our ability to successfully commercialize any product candidates, thereby adversely affecting 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.

Table of Contents

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, managed care organizations, third-party payors, 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

Table of Contents

risks and side effects may become more prevalent and/or clinically significant. In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers manufacturing facilities. We also might have to withdraw or recall our products from the marketplace. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in our 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 United States 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 twelve 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 United States government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act. These healthcare reform laws have the effect of increasing the number of individuals who receive health insurance coverage and closing 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

Table of Contents

law, however, also implements cost containment measures that could adversely affect our future revenue. These measures include increased drug rebates under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care. The legislation also extends certain discounted pricing on outpatient drugs to children s hospitals, critical access hospitals and rural health centers. This expansion reduces the amount of reimbursement received for drugs purchased by these newly covered entities.

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

As the market adjusts to the healthcare reform laws, 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 anti-kickback provisions of the Social Security Act, which prohibit, 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

Table of Contents

insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

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

Risks Related to Our Field

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.

Table of Contents

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 may be 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 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

Table of Contents

being conducted in the United States. If we encounter difficulties in protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

In addition, we rely on intellectual property assignment agreements with our strategic alliance partners, vendors, employees, consultants, 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 or derivation proceedings declared by the PTO or the third party to determine priority of invention in the United States. An adverse decision in an interference or derivation 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

Table of Contents

authorization. We could incur substantial costs and diversion of management and technical personnel in defending against any claims that the manufacture and sale of our potential products or use of our technologies infringes any patents, or defending against any claim that we are employing any proprietary technology without authorization. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop developing, manufacturing and/or commercializing the infringing product candidates or approved products;
- develop non-infringing product candidates, technologies and methods; and
- obtain one or more licenses from other parties, which could result in our paying substantial royalties or the granting of cross-licenses to our technologies.

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

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

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

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

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.

Table of Contents

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

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

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 collaboration and license agreement with AbbVie or our amended and restated development and license agreement with Takeda;
- 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;
- the regulatory approval of 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;

healthcare reform measures, including 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.

Table of Contents

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

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

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

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

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our organizational documents may make a change in control more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. For example, our charter authorizes our board of directors to issue up to 1,000,000 shares of undesignated preferred stock 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 bylaws 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% 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% 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% 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, 2014, stockholders holding 5% or more of our common stock, as well as our executive officers, directors, and their respective affiliates, owned in the aggregate approximately 55% 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;

Table of Contents

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease, under two lease agreements, an aggregate of approximately 116,000 square feet of laboratory and office space among three buildings located at 780, 784 and 790 Memorial Drive in Cambridge, Massachusetts. On September 25, 2014, we entered into a new lease covering 61,000 feet of office space located at 784 Memorial Drive. Due to our involvement in the renovation of the building, we are deemed for accounting purposes the owner of the building during the construction period (see note 11 of the consolidated financial statements). On November 6, 2014, we entered into a lease extension covering 54,861 square feet of laboratory and office space at 780 and 790 Memorial Drive. Each lease expires on March 31, 2025, and each contains two separate five-year options to extend its term to 2035.

Item 3. Legal Proceedings

We are not a party to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

Table of Contents

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

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

	2014		2013	
	High	Low	High	Low
First quarter	$ 16.70	$ 11.30	$ 50.51	$ 32.13
Second quarter	13.25	8.40	50.40	16.07
Third quarter	16.93	8.80	23.68	15.45
Fourth quarter	18.25	11.90	18.35	11.57

Holders

As of February 1, 2015, there were 52 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, 2009 through December 31, 2014 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, 2009, and that all dividends were reinvested. No cash dividends have been declared or paid on our common stock.

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

Table of Contents

Comparison of 5-Year Cumulative Total Return

among Infinity Pharmaceuticals, Inc.,

the NASDAQ Biotechnology Index,

and NASDAQ Stock Market (U.S.) Index

Table of Contents

Item 6. Selected Financial Data

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

	Year Ended December 31,				
	2014	2013	2012	2011	2010
Statement of Operations Data:					
Collaboration revenue	$ 164,995	$	$ 47,114	$ 92,773	$ 71,331
Operating expenses:					
Research and development	143,633	99,760	118,595	108,582	99,232
General and administrative	29,285	27,916	27,882	22,719	21,070
Total operating expenses	172,918	127,676	146,477	131,301	120,302
Gain on termination of Purdue entities alliance			46,555		
Loss from operations	(7,923)	(127,676)	(52,808)	(38,528)	(48,971)
Interest income (expense), net	(9,310)	896	(1,349)	(1,514)	(1,447)
Income from Therapeutic Discovery Grants					734
Income from Massachusetts tax incentive award			193		
Loss before income taxes	(17,233)	(126,780)	(53,964)	(40,042)	(49,684)
Income tax	(183)				700
Net loss	$ (17,416)	$ (126,780)	$ (53,964)	$ (40,042)	$ (48,984)
Basic and diluted loss per common share	$ (0.36)	$ (2.64)	$ (1.70)	$ (1.50)	$ (1.86)
Basic and diluted weighted average number of common shares outstanding	48,561,653	47,936,001	31,711,264	26,620,278	26,321,398

	As of December 31,				
	2014	2013	2012	2011	2010
Selected Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities, including long-term	$ 333,245	$ 214,468	$ 326,635	$ 115,937	$ 100,959
Working capital	289,691	202,735	311,086	88,995	75,378
Total assets	369,144	230,710	335,660	124,490	124,566
Long-term debt due to Purdue entities, net of debt discount(1)				37,553	
Due to Takeda, less current portion(2)		6,456	6,252		
Construction liability(3)	15,456				
Accumulated deficit	(467,212)	(449,796)	(323,016)	(269,052)	(229,010)
Total stockholders equity	209,472	201,275	310,205	15,433	49,484

(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 12 of the consolidated 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 Takeda Pharmaceuticals Company Limited, or Takeda. We paid $1.7

Table of Contents

million and $6.7 million of this $15 million release payment during the years ended December 31, 2012 and December 31, 2014, respectively, and recorded the remaining balance as a liability. As of December 31, 2014, we have a balance of $6.7 million in Due to Takeda, current.

(3) In September 2014, we entered into a lease agreement with BHX, LLC, as trustee of 784 Realty Trust, for the lease of office space at 784 Memorial Drive, Cambridge, Massachusetts. See note 11 of the consolidated financial statements. Upon lease commencement, building construction was initiated and we are involved in the construction project. We are deemed for accounting purposes to be the owner of the building during the construction period. As of December 31, 2014, we recorded building and accumulated construction costs of approximately $16.0 million and a construction liability of approximately $15.5 million. See note 11 of the consolidated financial statements.

Table of Contents

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

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

Business Overview

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. Our most advanced product candidate is duvelisib, also known as IPI-145, an oral inhibitor of the delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which is currently being evaluated in hematologic malignancies. Our dedicated discovery research program continues to work toward the goal of generating new product candidates.

Research and Development Programs

PI3 Kinase Inhibitor Program

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. Our lead product candidate, duvelisib, is an oral dual inhibitor of PI3K-delta and PI3K-gamma, which we believe is the only inhibitor of PI3K-delta and gamma being investigated in Phase 3 clinical trials.

We are conducting DUETTS (**Du**v**e**lisib **T**rials in Hema**t**ologic Malignancie**s**), a worldwide investigation of duvelisib 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 duvelisib dosed at 25 mg twice daily, or BID, in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL, including follicular lymphoma, marginal zone lymphoma and small lymphocytic lymphoma, or 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 DYNAMO study is designed with the potential to support accelerated approval of duvelisib in patients with follicular lymphoma, the most common subtype of iNHL assuming we are able to generate positive safety and efficacy data from the study and on the condition that we conduct a confirmatory study. Additionally, the U.S. Food and Drug Administration, or the FDA, has granted orphan drug designation to duvelisib for the potential treatment of follicular lymphoma. We expect to complete patient enrollment in DYNAMO in the first half and report topline data in the second half of 2015. The availability of accelerated approval is dependent on a number of factors including whether duvelisib has demonstrated a meaningful benefit over available therapies. For a further discussion of the FDA s accelerated approval pathway, and certain risks related to our ability to seek accelerated approval for duvelisib, see Government Regulation Review and Approval of Drugs in the United States and Risk Factors Risks Related to the Development and Commercialization of Our Product Candidates elsewhere in this report.

We are expanding the DUETTS program in lymphoma with the initiation of two new trials. The first, DYNAMO+R, is a Phase 3 randomized, placebo-controlled study evaluating duvelisib dosed at 25 mg BID in

Table of Contents

combination with rituximab compared to placebo plus rituximab in approximately 400 patients with previously treated follicular lymphoma and is designed to serve as our confirmatory study in the event we are able to receive accelerated approval of duvelisib for the treatment of patients with follicular lymphoma based on the results of our DYNAMO study. The second is a Phase 1b/2 clinical study of duvelisib in combination with obinutuzumab or rituximab, monoclonal antibody treatments, in patients with previously untreated follicular lymphoma.

Also part of the DUETTS program, we are enrolling patients in DUO™, a Phase 3 study of duvelisib in patients with chronic lymphocytic leukemia, or CLL. This randomized study is designed to evaluate the safety and efficacy of duvelisib dosed at 25 mg BID compared to ofatumumab, a monoclonal antibody therapy, 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 duvelisib for the potential treatment of CLL and SLL. We expect to complete enrollment of DUO in the second half of 2015. We are further expanding the DUETTS program in CLL with the initiation of a Phase 1b trial of duvelisib in combination with obinutuzumab in CLL patients whose disease has progressed following treatment with a Bruton s tyrosine kinase, or BTK, inhibitor.

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 duvelisib 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. Data from this study, presented in December 2014 at the Annual Meeting of the American Society for Hematology, or ASH, and in January 2015 at the 7th Annual T-Cell Lymphoma Forum, showed that duvelisib is clinically active in CLL, iNHL, and T-cell lymphoma, as well as other hematologic malignancies.

We are pursuing duvelisib in oncology in collaboration with AbbVie Inc., or AbbVie. For information regarding our collaboration, please see below under the heading *AbbVie* in the section entitled Strategic Alliances .

In 2014, we completed two Phase 2 studies of duvelisib in inflammation and concluded our investigation of duvelisib in this therapeutic area. We reported topline data in October 2014 from the first study, a randomized, double-blind, placebo-controlled crossover study of patients with mild, allergic asthma, which showed that the study primary endpoint was not met at any of the doses tested. However, clinical improvement in the late-phase response was observed at the 25 mg BID dose ($p = 0.052$) and multiple pre-specified secondary efficacy endpoints were positive at the 25 mg BID dose. Additionally, the 5 mg BID and 25 mg BID doses of duvelisib significantly decreased serum levels of key mediators of airway inflammation. We reported topline data in January 2015 from the second study, a Phase 2, double-blind, randomized, placebo-controlled study designed to evaluate the efficacy, safety and pharmacokinetics of duvelisib in adults with active moderate-to-severe rheumatoid arthritis, which demonstrated that the primary efficacy endpoint of the study was not met at any of the doses tested. Based on the results from these studies, we will not proceed with further clinical development of duvelisib or IPI-443, our second oral inhibitor of PI3K-delta and gamma, in inflammatory diseases, and we expect that any further development of IPI-443 in inflammatory diseases would be conducted through out-licensing or partnering efforts.

Other Programs

In August 2014, we licensed rights to our fatty acid amide hydrolase, or FAAH program, to FAAH Pharma Inc., or FAAH Pharma, a company pursuing the clinical development of IPI-940 to investigate its potential to treat neuropathic pain. We received a 23% ownership in FAAH Pharma in exchange for the license. FAAH Pharma receives funding from TVM Life Science Ventures VII, L.P., or TVM, under potential milestone payments.

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

Table of Contents

programs, all intended to help us realize the full potential of our product pipeline. To date, all of our revenue has been generated under research collaboration agreements, and all our revenue during 2014 was derived from our strategic alliance with AbbVie, which is discussed in detail below.

AbbVie

On September 2, 2014, we entered into a collaboration and license agreement with AbbVie, which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we will collaborate with AbbVie to develop and commercialize products containing duvelisib, which we refer to as Duvelisib Products, in oncology indications. Under the terms of the AbbVie Agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture Duvelisib Products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. We and AbbVie retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie Agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

Under the AbbVie Agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for Duvelisib Products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock.

We and AbbVie share oversight of development and have each agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We have primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and AbbVie has responsibility for the conduct of certain contemplated combination clinical studies, which we refer to as the AbbVie Studies. We have the responsibility to manufacture Duvelisib Products until we transition manufacturing responsibility to AbbVie, which we expect to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we are responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million after which we will share Duvelisib Product development and manufacturing costs equally with AbbVie. The development and manufacturing costs of the AbbVie Studies will be shared equally.

We and AbbVie share operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Specifically, we have the primary responsibility for advertising, distribution, and booking sales, and we share certain other commercialization functions with AbbVie. Assuming regulatory approval, we and AbbVie are obligated to each provide half of the sales representative effort to promote Duvelisib Products in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States, and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States.

AbbVie has paid us a non-refundable $275 million upfront payment and has agreed to pay us up to $530 million in potential future milestone payments comprised of $130 million associated with the completion of enrollment of either DYNAMO or DUO, which we expect to occur in 2015, up to $275 million associated with the achievement of specified regulatory filing and approval milestones, and up to $125 million associated with the achievement of specified commercialization milestones. Under the terms of the AbbVie Agreement, we and AbbVie will equally share commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for sales of Duvelisib Products in the United States, as well as sharing equally the existing U.S. milestone payment obligations to Takeda Pharmaceutical Company Limited, or Takeda. Additionally, AbbVie has agreed to pay us tiered royalties on net sales of Duvelisib Products outside the United States ranging from 23.5% to 30.5%, depending on annual net sales of Duvelisib Products by AbbVie, its affiliates and its sublicensees. We are responsible for the existing royalty

Table of Contents

obligations to Mundipharma and Purdue outside the United States and to Takeda worldwide, and AbbVie has agreed to reimburse us for our existing Duvelisib Product milestone payment obligations to Takeda outside the United States. The tiered royalty from AbbVie is subject to a reduction of 4% at each tier if our royalties to Mundipharma and Purdue are reduced according to the terms of our agreements with Mundipharma and Purdue. This tiered royalty can further be reduced based on specified factors, including patent expiry, generic entry, and royalties paid to third parties with blocking intellectual property. These royalties are payable on a product-by-product and country-by-country basis until AbbVie ceases selling the product in the country.

Subject to limited exceptions, we have agreed that we and our affiliates will not commercialize, or assist others in commercializing, in oncology indications any product that is a PI3K delta, gamma inhibitor that meets certain agreed-to criteria, other than Duvelisib Products, and AbbVie has agreed to similar restrictions. Registration-directed clinical trials and commercialization of Duvelisib Products for uses outside of oncology indications would require our and AbbVie s mutual consent.

The AbbVie Agreement will remain in effect until all development, manufacturing and commercialization of Duvelisib Products cease, unless terminated earlier. Either we or AbbVie may terminate the AbbVie Agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the AbbVie Agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances. However, we may terminate the AbbVie Agreement only on a country by country basis in the event AbbVie is not using diligent efforts to obtain regulatory approval or to commercialize Duvelisib Products in a country outside the United States. AbbVie may also terminate the AbbVie Agreement for convenience after a specified notice period. In the event there is a material uncured breach by either us or AbbVie of development or commercialization obligations, the non-breaching party may also have the right to assume and conduct such applicable development or commercialization obligations. If AbbVie or any of its affiliates or sublicensees challenges the patents we have licensed to AbbVie, we can terminate the AbbVie Agreement if the challenge is not withdrawn after a specified notice period.

If the AbbVie Agreement is terminated, we would receive all rights to the regulatory filings related to duvelisib upon our request, our license to AbbVie would terminate, and AbbVie would grant us a perpetual, irrevocable license to develop, manufacture and commercialize products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates. This license would be royalty free, unless the AbbVie Agreement is terminated for material breach, in which case, depending on the breaching party and the timing of the material breach, a royalty rate may be payable by us ranging from a low single-digit percentage to a low double-digit percentage of net sales, and, in some cases, subject to a payment cap.

If the AbbVie Agreement is terminated, there are certain wind-down obligations to ensure a smooth transition of the responsibilities of the parties.

Takeda

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 duvelisib, and we paid Intellikine a $13.5 million upfront license fee. In January 2012, Intellikine was acquired by Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Takeda. In December 2012, we amended and restated our development and license agreement with Takeda.

Under the terms of the amended and restated agreement, we retained worldwide development rights and in exchange for an agreement to pay Takeda $15 million in installments, we regained commercialization rights for products arising from the agreement for all therapeutic indications and are solely responsible for research conducted under the agreement.

In addition to developing duvelisib, we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. We are obligated to pay to Takeda up to $5 million in remaining success-based milestone payments for the development of a second product candidate and up to $450 million in

Table of Contents

success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Takeda a $10 million milestone payment in connection with the initiation of our Phase 3 study of duvelisib in patients with relapsed or refractory CLL. In addition, we are obligated to pay Takeda tiered royalties on worldwide net sales ranging from 7% to 11% 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 of the royalties, and, in certain circumstances, limits on the number of products subject to a royalty obligation.

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. Takeda 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 Takeda, demonstrate to Takeda s reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Takeda 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.

On July 29, 2014, we entered into an amendment to our amended and restated development and license agreement with Takeda. Under the terms of the Amendment, we paid to Takeda a one-time upfront payment of $5 million in exchange for the option to terminate our royalty obligations to Takeda under the amended and restated development and license agreement solely with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib. The option may be exercised by payment to Takeda of a fee of $52.5 million on or before March 31, 2015. If the option is not exercised, our royalty obligations to Takeda will remain unchanged.

Mundipharma and Purdue

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and we entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 Termination Agreements. The strategic 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 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.

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 resulting in the return to us of 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 strategic alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each strategic alliance program other than FAAH. We did not record a liability for amounts previously funded by Purdue and Mundipharma as this relationship was not considered a financing arrangement.

Table of Contents

We are obligated to pay Mundipharma and Purdue a 4% 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 1% 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 that were subject to the alliance, which products require significant further development. As such, there is significant uncertainty about whether any such products will ever be approved or commercialized. If no products are commercialized, no payments will be due by us to Mundipharma and Purdue; therefore, no amounts have been accrued.

Royalties are payable under these agreements until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the royalty rates is reduced by 50%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third-party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

Deerfield

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which, Deerfield agreed to loan us up to $100 million, subject to the terms and conditions set forth in the facility agreement. On September 22, 2014, we amended the facility agreement with Deerfield such that the maximum principal amount that we may draw down is reduced to $50 million. We refer to the facility agreement with Deerfield, as amended, as the Facility Agreement. Under the terms of the Facility Agreement, we had the right to draw down on the Facility Agreement in $25 million minimum disbursements, which we refer to as the Loan Commitment, at any time during a pre-specified draw period. The draw period has expired without us having drawn down on the Facility Agreement. On February 27, 2015, or upon the earlier termination of the facility, we are required to pay a fee equal to $1.5 million representing 3% of the total amount not drawn under the facility. 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. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock. The warrants expire on the seventh anniversary of their issuance and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it exceeding 9.985% of the total number of shares of common stock then issued and outstanding.

Financial Overview

Revenue

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, upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. 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.

Table of Contents

Research and Development Expense

We are a drug discovery and development company. Our research and development expense to date has primarily consisted of the following:

- compensation of personnel associated with research and development activities;
- clinical testing costs, including payments made to contract research organizations;
- costs of comparator drugs used in clinical studies;
- 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;
- 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

Investment and other income typically consists of interest earned on cash, cash equivalents and available-for-sale securities, net of interest expense, amortization of warrants and other revenue and loss. Interest expense is related to the amortization of the loan commitment asset

recognized under our Facility Agreement with Deerfield. 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.

Table of Contents

Revenue Recognition

To date, all of our revenue has been generated under research collaboration agreements, and all our revenue during 2014 was derived from our strategic alliance with AbbVie. The terms of these research collaboration agreements may include payment to us of non-refundable, upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using the proportional performance method. The proportional performance method is used when the level of effort to complete the performance obligations under an arrangement can be reasonably estimated. We recognize revenue based upon our best estimate of the selling price for each element when there is no other means to determine the fair value of that item and allocate the consideration based on the relative values. The process for determining the best estimate of the selling price involves significant judgment and estimates.

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.

In making this assessment, 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. 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.

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

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.

Table of Contents

Stock-Based Compensation

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

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2014, 2013 and 2012, in thousands, together with the change in each item as a percentage.

	2014	% Change	2013	% Change	2012
Collaboration revenue	$ 164,995		$	(100)%	$ 47,114
Research and development expense	(143,633)	44%	(99,760)	(16)%	(118,595)
General and administrative expense	(29,285)	5%	(27,916)	0%	(27,882)
Gain on termination of Purdue entities alliance				(100)%	46,555
Interest expense	(9,649)			(100)%	(1,908)
Interest and investment income	339	(62)%	896	60%	559
Income from Massachusetts incentive tax award				(100)%	193
Income taxes	(183)				

Revenue

Our revenue during the year ended December 31, 2014 consisted of approximately:

- $159.1 million related to license revenue recognized as part of the $275 million upfront payment received from our collaboration agreement with AbbVie; and
- $5.9 million of revenue related to development and committee services we performed under our collaboration agreement with AbbVie.

We recognized license revenue upon execution of the arrangement. Revenue related to development services and committee services are being recognized using the proportionate performance method as services are provided over the estimated service period of approximately five years. We have recorded the remaining amount of $110 million related to development and committee services as deferred revenue as of December 31, 2014.

The development, regulatory and commercialization milestones represent non-fundable amounts that would be paid by AbbVie to us if certain milestones are achieved in the future. We have elected to apply the milestones method of revenue recognition to these milestones. We have determined that all milestones, except for the first milestone, if achieved, are substantive as they relate solely to past performance, are commensurate with estimated enhancement of value associated with the achievement of each milestone as a result of our performance, which are reasonable relative to other deliverables and terms of the arrangement, and are unrelated to the delivery of any further elements under the arrangement. The first milestone, which we have determined not to be substantive based on risk and effort involved, will be recognized using the same method as the upfront payment when achieved.

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

Table of Contents

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.

We expect to recognize revenue related to license and development and committee services we perform under our collaboration agreement with AbbVie in 2015.

Research and Development Expense

Research and development expenses represented approximately 83% of our total operating expenses for the year ended December 31, 2014, 78% of our total operating expenses for the year ended December 31, 2013, and 81% of our total operating expenses for the year ended December 31, 2012.

The increase in research and development expense for the year ended December 31, 2014 compared to the year ended December 31, 2013 was primarily attributable to:

- $28.0 million increase in clinical development expenses related to duvelisib;
- $10.0 million milestone payment for the initiation of DUO, our first phase 3 study with a PI3K inhibitor, and $5.0 million option fee payment to Takeda in connection with the 2014 Takeda Amendment; and
- $9.2 million increase in compensation expense primarily due to an increase in contingent cash compensation and hiring of new personnel.

These increases were partially offset by a decrease of $5.8 million in clinical development expenses due to the conclusion of our development of our Hsp90 inhibitor program.

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 our Hedgehog pathway inhibitor program, as well as conclusion of our development of our Hsp90 inhibitor program;
- $14.4 million incurred in 2012 associated with the fair value of installment payments related to the amended and restated agreement with Takeda; and
- $5 million associated with the achievement of a milestone for the initiation of a Phase 2a clinical trial of duvelisib 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 duvelisib.

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, 2014. 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

Table of Contents

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, 2014	Year Ended December 31, 2013	Year Ended December 31, 2012	January 1, 2006 to December 31, 2014
			(in millions)	
PI3K Inhibitor(1)	$ 120.8	$ 71.7	$ 48.8	$ 282.8
Hsp90 inhibitor	1.6	12.1	21.3	137.7
Hedgehog pathway inhibitor	0.1	1.2	34.0	164.1

(1) Includes an upfront license fee of $13.5 million in 2010, $4 million in development milestones in 2011, $14.4 million recorded as fair value for the release payment for the amended and restated Takeda agreement and $6 million in development milestones in 2012, as well as a $10 million development milestone payment and a $5 million option fee payment in 2014.

We expect expenses related to our PI3K programs to increase as we continue clinical development of duvelisib. We expect to incur minimal expenses related to our Hsp90 program and Hedgehog pathway inhibitor program 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 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 and availability of comparator drugs;

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;

Table of Contents

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

- the effect of competing technological and market developments.

General and Administrative Expense

The increase in general and administrative expense for the year ended December 31, 2014 as compared to the year ended December 31, 2013 was primarily attributable to an increase of $1.5 million in compensation expense, primarily due to an increase in contingent cash compensation.

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

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

The increase in interest expense for the year ended December 31, 2014 as compared to the year ended December 31, 2013 was primarily attributable to the amortization of the loan commitment asset recognized under our Facility Agreement with Deerfield. In addition, in connection with the amendment of the Deerfield facility agreement on September 22, 2014, we reduced the loan commitment asset by 50% resulting in an additional expense of $1.8 million during 2014.

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

Interest and Investment Income

Interest and investment income decreased in the year ended December 31, 2014 as compared to the year ended December 31, 2013 primarily as a result of lower yields. In addition, during the year December 31, 2013, we received a non-recurring cash distribution received from one of our insurance carriers. 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.

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.

Income Taxes

Our income tax expense of approximately $0.2 million for the year ended December 31, 2014 is primarily related to alternative minimum tax which is driven by an upfront payment received in connection with the collaboration agreement with AbbVie we entered into during the year ended December 31, 2014. We do not expect to incur income tax expense in 2015.

Table of Contents

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, 2014, 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, 2014	December 31, 2013
	(in thousands)	
Cash, cash equivalents and available-for-sale securities	$ 333,245	$ 214,468
Working capital	289,691	202,735

	Year Ended December 31,		
	2014	2013	2012
		(in thousands)	
Cash (used in) provided by:			
Operating activities	$ 117,715	$ (113,907)	$ (80,135)
Investing activities	117,853	606	(61,998)
Capital expenditures (included in investing activities above)	(1,362)	(1,754)	(1,301)
Financing activities	3,723	5,673	293,678

Cash Flows

The principal use of cash in operating activities in all periods presented was related to our research and development programs. Our cash flow provided by operating activities during 2014 is primarily related to the $275 million upfront payment received in connection with our collaboration agreement with AbbVie. This is partially offset by a $10 million milestone payment, $6.7 million related to the second installment on a release payment and a $5 million option fee payment to Takeda. 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 and option payment to Takeda. We cannot be certain whether and when we may enter into any such collaboration agreements or in-licenses.

On February 24, 2014, we entered into a Facility Agreement with Deerfield, pursuant to which Deerfield agreed to loan us up to $100 million, subject to the terms and conditions set forth in the Facility Agreement, including the condition that we at all times maintain a cash, cash equivalents and available-for-sales securities balance of not less than $25 million. Under the terms of the Facility Agreement, we may draw down funds in minimum disbursements of $25 million at any time until February 27, 2015. On September 22, 2014, we amended the facility agreement with Deerfield such that the maximum principal amount that we may draw down is reduced to $50 million. No funds were drawn under the Facility Agreement as of December 31, 2014. On February 27, 2015, or upon the earlier termination or acceleration of the Facility Agreement, we are required to pay a fee equal to 3% of the then undrawn portion of the $50 million commitment.

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 year ended December 31, 2012, we received research and development funding from Mundipharma and Purdue totaling $55 million.

Table of Contents

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 with Mundipharma and Purdue. 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.

Our investing activities for the years ended December 31, 2014, 2013 and 2012 included purchases 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, 2014 included $21.8 million in purchases of available-for-sale securities and proceeds of $141.0 million from maturities of available-for-sale securities. Capital expenditures for the year ended December 31, 2014 of $1.4 million primarily consisted of leasehold improvements. We expect that capital expenditures will increase in 2015 as a result of additional leasehold improvements in connection with our lease agreement with BHX, LLC at 784 Memorial Drive, Cambridge, Massachusetts.

Net cash from financing activities for the year ended December 31, 2014 included $3.9 million of proceeds from issuances of common stock from stock option exercises related to stock incentive plans, $1.0 million related to restricted cash held on deposit with a bank to collateralize a letter of credit in the name of our facility lessor in accordance with our facility lease agreement, $0.8 million of proceeds from issuances of common stock related to our employee stock purchase plan, $0.5 million related to a decrease in restricted cash held on deposit with a bank to collateralize a letter of credit in the name of our facility lessor in accordance with our amended facility lease agreement and $0.4 million of transaction costs related to the Facility Agreement with Deerfield.

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.

We will need substantial additional funds to support our planned operations. AbbVie has paid us a $275 million upfront payment during the year ended December 31, 2014. In addition, AbbVie has agreed to pay us milestone payments associated with specified development, regulatory and commercialization events, up to an aggregate of $530 million if all the milestones are achieved. We expect to achieve the first milestone payment of $130 million associated with the completion of enrollment of either DYNAMO or DUO from AbbVie in 2015. In the absence of additional funding or business development activities and based on our current operating plans, we believe that our existing cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs through at least the next twelve months. Until we can generate sufficient levels of cash from operations, which we do not expect to achieve for at least the next two years, and because sufficient funds may not be available to us when needed from collaborations, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities, through licensing select programs or partial economic rights that include up-front, royalty and/or milestone payments. 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

Table of Contents

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;
- the cost or quantity required of comparator drugs used in clinical studies increases;
- 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 financings 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% compared to 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 were made in 2013.

62

Table of Contents

Contractual Obligations

As of December 31, 2014, we had the following contractual obligations, excluding contingent milestone payments:

		Payments Due by Period (in thousands)					
Contractual Obligations	**Total**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020 and beyond**
Due to Takeda	$ 6,667	$ 6,667	$	$	$	$	$
784 facility lease	21,485	1,362	2,044	2,044	2,044	2,044	11,947
780/790 facility lease	37,335	2,792	3,556	3,470	3,516	3,840	20,161
Software contract obligations	1,302	892	380	30			
Total contractual cash obligations	$ 66,789	$ 11,713	$ 5,980	$ 5,544	$ 5,560	$ 5,884	$ 32,108

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 Takeda. For a description of these obligations, please see our description of our license agreement with Takeda under the heading Strategic Alliances Takeda above. We are obligated to pay to Takeda up to $5 million in remaining success-based milestones for the development of a second product candidate, and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. Because the achievement of these milestones had not occurred as of December 31, 2014, such contingencies have not been recorded in our financial statements.

During the year ended December 31, 2014, we entered into a lease agreement with BHX, LLC for the lease of 61,000 square feet of office space at 784 Memorial Drive, Cambridge, Massachusetts. Upon lease commencement, building construction was initiated and we are involved in the construction project. We are deemed for accounting purposes to be the owner of the building during the construction period. As of December 31, 2014, we recorded building and accumulated construction costs of approximately $16.0 million and a construction liability of approximately $15.5 million (see note 11 of the financial statements).

In November 2014, we entered into an operating lease amendment with ARE-770/784/790 Memorial Drive, LLC for 54,861 square feet of leased premises at 780 and 790 Memorial Drive, Cambridge, Massachusetts.

Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones, which may not be achieved.

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.

Table of Contents

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 $0.1 million decrease in the fair value of our investments as of December 31, 2014, as compared to an approximately $0.8 million decrease as of December 31, 2013. 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.

Table of Contents

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of

Infinity Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Infinity Pharmaceuticals, Inc. as of December 31, 2014 and 2013, 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, 2014. 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, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 24, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 24, 2015

Table of Contents

INFINITY PHARMACEUTICALS, INC.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 307,405	$ 68,114
Available-for-sale securities	25,321	145,772
Loan commitment asset, net (note 9)	647	
Prepaid expenses and other current assets	11,195	11,055
Total current assets	344,568	224,941
Property and equipment, net	18,970	4,010
Long-term available-for-sale securities	519	582
Restricted cash	1,680	1,130
Long-term receivable (note 11)	3,006	
Other assets	401	47
Total assets	$ 369,144	$ 230,710
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 5,947	$ 6,375
Accrued expenses	17,768	9,164
Due to Takeda, current	6,667	6,667
Deferred revenue, current	24,495	
Total current liabilities	54,877	22,206
Due to Takeda, less current portion		6,456
Deferred revenue, less current portion	85,510	
Deferred rent (note 11)	3,375	458
Construction liability (note 11)	15,456	
Other liabilities	454	315
Total liabilities	159,672	29,435
Commitments and contingencies (note 11)		
Stockholders equity:		
Preferred Stock, $.001 par value; 1,000,000 shares authorized, no shares issued and outstanding at December 31, 2014 and 2013		
Common Stock, $.001 par value; 100,000,000 shares authorized, 48,878,828 and 48,227,838 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively	49	48
Additional paid-in capital	676,521	650,867
Accumulated deficit	(467,212)	(449,796)
Accumulated other comprehensive income	114	156
Total stockholders equity	209,472	201,275
Total liabilities and stockholders equity	$ 369,144	$ 230,710

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

66

Table of Contents

INFINITY PHARMACEUTICALS, INC.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Years Ended December 31,		
	2014	2013	2012
Collaboration revenue	$ 164,995	$	$ 47,114
Operating expenses:			
Research and development	143,633	99,760	118,595
General and administrative	29,285	27,916	27,882
Total operating expenses	172,918	127,676	146,477
Gain on termination of Purdue entities alliance			46,555
Loss from operations	(7,923)	(127,676)	(52,808)
Other income (expense):			
Interest expense	(9,649)		(1,908)
Income from Massachusetts tax incentive award			193
Investment and other income	339	896	559
Total other income (expense)	(9,310)	896	(1,156)
Loss before income taxes	(17,233)	(126,780)	(53,964)
Income tax	(183)		
Net loss	$ (17,416)	$ (126,780)	$ (53,964)
Basic and diluted loss per common share	$ (0.36)	$ (2.64)	$ (1.70)
Basic and diluted weighted average number of common shares outstanding	48,561,653	47,936,001	31,711,264
Other comprehensive income (loss):			
Net unrealized holding gains (losses) on available-for-sale securities arising during the period	$ (42)	$ 22	$ 112
Comprehensive loss	$ (17,458)	$ (126,758)	$ (53,852)

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

Table of Contents

INFINITY PHARMACEUTICALS, INC.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2014	**2013**	**2012**
Operating activities			
Net loss	$ (17,416)	$ (126,780)	$ (53,964)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,773	1,823	1,643
Stock-based compensation, including 401(k) match	12,588	12,155	7,811
Non-cash interest expense on long-term debt due to Purdue entities			1,908
Non-cash interest expense on amount Due to Takeda	211	415	
Amortization of loan commitment asset	9,649		
Net amortization of premium/discount on available-for-sale securities	1,257	2,201	1,653
Impairment of property and equipment			161
Other, net	83	(2)	46
Changes in operating assets and liabilities:			
Unbilled accounts receivable			218
Prepaid expenses and other assets	(494)	(7,284)	(1,037)
Accounts payable, accrued expenses and other liabilities	6,815	3,565	(12,395)
Due to Takeda	(6,667)		12,708
Deferred revenue	110,005		(38,887)
Deferred rent	(89)		
Net cash provided by (used in) operating activities	117,715	(113,907)	(80,135)
Investing activities			
Purchases of property and equipment	(1,362)	(1,754)	(1,301)
Purchases of available-for-sale securities	(21,789)	(249,764)	(180,498)
Proceeds from maturities of available-for-sale securities	141,004	251,093	113,520
Proceeds from sales of available-for-sale securities		1,031	6,281
Net cash provided by (used in) investing activities	117,853	606	(61,998)
Financing activities			
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	3,881	5,299	21,386
Proceeds from issuances of common stock related to employee stock purchase plan	836	374	
Restricted cash	(548)		
Deferred transaction costs	(446)		
Net cash provided by financing activities	3,723	5,673	293,678
Net increase (decrease) in cash and cash equivalents	239,291	(107,628)	151,545
Cash and cash equivalents at beginning of period	68,114	175,742	24,197
Cash and cash equivalents at end of period	$ 307,405	$ 68,114	$ 175,742
Supplemental schedule of noncash investing and financing activities			
Receivable for stock option exercises	$	$ 152	$ 200
Loan commitment asset	$ 9,850	$	$
Facility fee	$ 1,500	$	$

Construction liability	$ 15,456	$	$
Warrants issued	$ 8,350	$	$
Issuance of common stock to extinguish debt from Purdue entities	$	$	$ 51,277

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

Table of Contents

INFINITY PHARMACEUTICALS, INC.

Consolidated Statements of Stockholders Equity

(in thousands, except share amounts)

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

Table of Contents

INFINITY PHARMACEUTICALS, INC.

Consolidated Statements of Stockholders Equity (Continued)

(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity
	Shares	Amount				
Balance at December 31, 2013	48,227,838	$ 48	$ 650,867	$ (449,796)	$ 156	$ 201,275
Exercise of stock options	523,954		3,881			3,881
Valuation of initial warrants			8,350			8,350
Stock-based compensation expense			11,878			11,878
401(k) plan match issued in common stock	50,464		710			710
Issuance of common stock related to employee stock purchase plan	76,572	1	835			836
Unrealized loss on marketable securities					(42)	(42)
Net loss				(17,416)		(17,416)
Balance at December 31, 2014	48,878,828	$ 49	$ 676,521	$ (467,212)	$ 114	$ 209,472

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

Table of Contents

INFINITY PHARMACEUTICALS, INC.

Notes to Consolidated Financial Statements

1. Organization

Infinity Pharmaceuticals, Inc. is an innovative biopharmaceutical company dedicated to discovering, developing and delivering best-in-class medicines to patients with 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.

Reclassifications

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

Cash Equivalents and Available-For-Sale Securities

Cash equivalents and available-for-sale securities primarily consist of money market funds, U.S. government-sponsored enterprise obligations, corporate obligations and mortgage-backed securities. Corporate obligations include obligations issued by corporations in countries other than the United States, including some 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, corporate obligations and U.S. government-sponsored enterprise 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, 2014 and 2013 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.

Table of Contents

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

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

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

Concentration of Risk

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 year ended December 31, 2012. 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 12).

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 12).

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. Assets included in construction in process are not depreciated until placed into service. 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

Table of Contents

charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

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

Impairment of Long-Lived Assets

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

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 Takeda based on a discounted cash flow model (see note 12).

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, upfront license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved, and/or royalties on product sales. We evaluate all deliverables within an arrangement to determine whether or not they provide value on a stand-alone basis. Based on this evaluation, the deliverables are separated into units of accounting. For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using the proportional performance method. The proportional performance method is used when the level of effort to complete the performance obligations under an arrangement can be reasonably estimated. We recognize revenue based upon our best estimate of the selling price for each element when there is no other means to determine the fair value of that item and allocate the consideration based on the relative values. The process for determining the best estimate of the selling price involves significant judgment and estimates.

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,

Table of Contents

the consideration relates solely to past performance, and

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

In making this assessment, 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. 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.

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

Income Taxes

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

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

Due to the uncertainty surrounding the realization of the net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of December 31, 2014 and 2013.

Basic and Diluted Net Loss per Common Share

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

	At December 31,		
	2014	**2013**	**2012**
Stock options	6,577,296	6,083,318	5,574,527
Warrants	1,000,000		50,569

Table of Contents

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, 2014, 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. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance conditions, which affects the period over which the expense is recognized, and recognize the expense over the requisite service period on a straight-line basis. We have no awards with market 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, comparator drug expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. We also include as research and development expense upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative use. We expense research and development costs as they are incurred. Prepaid comparator drug expenses are capitalized and then recognized as expense when title transfers to us. We have been a party to collaboration agreements in which we were reimbursed for work performed on behalf of the collaborator, as well as one in which we reimbursed the collaborator for work it had 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 we record the reimbursement as revenue. If the arrangement provides for us to reimburse the collaborator for research and development expenses or for the achievement of 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 Takeda.

3. Stock-Based Compensation

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

2010 Stock Incentive Plan

Our 2010 Stock Incentive Plan, or the 2010 Plan, was approved by our stockholders in May 2010. The 2010 Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, or IRC, as well as, 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

Table of Contents

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, 2014, an aggregate of 4,113,803 shares of our common stock were reserved for issuance upon the exercise of outstanding awards, and up to 2,903,202 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, as well as nonstatutory stock options and restricted stock. As of December 31, 2014, an aggregate of 2,420,345 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, 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, 2014, an aggregate of 43,148 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% 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 2014, 76,572 shares of common stock were purchased for total proceeds of $0.8 million. 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,		
	2014	2013	2012
		(in thousands)	
Research and development	$ 7,502	$ 6,213	$ 3,177
General and administrative	5,086	5,942	4,634

As of December 31, 2014, we had approximately $17.1 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 2.2 years.

Table of Contents

Stock Options

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,		
	2014	2013	2012
Risk-free interest rate	1.7%	1.1%	1.1%
Expected annual dividend yield			
Expected stock price volatility	70.9%	64.6%	63.3%
Expected term of options	5.0 years	5.4 years	6.1 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 our available implied and historical price information.

Expected term of options: The expected term of the awards represents 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, 2014, 2013 and 2012, the weighted-average forfeiture rate was estimated to be 14%, 13% and 12%, respectively.

All options granted to employees during the years ended December 31, 2014, 2013 and 2012 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, 2014 is as follows:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2014	6,083,318	$ 14.04		

Granted	1,576,734		12.60		
Exercised	(523,954)		7.41		
Forfeited	(558,802)		19.53		
Outstanding at December 31, 2014	6,577,296	$	13.76	6.3	$ 37.5
Vested or expected to vest at December 31, 2014	6,274,310	$	13.59	6.1	$ 36.5
Exercisable at December 31, 2014	4,704,549	$	12.08	5.3	$ 31.1

Table of Contents

The weighted-average fair value per share of options granted during the years ended December 31, 2014, 2013 and 2012 was $7.45, $18.07 and $6.00, respectively.

The aggregate intrinsic value of options outstanding at December 31, 2014 was calculated based on the positive difference between the closing fair market value of our common stock on December 31, 2014 and the exercise price of the underlying options. The aggregate intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 was $4.0 million, $16.0 million and $34.1 million, respectively. The total cash received from employees and non-employees as a result of stock option exercises during the year ended December 31, 2014 was $3.9 million.

No related income tax benefits were recorded during the years ended December 31, 2014, 2013 or 2012.

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

During the year ended December 31, 2014, two members of our board of directors retired, and we extended these directors rights to exercise their vested stock options for an additional six-month period. In addition, one employee whose employment terminated received an accelerated vesting of his unvested options. In connection with these modifications, we recognized an additional $0.4 million of stock-based compensation expense during the year ended December 31, 2014.

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. The amount recognized related to the remeasurement and continued vesting of these options during the year ended December 31, 2014 was not material.

Employee Stock Purchase Plan

The weighted-average fair value of each purchase right granted during the year ended December 31, 2014 and 2013 was $5.66 and $8.68, respectively. For the years ended December 31, 2014 and 2013, the fair values were estimated using the Black-Scholes valuation model using the following weighted-average assumptions:

	December 31, 2014	December 31, 2013
Risk-free interest rate	0.3%	0.3%
Expected annual dividend yield		
Expected stock price volatility	66.7%	91.5%
Expected term of options	1.25 years	1.25 years

Table of Contents

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

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

	December 31, 2014			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
		(in thousands)		
Cash and cash equivalents due in 90 days or less	$ 307,405	$	$	$ 307,405
Available-for-sale securities:				
Corporate obligations due in one year or less	21,324	6	(1)	21,329
Mortgage-backed securities due after ten years	412	107		519
U.S. government-sponsored enterprise obligations due in one year or less	3,990	2		3,992
Total available-for-sale securities	25,726	115	(1)	25,840
Total cash, cash equivalents and available-for-sale securities	$ 333,131	$ 115	$ (1)	$ 333,245

	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

We held four debt securities at December 31, 2014 that had been in an unrealized loss position for less than twelve months. The fair value of these securities was $15.0 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 four 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, 2014.

As of December 31, 2014, we held securities of six financial institutions and other corporate debt securities located in Canada, Sweden, France, the United Kingdom and Japan with a fair value of $50.7 million. These securities are short term in nature and are all scheduled to mature within twelve months. There were no material unrealized losses incurred by these securities.

We had no material realized gains or losses on our available-for-sale securities for the years ended December 31, 2014, 2013 and 2012. There were no other-than-temporary impairments recognized for the years ended December 31, 2014, 2013 and 2012.

79

Table of Contents

5. Fair Value

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, 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, 2014 and 2013.

The following table provides the assets carried at fair value measured on a recurring basis as of December 31, 2014:

	Level 1	Level 2
	(in thousands)	
Assets:		
Cash and cash equivalents	$ 256,559	$ 50,846
Corporate obligations (including commercial paper)		21,329
Mortgage-backed securities		519
U.S. government-sponsored enterprise obligations		3,992
Total	$ 256,559	$ 76,686

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 Takeda is recorded at its carrying value at December 31, 2014. The fair value of the amount due to Takeda, a Level 2 measurement, was approximately $6.7 million as of December 31, 2014 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, 2014 (see note 12).

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 their fair value due to their short term maturities.

Table of Contents

There have been no changes to the valuation methods during the year ended December 31, 2014. 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, 2014. We had no available-for-sale securities that were classified as Level 3 at any point during the years ended December 31, 2014 or 2013.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2014	2013
	(in thousands)	
Prepaid comparator drug	$ 5,085	$ 6,673
Prepaid expenses	4,124	2,044
Other current assets	1,986	2,338
Total prepaid expenses and other current assets	$ 11,195	$ 11,055

7. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2014	2013
	(in thousands)	
Laboratory equipment	$ 12,615	$ 14,958
Computer hardware and software	5,550	6,488
Office equipment and furniture and fixtures	720	872
Construction in process	16,004	
Leasehold improvements	5,041	4,982
	39,930	27,300
Less accumulated depreciation	(20,960)	(23,290)
	$ 18,970	$ 4,010

During the year ended December 31, 2014, we entered into a lease agreement for the lease of office space at 784 Memorial Drive, Cambridge, Massachusetts. Upon lease commencement, building construction was initiated and we are involved in the construction project. We are deemed for accounting purposes to be the owner of the building during the construction period. As of December 31, 2014, we recognized the building as construction in process for $14.7 million on our consolidated balance sheet (see note 11).

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 $0.1 million and $49 thousand during 2014 and 2013, respectively.

8. Restricted Cash

We held $1.7 million and $1.1 million in restricted cash as of December 31, 2014 and December 31, 2013, respectively. The balances are held on deposit with a bank to collateralize standby letters of credit in the name of our facility lessors in accordance with our facility lease agreements.

9. Debt Facility Agreement

On February 24, 2014, we entered into a facility agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which, Deerfield agreed to loan us up to $100 million, subject to the terms and conditions set forth in the facility agreement. On September 22, 2014, we amended the facility

Table of Contents

agreement with Deerfield such that the maximum principal amount that we may draw down is reduced to $50 million. We refer to the facility agreement with Deerfield, as amended, as the Facility Agreement. Under the terms of the Facility Agreement, we had the right to draw down on the Facility Agreement in $25 million minimum disbursements, which we refer to as the Loan Commitment, at any time on 22 business days prior notice until February 27, 2015, which we refer to as the Draw Period. The Draw Period has expired without us having drawn down on the Facility Agreement.

On February 27, 2015, or upon the earlier termination of the facility, we are required to pay a fee equal to 3% of the difference between the $50 million commitment and the aggregate amount of any disbursements under the Facility Agreement made prior to such date, which we refer to as the Facility Fee. As no disbursements have been made under the Facility Agreement and the Draw Period has expired, we have determined it probable that we will be required to pay a Facility Fee amount of $1.5 million on February 27, 2015. We have recorded the full $1.5 million Facility Fee on the December 31, 2014 consolidated balance sheet as a component of both the loan commitment asset and accrued expenses line items. The loan commitment asset is being amortized to interest expense in the consolidated statements of operations and comprehensive loss on a straight line basis over the Draw Period.

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. The warrants have dividend rights to the same extent as if the warrants were exercised into shares of common stock. The warrants expire on the seventh anniversary of their issuance and contain certain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it exceeding 9.985% of the total number of shares of common stock then issued and outstanding.

Our total cost of securing the Loan Commitment was $11.8 million and is comprised of $8.4 million representing the fair value of the 1,000,000 warrants issued on February 24, 2014, discussed below; $3 million representing the Facility Fee; and $0.4 million of transaction costs. As a result of the amendment of the Facility Agreement, we reduced the Facility Fee by 50%, or $1.5 million and recorded a corresponding decrease in the loan commitment asset. In addition, since our borrowing capacity was reduced by 50%, the remaining loan commitment asset outstanding as of September 22, 2014 was also reduced by 50% resulting in an additional expense of $1.8 million during the year ended December 31, 2014. The total fair value is considered a Loan Commitment Asset which has been classified as a current asset on the December 31, 2014 consolidated balance sheets. This amount is considered a fee to secure the Loan Commitment and is being amortized to interest expense in the year ended December 31, 2014 consolidated statements of operations and comprehensive loss on a straight line basis over the Draw Period. We recorded $9.6 million of interest expense associated with the amortization and write-off of the loan commitment asset pursuant to the modification of the facility for the year ended December 31, 2014.

10. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2014	2013
	(in thousands)	
Accrued compensation and benefits	$ 7,353	$ 1,839
Accrued drug manufacturing costs	1,280	991
Accrued clinical studies	5,134	4,009
Accrued preclinical studies	543	303
Facility fee	1,500	
Other	1,958	2,022
Total accrued expenses	$ 17,768	$ 9,164

Table of Contents

11. Commitments and Contingencies

We lease our office and laboratory space under two separate lease agreements with BHX, LLC, as trustee of 784 Realty Trust, and ARE-770/784/790 Memorial Drive, LLC.

BHX, LLC, as Trustee of 784 Realty Trust

On September 25, 2014, we entered into a lease agreement, or the Lease, with BHX, LLC, as trustee of 784 Realty Trust, or the Landlord, for the lease of office space at 784 Memorial Drive, Cambridge, Massachusetts. The term of the Lease commenced on November 1, 2014, the Commencement Date, and expires on March 31, 2025, the Expiration Date. Pursuant to the Lease, on the Commencement Date we agreed to lease 61,000 square feet of the leased premises, which represents the entire building, the Leased Premises.

From the Commencement Date until April 1, 2015, the total base rent of the Lease will be zero per month. From April 1, 2015 through March 31, 2020, the total base rent of the Lease will be $170,292 per month. From April 1, 2020 until the Expiration Date, the total base rent of the Lease will be $190,625 per month. In addition to the base rent, we are also responsible for our share of the operating expenses, utility costs and real estate taxes, in accordance with the terms of the Lease. Pursuant to the terms of the Lease, we provided a security deposit in the form of a letter of credit in the initial amount of $1.0 million, which may be reduced by up to $750,000 over time in accordance with the terms of the Lease. The Landlord has agreed to pay up to $5,856,100 for certain updates and repairs to be made to the Leased Premises. We are responsible for the construction and bear the risk of cost over-runs.

We have two consecutive rights to extend the term of the Lease for five years under each extension, provided that we provide notice to the Landlord no earlier than 18 months or later than 12 months prior to expiration of the Lease. The base rent for each extension term shall be equal to 95% of the then fair market base rent per square foot for the premises.

The Lease contains customary provisions allowing the Landlord to terminate the lease if we fail to remedy a default of any of our obligations under the Lease within specified time periods or upon our bankruptcy or insolvency.

Upon lease commencement on November 1, 2014, building construction was initiated to suit our future needs. We are involved in the construction project, including having responsibility to pay for a portion of the structural elements of the building and bear the risk of cost over-runs. Therefore, we are deemed for accounting purposes to be the owner of the building during the construction period. Accordingly, we determined the fair value of the building as of November 1, 2014 through an independent appraisal and recorded the building as an asset on our consolidated balance sheet, together with a corresponding construction financing obligation, in November 2014 when the lease and construction commenced. On our consolidated balance sheet, we record project construction costs as an asset during the construction period and reflect an increase in the construction financing obligation for the amount of Landlord incentives received. When the construction is substantially complete and the Leased Premises is available for occupancy, the construction-in-progress will be placed in service and the construction liability will be reclassified to a financing obligation. We will commence depreciation on the building and accumulated construction costs over the term of the lease using a residual value equal to the financing obligation at the end of the lease term as such transaction is not expected to qualify for sale-leaseback accounting. Interest expense will be recorded on a monthly basis using an estimated incremental borrowing rate and will commence at the time the building is placed into service. The construction financing obligation will be reduced on a monthly basis commencing in April 2015 by that portion of the lease payment allocated to construction financing obligation principal.

At December 31, 2014, the accompanying consolidated balance sheet reflects the building and accumulated construction costs of approximately $16.0 million and a construction liability of approximately $15.5 million.

We divide our future lease payments into a portion that is allocated to the financing obligation and a portion that is allocated to the land on which the building is located. The portion of the lease obligation allocated to the

Table of Contents

land is treated for accounting purposes as an operating lease commencing in November 2014 and recorded on a straight-line basis over the initial lease term. Rent expense pertaining to the land was approximately $68,000 for the year ended December 31, 2014.

We will make our first monthly lease payment under the Lease on April 1, 2015, which provides us a rent free period of five months. Upon signing the lease agreement, we paid the first month s rent in the amount of $170,292, which was recorded as a prepaid expense on the accompanying consolidated balance sheets. In addition, we provided a letter of credit in the amount of $1.0 million to the Landlord as security for the lease. The letter of credit plus the associated bank fee of $30,000 has been recorded in our accompanying consolidated balance sheets as restricted cash.

ARE-770/784/790 Memorial Drive, LLC

On November 6, 2014, we entered into a Seventh Amendment to Lease, the Lease Amendment, by and between us and ARE-770/784/790 Memorial Drive, LLC, the landlord, or ARE, which amends the lease agreement originally dated July 2, 2002, as amended to date, or the Original Lease. We shall refer to the Original Lease together with the Lease Amendment as the Memorial Drive Lease. We shall refer to the area rented under the Memorial Drive Lease as the Premises.

Under the Lease Amendment: (i) the Premises consist of 54,861 square feet, of which 51,000 square feet are located at 780 Memorial Drive, or the 780 Premises, and the remaining 3,861 square feet are located at 790 Memorial Drive, or the 790 Premises; effective February 1, 2016 we will surrender 13,159 square feet of the previously leased 17,020 square feet at the 790 Premises; (ii) we have extended the base term of the Memorial Drive Lease through March 31, 2025; and (iii) we have two separate five-year options to extend the term of the Memorial Drive Lease to 2035 on the same terms and conditions (other than with respect to base rent or any work letter). The Memorial Drive Lease provides that we shall continue to pay the base rent as provided in the Original Lease until January 31, 2016. The base rent shall then increase to $69.00 per square foot of the Premises on February 1, 2016 and again to $70.00 per square foot of the Premises on February 1, 2018. The Memorial Drive Lease provides that no base rent for the Premises shall be due (i) for the period commencing on February 1, 2015 through July 31, 2015, (ii) for the period commencing on February 1, 2016 through February 29, 2016, (iii) for the period commencing on February 1, 2017 through February 28, 2017, and (iv) for the period commencing on February 1, 2018 through February 28, 2018. We also received allowances of $3.0 million for the design and construction of tenant improvements. The total of these allowances of $3.0 million has been reflected on our Consolidated Balance Sheet at December 31, 2014 as a long-term receivable, with a corresponding amount included in deferred rent liability. The deferred rent is being amortized to rent expense over the term of the lease.

We have determined that the proposed improvements on the 780 Premises generally consists of normal tenant improvements and that we will not be deemed for accounting purposes to be the owner of the building during the construction period.

Future minimum payments, excluding operating costs and taxes, under the two lease agreements described above are as follows:

	784 Facility Lease	780/790 Facility Lease
	(in thousands)	
Years Ending December 31:		
2015	$ 1,362	$ 2,792
2016	2,044	3,556
2017	2,044	3,470
2018	2,044	3,516
2019	2,044	3,840
2020 and beyond	11,947	20,161
Total minimum lease payments	$ 21,485	$ 37,335

Table of Contents

Rent expense of $4.7 million, $4.7 million and $4.8 million, before considering sublease income, was incurred during the years ended December 31, 2014, 2013 and 2012, respectively. Deferred rent is being amortized to rent expense over the life of the lease. During the years ended December 31, 2014, 2013 and 2012, we subleased a portion of our facility space for total sublease income of $0.2 million, $0.2 million and $0.7 million, respectively. We record sublease payments as an offset to rental expense in our consolidated statements of operations and comprehensive loss. The sublease expires January 2016. Future minimum sublease income under the existing sublease is expected to be $0.2 million for the year ended December 31, 2015.

12. Collaborations

AbbVie

On September 2, 2014, we entered into a collaboration and license agreement with AbbVie Inc., or AbbVie, which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we will collaborate with AbbVie to develop and commercialize products containing duvelisib, which we refer to as Duvelisib Products, in oncology indications. Under the terms of the AbbVie Agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture Duvelisib Products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize Duvelisib Products outside the United States. We and AbbVie retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie Agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

Under the AbbVie Agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for Duvelisib Products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock.

We and AbbVie share oversight of development and have each agreed to use diligent efforts, as defined in the AbbVie Agreement, to carry out our development activities under an agreed upon development plan. We have primary responsibility for the conduct of development of Duvelisib Products, unless otherwise agreed, and AbbVie has responsibility for the conduct of certain contemplated combination clinical studies, which we refer to as the AbbVie Studies. We have the responsibility to manufacture Duvelisib Products until we transition manufacturing responsibility to AbbVie, which we expect to occur as promptly as practicable while ensuring continuity of supply. Excluding the AbbVie Studies, we are responsible for all costs to develop and manufacture Duvelisib Products up to a maximum amount of $667 million after which we will share Duvelisib Product development and manufacturing costs equally with AbbVie. The development and manufacturing costs for the AbbVie Studies will be shared equally.

We and AbbVie share operational responsibility and decision making authority for commercialization of Duvelisib Products in the United States. Specifically, we have the primary responsibility for advertising, distribution, and booking sales, and we share certain other commercialization functions with AbbVie. Assuming regulatory approval, we and AbbVie are obligated to each provide half of the sales representative effort to promote Duvelisib Products in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize Duvelisib Products. We and AbbVie will share the cost of manufacturing and supply for commercialization of Duvelisib Products in the United States and AbbVie will bear the cost of manufacturing and supply for commercialization of Duvelisib Products outside the United States. Prior to commercialization and regulatory approval, we will recognize these costs as a component of research and development and general and administrative expenses. Subsequent to regulatory approval and commercial launch, the cost of manufacturing will be recorded as cost of goods sold. We recognize these costs as a component of research and development and general and administrative expenses. During the year ended December 31, 2014, we recognized a credit of $0.1 million in general and administrative expenses related to these costs.

Table of Contents

AbbVie has paid us a non-refundable $275 million upfront payment and has agreed to pay us up to $530 million in potential future milestone payments comprised of $130 million associated with the completion of enrollment of either DYNAMO or DUO, which we expect to occur in 2015, up to $275 million associated with the achievement of specified regulatory filing and approval milestones, and up to $125 million associated with the achievement of specified commercialization milestones. Under the terms of the AbbVie Agreement, we and AbbVie will equally share commercial profits or losses of Duvelisib Products in the United States, including sharing equally the existing royalty obligations to Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for sales of Duvelisib Products in the United States, as well as sharing equally the existing U.S. milestone payment obligations to Takeda. Additionally, AbbVie has agreed to pay us tiered royalties on net sales of Duvelisib Products outside the United States ranging from 23.5% to 30.5%, depending on annual net sales of Duvelisib Products by AbbVie, its affiliates and its sublicensees. We are responsible for the existing royalty obligations to Mundipharma and Purdue outside the United States and to Takeda worldwide, and AbbVie has agreed to reimburse us for our existing Duvelisib Product milestone payment obligations to Takeda outside the United States. The tiered royalty from AbbVie is subject to a reduction of 4% at each tier if our royalties to Mundipharma and Purdue are reduced according to the terms of our respective agreements with them. This tiered royalty can further be reduced based on specified factors, including patent expiry, generic entry, and royalties paid to third parties with blocking intellectual property. These royalties are payable on a product-by-product and country-by-country basis until AbbVie ceases selling the product in the country.

We have evaluated the deliverables within the AbbVie Agreement to determine whether or not they provide value on a standalone basis. Based on our evaluation, we have determined that there are three deliverables: the license, the development services and the committee services, and each provides value on a stand-alone basis and represents a separate unit of accounting. We determined the best estimate of selling price for each unit of accounting using a discounted cash-flow model. The valuation for each deliverable involves significant estimates and assumptions, including but not limited to, expected market opportunity, assumed royalty rates, pricing objectives, clinical trial timelines, likelihood of success and projected costs. The resulting estimate of selling prices for the license and development services consider the benefits that have been retained by us.

Of the $275 million upfront payment received during the year ended December 31, 2014, $159.1 million was allocated to the license, $115.6 million to the development services and $0.3 million to committee services based on the allocation of best estimate of selling price on a relative basis. We determined the best estimate of selling prices for the license unit of accounting based on estimates and assumptions resulting in an expected future cash flow which was discounted based on estimated weighted average cost of capital of 11.5%. We determined the best estimate of selling prices for development and committee services based on the nature of the services to be performed and estimates of the associated efforts and third-party rates for similar services using a discount rate of 8% for development services and 11.5% for committee services. We recognized license revenue upon execution of the arrangement. Revenue related to development services and committee services are being recognized using the proportionate performance method as services are provided over the estimated service period of approximately five years. During the year ended December 31, 2014, we recognized $159.1 million of revenue related to the license and $5.9 million of revenue related to development and committee services. We have recorded the remaining amount of $110 million related to development and committee services as deferred revenue as of December 31, 2014.

The development, regulatory and commercialization milestones represent non-fundable amounts that would be paid by AbbVie to us if certain milestones are achieved in the future. We have elected to apply the milestones method of revenue recognition to these milestones. We have determined that all milestones, except for the first milestone, if achieved, are substantive as they relate solely to past performance, are commensurate with estimated enhancement of value associated with the achievement of each milestone as a result of our performance, which are reasonable relative to other deliverables and terms of the arrangement, and are unrelated to the delivery of any further elements under the arrangement. The clinical development milestone, which we have determined not to be substantive based on risk and effort involved, will be recognized using the same method as the upfront payment when achieved.

Table of Contents

Subject to limited exceptions, we have agreed that we and our affiliates will not commercialize, or assist others in commercializing, in oncology indications any product that is a PI3K delta, gamma inhibitor that meets certain agreed-to criteria, other than Duvelisib Products, and AbbVie has agreed to similar restrictions. Registration-directed clinical trials and commercialization of Duvelisib Products for uses outside of oncology indications would require our and AbbVie s mutual consent.

The AbbVie Agreement will remain in effect until all development, manufacturing and commercialization of Duvelisib Products cease, unless terminated earlier. Either we or AbbVie may terminate the AbbVie Agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the AbbVie Agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances. However, we may terminate the AbbVie Agreement only on a country by country basis in the event AbbVie is not using diligent efforts to obtain regulatory approval or to commercialize Duvelisib Products in a country outside the United States. AbbVie may also terminate the AbbVie Agreement for convenience after a specified notice period. In the event there is a material uncured breach by either us or AbbVie of development or commercialization obligations, the non-breaching party may also have the right to assume and conduct such applicable development or commercialization obligations. If AbbVie or any of its affiliates or sublicensees challenges the patents we have licensed to AbbVie, we can terminate the AbbVie Agreement if the challenge is not withdrawn after a specified notice period.

If the AbbVie Agreement is terminated, we would receive all rights to the regulatory filings related to duvelisib upon our request, our license to AbbVie would terminate, and AbbVie would grant us a perpetual, irrevocable license to develop, manufacture and commercialize products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates. This license would be royalty free, unless the AbbVie Agreement is terminated for material breach, in which case, depending on the breaching party and the timing of the material breach, a royalty rate may be payable by us ranging from a low single-digit percentage to a low double-digit percentage of net sales, and, in some cases, subject to a payment cap.

If the AbbVie Agreement is terminated, there are certain wind-down obligations to ensure a smooth transition of the responsibilities of the parties including, unless the AbbVie Agreement is terminated by AbbVie for our material breach, the continued conduct of certain development and commercialization activities by AbbVie for a limited transition period and the continued funding by AbbVie of its half of the cost of the AbbVie Studies ongoing at the time of termination.

Takeda

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 duvelisib, 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 Takeda. In December 2012, we amended and restated our development and license agreement with Takeda.

Under the terms of the amended and restated agreement, we retained worldwide development rights and, in exchange for an agreement to pay Takeda $15 million in installments, we regained commercialization rights for products arising from the agreement for all therapeutic indications and are solely responsible for research conducted under the agreement. 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. During the year ended December 31, 2014, we paid to Takeda the second installment of $6.7 million. The remaining amount is due in January 2015, which we recorded as short-term liability due to Takeda on our consolidated balance sheet.

In addition to developing duvelisib, we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. We are obligated to pay to Takeda up to $5 million in remaining

Table of Contents

success-based milestone payments for the development of a second product candidate and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Takeda a $10 million milestone payment in connection with the initiation of our Phase 3 study of duvelisib in patients with relapsed or refractory chronic lymphocytic leukemia, or CLL. We recognized the $10 million payment as research and development expense during the year ended December 31, 2014. In addition, we are obligated to pay Takeda tiered royalties on worldwide net sales ranging from 7% to 11% 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 of the royalties, and, in certain circumstances, limits on the number of products subject to a royalty obligation.

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. Takeda 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 Takeda, demonstrate to Takeda s reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Takeda 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.

On July 29, 2014, we entered into an amendment to amended and restated development and license our agreement with Takeda. Under the terms of the amendment, we paid to Takeda a one-time upfront payment of $5 million in exchange for the option to terminate our royalty obligations to Takeda under the amended and restated development and license agreement solely with respect to worldwide net sales in oncology indications of products containing or comprised of duvelisib. The option may be exercised by payment to Takeda of a fee of $52.5 million on or before March 31, 2015. If the option is not exercised, our royalty obligations to Takeda will remain unchanged. We recognized the $5 million upfront payment as research and development expense during the year ended December 31, 2014 as there is no alternative future use beyond the existing research and development activities.

FAAH Program License

In August 2014, we licensed rights to our fatty acid amide hydrolase, or FAAH program, to FAAH Pharma Inc., or FAAH Pharma, a start-up company pursuing the clinical development of IPI-940 to investigate its potential to treat neuropathic pain. We received a 23% ownership in FAAH Pharma in exchange for the license. FAAH Pharma receives funding from TVM Life Science Ventures VII, L.P., or TVM, under potential milestone payments. We have elected to use the carryover basis of measurement and no gain or loss is recognized related to this transaction.

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 we entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 Termination Agreements. 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. The strategic 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

Table of Contents

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.

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, resulting in the return to us of 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 strategic alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each strategic alliance program other than FAAH. 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 4% 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 1% 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%. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third-party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

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

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.

Table of Contents

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

13. Income Taxes

Our income tax expense for the year ended December 31, 2014 of $0.2 million consisted primarily of current US federal taxes. We had no income tax expense or benefit for the years ended December 31, 2013 and 2012.

Our income tax expense for the years ended December 31, 2014, 2013 and 2012 differed from the expected U.S. federal statutory income tax expense as set forth below:

	2014	2013	2012
		(in thousands)	
Expected federal tax expense (benefit)	$ (5,872)	$ (43,105)	$ (18,348)
Permanent differences	3,537	2,681	(4,685)
State taxes, net of the deferred federal benefit	(912)	(6,694)	(2,849)
Tax credit carryforwards	(9,510)	(11,534)	(589)
Adjustments to deferred tax assets and deferred tax liabilities	776	129	3,371
Alternative minimum tax	183		
Other	79	62	34
Change in valuation allowance	11,902	58,461	23,066
Income tax expense	$ 183	$	$

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

	Year Ended December 31,	
	2014	2013
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 133,180	$ 136,879
Tax credit carryforwards	37,278	27,768
Intangible assets	16,250	13,413
Accrued expenses	2,666	194
Stock-based compensation	10,031	9,842
Other	1,428	715
Valuation allowance	(200,833)	(188,811)
Net deferred tax assets	$	$

90

Table of Contents

We have recorded a valuation allowance against our deferred tax assets in each of the years ended December 31, 2014, 2013 and 2012 because management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by approximately $12.0 million during the year ended December 31, 2014 primarily as a result of increases in unbenefited deferred tax assets such as tax credits and intangible assets. The valuation allowance increased by approximately $59.1 million during the year ended December 31, 2013 primarily as a result of increases in unbenefited deferred tax assets such as tax losses and credits. The valuation allowance increased by approximately $24.2 million during the year ended December 31, 2012 primarily as a result of increases in unbenefited deferred tax assets such as tax losses and credits and intangible assets.

Subject to the limitations described below, at December 31, 2014, we had cumulative net operating loss carryforwards of approximately $386.3 million and $270.1 million available to reduce federal and state taxable income, which expire through 2034, and have begun to expire and expire through 2034, respectively. In addition, we have cumulative federal and state tax credit carryforwards of $31.2 million and $9.2 million, respectively, available to reduce federal and state income taxes which expire through 2034 and 2029, respectively. The net operating loss carryforwards include approximately $36.5 million of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net operating losses nor the cumulative net operating loss carryforward disclosures above. Additionally, our net operating loss carryforwards and tax credit carryforwards are limited as a result of certain ownership changes, as defined under Sections 382 and 383 of the Internal Revenue Code. This limits the annual amount of these tax attributes that can be utilized to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to an ownership change. Subsequent ownership changes may affect the limitation in future years. The net operating losses and tax credit carryforwards that have and will expire unused in the future as a result of Section 382 and 383 limitations have been excluded from the amounts disclosed above.

At December 31, 2014 and 2013, we had no unrecognized tax benefits. As of December 31, 2014, 2013 and 2012, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our consolidated statements of operations. We will recognize interest and penalties related to uncertain tax positions in income tax expense.

We file income tax returns in the U.S. federal, Massachusetts, and other state jurisdictions. The statute of limitations for assessment by the Internal Revenue Service, or IRS, and state tax authorities is closed for tax years prior to 2011, although carryforward attributes that were generated prior to tax year 2011 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period.

14. Stockholders Equity

Common Stock Offerings

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

Warrants

In July 2002, IPI issued warrants to purchase shares of convertible preferred stock, which subsequently in the DPI merger became warrants to purchase shares of common stock in the DPI merger, in conjunction with the entry into our facility lease. At December 31, 2012, warrants to purchase 50,569 shares of our common stock were outstanding. All of these outstanding warrants were exercised in January 2013 at $13.35 per share.

Table of Contents

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. See note 9 for additional details related to the Facility Agreement.

15. 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. As the award is not related to our ordinary course of operations, we have recorded the amount as other income.

16. Restructuring Activities

In June 2012, we voluntarily stopped all company-sponsored clinical trials of saridegib, our Hedgehog pathway inhibitor. In July 2012, we restructured our strategic alliance agreement with Mundipharma and Purdue such that we are no longer entitled to research and development funding (see note 12), and therefore we undertook a subsequent workforce reduction.

The associated restructuring expenses were recorded as research and development and general and administrative expenses. We recorded a restructuring expense of $2.6 million during the year ended December 31, 2012. The remaining balance payable as of December 31, 2012 was $0.4 million related to employee severance, benefits and related costs. All amounts have been paid as of December 31, 2014.

17. Defined Contribution Benefit Plan

We sponsor a 401(k) retirement plan in which substantially all of our full-time employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. During the years ended December 31, 2014, 2013 and 2012, we matched 50% of the first 6% of participant contributions with shares of our common stock. Our matching contributions during the years ended December 31, 2014, 2013 and 2012 were $0.7 million each year.

Table of Contents

18. Quarterly Financial Information (unaudited)

	Quarter Ended March 31, 2014	Quarter Ended June 30, 2014	Quarter Ended September 30, 2014	Quarter Ended December 31, 2014
	(in thousands, except shares and per share amounts)			
Collaboration revenue	$	$	$ 160,639	$ 4,356
Operating expenses:				
Research and development	34,491	28,165	44,895	36,082
General and administrative	6,804	7,057	8,042	7,382
Total operating expenses	41,295	35,222	52,937	43,464
Income (loss) from operations	(41,295)	(35,222)	107,702	(39,108)
Other income (expenses):				
Interest expense	(1,139)	(2,938)	(4,537)	(1,035)
Interest and investment income	168	136	52	(17)
Total other income (expense)	(971)	(2,802)	(4,485)	(1,052)
Loss before income taxes	(42,266)	(38,024)	103,217	(40,160)
Income tax				(183)
Net income (loss)	$ (42,266)	$ (38,024)	$ 103,217	$ (40,343)
Income (loss) per common share:				
Basic	$ (0.87)	$ (0.78)	$ 2.08	$ (0.83)
Diluted	$ (0.87)	$ (0.78)	$ 2.03	$ (0.83)
Weighted average number of common shares outstanding:				
Basic	48,348,767	48,543,853	48,632,888	48,788,917
Diluted	48,348,767	48,543,853	49,735,303	48,788,917

	Quarter Ended March 31, 2013	Quarter Ended June 30, 2013	Quarter Ended September 30, 2013	Quarter Ended December 31, 2013
	(in thousands, except shares and per share amounts)			
Operating expenses:				
Research and development	$ 20,231	$ 26,080	$ 26,857	$ 26,592
General and administrative	7,430	6,675	7,319	6,492
Total operating expenses	27,661	32,755	34,176	33,084
Loss from operations	(27,661)	(32,755)	(34,176)	(33,084)
Other income:				
Interest and investment income	335	164	238	159
Total other income	335	164	238	159

Net loss	$ (27,326)	$ (32,591)	$ (33,938)	$ (32,925)
Basic and diluted net loss per common share	$ (0.57)	$ (0.68)	$ (0.71)	$ (0.68)
Basic and diluted weighted average number of common shares outstanding	47,620,147	47,915,726	48,052,939	48,114,922

Table of Contents

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

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

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2014. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2014, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our management including our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

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

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Internal Control Over Financial Reporting

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

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

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

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

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance

Table of Contents

with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control Integrated Framework (2013)*. Based on its assessment, management believes that, as of December 31, 2014, our internal control over financial reporting is effective based on those criteria.

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

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

The Board of Directors and Stockholders of

Infinity Pharmaceuticals, Inc.

We have audited Infinity Pharmaceuticals, Inc. s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (the COSO criteria). Infinity Pharmaceuticals, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

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

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

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

Table of Contents

In our opinion, Infinity Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2014 and 2013, 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, 2014 of Infinity Pharmaceuticals, Inc. and our report dated February 24, 2015 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts

February 24, 2015

(c) Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal year ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The sections titled Proposal 1 Election of Directors, Board and Committee Meetings, Section 16(a) Beneficial Ownership Reporting Compliance and Corporate Governance Guidelines; Code of Conduct and Ethics appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 15, 2015 are incorporated herein by reference. The information required by this item relating to executive officers may be found in Part I, Item 1 of this report under the heading Business Executive Officers.

Item 11. Executive Compensation

The section titled Compensation of Executive Officers appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 15, 2015 is incorporated herein by reference.

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

The sections titled Stock Ownership of Certain Beneficial Owners and Management and Securities Authorized for Issuance under Equity Compensation Plans appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 15, 2015 are incorporated herein by reference.

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

The sections titled Transactions with Related Persons, Policies and Procedures for Related Persons Transactions, and Determination of Independence appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 15, 2015 are incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The section titled Audit Fees appearing in the definitive proxy statement we will file in connection with our Annual Meeting of Stockholders to be held on June 15, 2015 is incorporated herein by reference.

Table of Contents

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

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

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INFINITY PHARMACEUTICALS, INC.

Date: February 24, 2015

By: /s/ Adelene Q. Perkins
Adelene Q. Perkins

President & Chief Executive Officer

(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Adelene Q. Perkins **Adelene Q. Perkins**	President, Chief Executive Officer; Chair of the Board of Directors *(Principal Executive Officer)*	February 24, 2015
/s/ Lawrence E. Bloch, M.D., J.D. **Lawrence E. Bloch, M.D., J.D.**	Executive Vice President, Chief Financial Officer and Chief Business Officer; Secretary and Treasurer *(Principal Financial Officer, Principal Accounting Officer)*	February 24, 2015
/s/ José Baselga, M.D., Ph.D. **José Baselga, M.D., Ph.D.**	Director	February 23, 2015
/s/ Jeffrey Berkowitz, J.D. **Jeffrey Berkowitz, J.D.**	Director	February 18, 2015
/s/ Anthony B. Evnin, Ph.D. **Anthony B. Evnin, Ph.D.**	Director	February 24, 2015
/s/ Gwen A. Fyfe, M.D. **Gwen A. Fyfe, M.D.**	Director	February 18, 2015
/s/ Eric S. Lander, Ph.D. **Eric S. Lander, Ph.D.**	Director	February 18, 2015
/s/ Norman C. Selby **Norman C. Selby**	Director	February 24, 2015
/s/ Ian F. Smith	Director	February 24, 2015

	Ian F. Smith		
/s/ Michael C. Venuti, Ph.D.	Director		February 24, 2015
Michael C. Venuti, Ph.D.			

Table of Contents

EXHIBIT INDEX

		Incorporated by Reference			
Exhibit No.	**Description**	**Form**	**SEC Filing date**	**Exhibit Number**	**Filed with this 10-K**
3.1	Restated Certificate of Incorporation of the Registrant.	10-Q	8/9/07	3.1	
3.2	Amended and Restated Bylaws of the Registrant.	8-K	03/17/09	3.1	
4.1	Form of Common Stock Certificate.	10-K	3/14/08	4.1	
10.1	Amendment to Amended and Restated Development and License Agreement, dated as of dated July 29, 2014, by and between Infinity Pharmaceuticals, Inc. and Intellikine LLC.	10-Q	11/10/2014	10.1	
10.2	Collaboration and License Agreement, dated as of September 2, 2014, between Infinity Pharmaceuticals, Inc. and AbbVie Inc.	10-Q	11/10/2014	10.2	
10.3	First Amendment to Facility Agreement, dated as of September 22, 2014, between Infinity Pharmaceuticals, Inc. and Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Partners, L.P., and Deerfield International Master Fund, L.P.	10-Q	11/10/2014	10.3	
10.4	Lease Agreement, dated as of September 25, 2014, between Infinity Pharmaceuticals, Inc. and BHX, LLC, as trustee of 784 Realty Trust.	10-Q	11/10/2014	10.4	
10.5	Seventh Amendment to Lease, dated as of November 6, 2014, between Infinity Pharmaceuticals, Inc. and ARE-770/784/790 Memorial Drive, LLC.	10-Q	11/10/2014	10.5	
10.6	Facility Agreement dated February 24, 2014 between Infinity Pharmaceuticals, Inc. and Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Partners, L.P., and Deerfield International Master Fund, L.P. (collectively, the Deerfield Entities).	10-Q	05/06/2014	10.1	
10.7	Form of Warrant to Purchase Common Stock of Infinity Pharmaceuticals, Inc., issued to the Deerfield Entities, together with a schedule of holders and amounts (issued February 24, 2014).	10-Q	05/06/2014	10.2	
10.8	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between the Registrant and Mundipharma International Corporation Limited.	8-K	07/19/12	10.2	
10.9	Termination and Revised Relationship Agreement, dated as of July 17, 2012, between the Registrant and Purdue Pharmaceutical Products L.P.	8-K	7/19/12	10.3	
10.10	Amended and Restated Development and License Agreement, dated as of December 24, 2012, by and between the Registrant and Intellikine, LLC.	10-K	3/5/13	10.4	

Table of Contents

		Incorporated by Reference			
Exhibit No.	Description	Form	SEC Filing date	Exhibit Number	Filed with this 10-K
10.11	Lease Agreement dated July 2, 2002 between IDI and ARE-770/784/790 Memorial Drive LLC (the Lease), as amended by First Amendment to Lease dated March 25, 2003, Second Amendment to Lease dated April 30, 2003, Third Amendment to Lease dated October 30, 2003 and Fourth Amendment to Lease dated December 15, 2003.	8-K	9/18/06	10.36	
10.12	Fifth Amendment to Lease dated July 8, 2011 between the Registrant and ARE-770/784/790 Memorial Drive LLC.	10-Q	8/9/11	10.1	
10.13	Sixth Amendment to Lease dated July 8, 2012 between the Registrant and ARE-770/784/790 Memorial Drive LLC.	10-Q	8/7/12	10.2	
10.14*	Offer Letter between the Registrant and Lawrence E. Bloch, M.D., J.D. dated May 15, 2012.	8-K	7/25/12	10.1	
10.15*	Offer Letter between IDI and Julian Adams dated as of August 19, 2003.	8-K	9/18/06	10.10	
10.16*	Amendment to Offer Letter between IDI and Julian Adams dated as of October 25, 2007.	8-K	10/30/07	99.4	
10.17*	Offer Letter between IDI and Adelene Perkins dated as of February 6, 2002.	8-K	9/18/06	10.11	
10.18*	Amendment to Offer Letter between IDI and Adelene Perkins dated as of October 25, 2007.	8-K	10/30/07	99.5	
10.19*	Pre-Merger Stock Incentive Plan.	8-K	9/18/06	10.18	
10.20*	Form of Incentive Stock Agreement entered into with each of the officers identified on the schedule thereto.	8-K	9/18/06	10.25	
10.21*	Form of Nonstatutory Stock Option Agreement entered into with each of the officers identified on the schedule thereto.	8-K	9/18/06	10.27	
10.22*	2000 Stock Incentive Plan.	S-1	5/9/2000	10.59	
10.23*	Amendment No. 1 to 2000 Stock Incentive Plan; Amendment No. 2 to 2000 Stock Incentive Plan; Amendment No. 3 to 2000 Stock Incentive Plan.	8-K	9/18/06	10.32	
10.24*	Amendment No. 4 to 2000 Stock Incentive Plan.	10-Q	8/9/07	10.1	
10.25*	Amendment No. 5 to 2000 Stock Incentive Plan.	S-8	5/23/08	99.4	
10.26*	Form of Incentive Stock Option Agreement under 2000 Stock Incentive Plan.	8-K	9/18/06	10.33	
10.27*	Form of Nonstatutory Stock Option Agreement under 2000 Stock Incentive Plan.	8-K	9/18/06	10.34	
10.28*	2010 Stock Incentive Plan.	8-K	5/28/10	10.1	
10.29*	Form of Incentive Stock Option Agreement under 2010 Stock Incentive Plan.	8-K	5/28/10	10.2	

Table of Contents

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing date	Exhibit Number	
10.30*	Form of Nonstatutory Stock Option Agreement under 2010 Stock Incentive Plan.	8-K	5/28/10	10.3	
10.31*	Amendment No. 1 to 2010 Stock Incentive Plan.	8-K	12/14/10	99.2	
10.32*	Amendment No. 2 to 2010 Stock Incentive Plan.	8-K	5/18/12	99.1	
10.33*	Amendment No. 3 to 2010 Stock Incentive Plan.	8-K	6/13/13	10.1	
10.34*	Amendment No. 4 to 2010 Stock Incentive Plan.	8-K	6/13/13	10.1	
10.35*	Infinity Pharmaceuticals, Inc. Executive Severance Benefits Plan effective February 6, 2013.	8-K	2/12/13	10.1	
10.36*	2013 Employee Stock Purchase Plan, as amended.	8-K	6/13/13	99.1	
21.1	Subsidiaries of the Registrant. Filed herewith.				X
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. Filed herewith.				X
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.				X
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended. Filed herewith.				X
32.1	Statement of principal executive officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.				X
32.2	Statement of principal financial officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Filed herewith.				X
101	The following materials from the Registrant s Annual Report on Form 10-K for the year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statements of Cash Flows, (iv) the Consolidated Statements of Stockholders Equity, and (v) Notes to Consolidated Financial Statements.				X

* Indicates management contract or compensatory plan

Confidential treatment has been requested and/or granted as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.