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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2013

OR

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

For the transition period from _____ to _____

Commission file number 001-36172

ARIAD Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**22-3106987**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
26 Landsdowne Street, Cambridge, Massachusetts	**02139-4234**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 494-0400

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

Title of each class	Name of each exchange on which registered
Common Stock, $.001 par value	**The NASDAQ Global Select Market**
Preferred Stock Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act: None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See

definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant’s common stock held by nonaffiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate), computed by reference to the price at which the common stock was last sold, as of the last business day of the registrant’s most recently completed second fiscal quarter was approximately $3.1 billion.

As of February 24, 2014, the registrant had 186,323,396 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant’s Definitive Proxy Statement for the 2014 Annual Meeting of Stockholders.

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PART I

ITEM 1: BUSINESS

The following Business Section contains forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain risks, uncertainties and other factors including the risk factors set forth in Part I, Item 1A of this annual report. Unless the content requires otherwise, references to "ARIAD," "company," "we," "our," and "us," in this annual report refer to ARIAD Pharmaceuticals, Inc. and our subsidiaries.

Overview

ARIAD is a global oncology company whose vision is to transform the lives of cancer patients with breakthrough medicines. Our mission is to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest unmet medical need – aggressive cancers where current therapies are inadequate.

Our first approved cancer medicine, Iclusig® (ponatinib), and our product candidates, AP26113 and ridaforolimus, were discovered internally by our scientists based on our expertise in computational and structure-based drug design. Ridaforolimus is being developed for cardiovascular indications by Medinol, Ltd., or Medinol, and ICON Medical Corp., or ICON, pursuant to license agreements entered into in 2005 and 2007, respectively.

Iclusig (ponatinib)

Iclusig is a tyrosine kinase inhibitor, or TKI, which is approved in the United States and Europe for the treatment of adult patients with chronic myeloid leukemia, or CML, and Philadelphia chromosome-positive acute lymphoblastic leukemia, or Ph+ ALL.

Background of CML and Ph+ ALL

CML is a rare form of leukemia that is characterized by an excessive and unregulated production of white blood cells by the bone marrow due to a genetic abnormality that produces the BCR-ABL protein. After a chronic phase of production of too many white blood cells, CML typically evolves to the more aggressive phases referred to as accelerated phase and blast phase. Ph+ ALL is a subtype of acute lymphoblastic leukemia that carries the Ph+ chromosome that produces BCR-ABL. It has a more aggressive course than CML and is often treated with a combination of chemotherapy and tyrosine kinase inhibitors. The BCR-ABL protein is expressed in both of these diseases.

According to the National Cancer Institute, approximately 5,000 new cases of CML and 1,800 new cases of Ph+ ALL are diagnosed each year in the United States. CML and Ph+ ALL patients treated with TKIs can develop resistance or intolerance over time to these therapies. Iclusig was designed by ARIAD scientists to inhibit the BCR-ABL protein, including drug-resistant mutants that arise during treatment. Iclusig is the only approved TKI that is currently known to demonstrate activity against the T315I gatekeeper mutation of BCR-ABL, the most common mutation occurring in approximately 10 percent of patients with drug resistance.

United States

Initial Regulatory Approval in December 2012

On December 14, 2012, we obtained accelerated approval from the U.S. Food and Drug Administration, or FDA, to sell Iclusig. Iclusig was initially approved in the United States for the treatment of adult patients with chronic, accelerated or blast phase CML who are resistant or intolerant to prior TKI therapy, and the treatment of adult patients with Ph+ ALL who are resistant or intolerant to prior TKI therapy. We

commenced sales and marketing of Iclusig in the United States in the first quarter of 2013 through a limited number of specialty pharmacies and specialty distributors and we charged approximately $115,000, on a wholesale basis, for an annual supply of the approved dose of Iclusig. The recommended dose of Iclusig is a 45mg tablet taken once daily, with or without food. As discussed below, on October 31, 2013, we temporarily suspended marketing and commercial distribution of Iclusig in the United States due to safety concerns raised by the FDA, and in December 2013, the FDA approved revised prescribing information for Iclusig. We resumed marketing and commercial distribution of Iclusig in the United States in January 2014.

The FDA approval of Iclusig in December 2012 was based on results from the pivotal Phase 2 PACE (**P**onatinib Ph+ **A**LL and **C**ML **E**valuation) trial in patients with CML or Ph+ ALL who were resistant or intolerant to prior TKI therapy, or who had the T315I mutation of BCR-ABL. In that trial, Iclusig demonstrated robust anti-leukemic activity, with 54 percent of chronic-phase CML patients, including 70 percent of patients with the T315I mutation, achieving a major cytogenetic response, or MCyR, which was the primary endpoint of the PACE trial for chronic-phase patients. A MCyR means that 35 percent or less of the cells in a patient's bone marrow test positive for the Philadelphia chromosome. In patients with advanced disease, 52 percent of accelerated-phase CML patients, 31 percent of blast-phase CML patients and 41 percent of Ph+ ALL patients achieved a major hematologic response, or MaHR, to Iclusig. MaHR was the primary endpoint in the trial for patients with advanced disease. A MaHR, as measured through the counting of white blood cells in blood and bone marrow, means that either a complete hematologic response has occurred or there is no evidence of leukemia. The most common non-hematologic adverse reactions reported (greater than or equal to 20 percent) were hypertension, rash, abdominal pain, fatigue, headache, dry skin, constipation, arthralgia, nausea, and pyrexia. Hematologic adverse reactions included thrombocytopenia, anemia, neutropenia, lymphopenia, and leukopenia.

At the time of its approval in December 2012, the full prescribing information for Iclusig included a boxed warning specifying that arterial thrombosis and hepatotoxicity had occurred in some patients during clinical trials of Iclusig. Specifically, the warning indicated that cardiovascular, cerebrovascular, and peripheral vascular thrombosis, including fatal myocardial infarction and stroke, occurred in Iclusig-treated patients; that serious arterial thrombosis occurred in 8 percent of Iclusig-treated patients; and that hepatotoxicity, liver failure and death occurred in Iclusig-treated patients.

Regulatory Actions in the Fourth Quarter of 2013

On October 9, 2013, we announced results of our review of updated clinical data from the PACE trial of Iclusig and actions that we were taking following consultations with the FDA. In the review of the clinical data, with a median follow up of 24 months, serious arterial thrombosis occurred in 11.8 percent of Iclusig-treated patients, compared to 8 percent after 11 months of follow-up reflected in the then-current U.S. prescribing information. In addition, at 24 months, serious venous occlusion occurred in 2.9 percent of Iclusig-treated patients, compared to 2.2 percent in the then-current U.S. prescribing information. Based upon our review and the FDA consultations, we paused patient enrollment in all clinical trials of Iclusig and the FDA placed a partial clinical hold on all additional patient enrollment in clinical trials of Iclusig. Except with respect to the Phase 3 EPIC clinical trial in adult patients with newly diagnosed CML in the chronic phase, which was discontinued in October 2013 as discussed under "Pipeline" below, patients receiving Iclusig in clinical trials continue on therapy and reductions in Iclusig dose from 45mg daily, the approved dosage, are being implemented or considered on a trial-by-trial basis for patients. Before being able to restart enrollment, we expect that the eligibility criteria for Iclusig trials will be modified. We also sent a written communication to health care providers and informed the European Medicines Agency, or EMA, and other regulatory agencies of the actions described above.

The FDA issued several Drug Safety Communications during the fourth quarter of 2013, which noted an increasing frequency of reports of serious and life-threatening blood clots and severe narrowing of blood vessels (arteries and veins) of patients taking Iclusig, and recommended that health care professionals should consider for each patient whether the benefits of Iclusig treatment are likely to exceed the risks of treatment.

On October 31, 2013, we announced that we were temporarily suspending the marketing and commercial distribution of Iclusig in the United States while we negotiated updates to the United States prescribing information for Iclusig and implementation of a risk mitigation strategy with the FDA. Our actions were taken in response to a request by the FDA.

Re-approval and Resumption of Marketing and Commercial Distribution

On December 20, 2013, we announced that the FDA had approved revised U.S. Prescribing Information, or USPI, and a Risk Evaluation and Mitigation Strategy, or REMS, for Iclusig that allowed for immediate resumption of the marketing and commercial distribution of Iclusig. Iclusig is now approved in the United States for the treatment of adult patients with:

- T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL, and
- Chronic phase, accelerated phase, or blast phase CML or Ph+ ALL for whom no other tyrosine-kinase inhibitor therapy is indicated.

The FDA granted approval of the revised USPI based on its review of the Iclusig clinical trial data, including 24-month follow-up of the PACE trial. The boxed warning has been revised to alert patients and healthcare professionals to the risk of vascular occlusive events and includes a new warning for heart failure. In addition, neuropathy and ocular toxicity have been added as warnings, and dose reduction recommendations have been strengthened. We also agreed to additional post-marketing requirements as described further below. The starting dose of Iclusig remains 45mg daily. On January 17, 2014, we announced that we had resumed marketing and commercial distribution of Iclusig in the United States through an exclusive specialty pharmacy with a wholesale price of approximately $125,000 for an annual supply of the approved dose of Iclusig.

On November 1, 2013, when marketing and commercial distribution of Iclusig was temporarily suspended in the United States, there were approximately 640 patients receiving Iclusig obtained through commercial channels in the United States. Between that time and January 17, 2014, when Iclusig was re-launched, the drug was made available through emergency and single-patient investigational new drug (IND) applications, which were reviewed and approved by the FDA on a case-by-case basis. The FDA approved more than 370 INDs during that period, and more than 300 patients received Iclusig at no cost through this process. We expect most of these patients, many of whom received a three-month supply of Iclusig, to transition from the IND program to commercial supply by the end of the first quarter of 2014. As of January 17, 2014, the Iclusig IND program was no longer accepting new patients.

In addition to focusing our efforts on the re-launch of Iclusig in the United States, in 2014, we plan to invest in studies designed to better understand the safety profile of Iclusig in resistant and intolerant CML and Ph+ ALL patients with the objective of improving the balance of benefit and risk for these patients as post-marketing commitments. We expect that these studies will include a randomized clinical trial of Iclusig in this patient population to evaluate multiple dose levels and we expect to begin this trial in the second half of 2014. Our post-marketing commitments with regulatory authorities also include a pharmacovigilance study and a prospective observational study of safety events.

International Markets

On July 2, 2013, we announced the granting of our marketing authorization for Iclusig by the European Commission, or EC, as an orphan medicinal product for two indications:

- The treatment of adult patients with chronic phase, accelerated phase or blast phase CML who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, and
- The treatment of adult patients with Ph+ ALL who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

We began to obtain pricing and reimbursement approvals in certain European countries in the second half of 2013 and began selling Iclusig in those countries. In 2013, the price charged for an annual supply of Iclusig in these European countries was approximately 80% of the price charged in the United States, on a wholesale basis.

Based upon our announcements and actions taken in October 2013, concerning the safety, marketing and commercial distribution, and further clinical development of Iclusig in the United States, we engaged in discussions with the European Medicines Agency, or EMA, regarding potentially revised prescribing information for Iclusig. On November 8, 2013, the EMA announced that Iclusig's product information should be updated to include strengthened warnings for cardiovascular risk and guidance on optimizing the patient's cardiovascular therapy before starting treatment. In addition, the EMA has commenced an in-depth review, known as an Article 20 referral, of the benefits and risks of Iclusig to better understand the nature, frequency and severity of events obstructing the arteries or veins, the potential mechanism that leads to these side effects and whether there needs to be a revision in the dosing recommendation for Iclusig. We expect the results of this review in mid-2014.

We have also filed marketing authorization applications for Iclusig in Switzerland (which was approved in February 2014), Canada and Australia and plan to file for marketing authorization for Iclusig with regulatory authorities in Japan. Each of these regulatory authorities has its own processes and timelines for the review and approval of marketing authorization applications and such reviews are ongoing at this time. We are discussing the updated Iclusig clinical data with these other foreign regulatory agencies.

Commercial Strategy and Impact on Operations

Our long-term strategy includes the commercialization of Iclusig and future products in the United States, Europe and other selected territories worldwide. In 2012 and 2013, we prepared for, and implemented, the commercial launch of Iclusig in the United States and Europe. In the United States, this included establishing an experienced and trained sales force and other professional staff necessary for an effective launch, implementing systems and processes to support launch, developing tools and materials to be utilized during the commercialization of Iclusig and other activities, and arranging for Iclusig to be provided for patients through a network of specialty pharmacies and specialty distributors. In the United States, in connection with the initial launch of Iclusig, we hired an experienced hematology/oncology team of approximately 60 professionals, including experienced account specialists, regional business directors, corporate account directors and medical science liaisons, who targeted the approximate 5,000 physicians who generate the majority of TKI prescriptions.

In Europe, we established operations with headquarters in Switzerland and hired management and other key personnel who have been building our business infrastructure and capabilities in Europe. We established early-access programs for Iclusig in Europe and established the supply chain in key markets. We hired country-level personnel in key markets in Europe to build company and brand awareness upon approval, while managing the local country pricing and reimbursement process.

In November 2013, following the decision to suspend the marketing and commercial distribution of Iclusig in the United States, we announced a reduction in our work force in the United States and other actions to significantly reduce operating expenses and extend our cash runway. We eliminated approximately 40 percent of the US workforce. In addition to personnel-related expense

reductions, we implemented reductions in expenses related to marketing and commercial distribution of Iclusig in the United States, development and manufacturing activities for Iclusig, including reductions related to the discontinuation of the EPIC clinical trial discussed under "Pipeline" below and certain other trials, as well as AP26113, and reductions in expenses for discovery research and general and administrative activities.

With the resumption of marketing and commercial distribution of Iclusig in the United States in January 2014, we have re-established key operating processes and systems and hired key personnel to implement the re-launch. Given the revised indication statement for Iclusig in the United States, we plan to distribute Iclusig in the United States through an exclusive specialty pharmacy, Biologics, Inc., and manage the marketing and distribution with fewer personnel and lower operating expenses than was required to support the original indication statement and launch in 2013. In January 2014, we entered into an exclusive Master Services Agreement and related statements of work with Biologics, Inc. to provide for the distribution of Iclusig in the United States to patients, physicians, health care providers and payers, including management of all data reporting, patient access and support services and our copay program. The term of the agreement is for one year with two automatically renewing one year extensions unless terminated earlier by either party. The agreement may be terminated by either party on 30 days' notice, upon the bankruptcy or insolvency of either party, or upon a party's breach that is not cured within specified periods.

In January 2014, we also entered into an exclusive agreement with a specialty pharmacy in Australia to provide for the marketing and distribution of Iclusig in Australia and New Zealand. The term of the agreement is seven years from first commercial sale of Iclusig in the territory following reimbursement approval. We expect to receive marketing approval and to launch Iclusig in Australia in the fourth quarter of 2014.

Competition

Novartis and Bristol-Myers Squibb, the current leading marketers of TKI's to treat CML and Ph+ ALL, have reported combined annual revenues in 2013 of nearly $6 billion for these drugs. The worldwide market for these therapies is growing annually. It is estimated that the markets in the United States and Europe account for about 70 percent of those revenues, with Japan accounting for an additional 10 percent. The number of newly diagnosed patients in these three geographies was estimated to be approximately 13,000 in 2013 and is expected to grow to approximately 14,000 in five years, based on data from third-party healthcare information providers. Through chronic treatment of their disease with available TKIs, we estimate that most of these patients will benefit from one or more therapies for over a decade. We believe that the majority of patients will likely switch therapies in the course of managing this chronic disease due to resistance or intolerance. We estimate that there are approximately 3,100 patients in the United States, 3,800 patients in Europe and 600 patients in Japan with CML and Ph+ ALL who will become resistant or intolerant to their existing TKI therapy in 2014, based on healthcare information providers and published data from clinical trials for existing CML therapies. Of the 3,100 U.S. patients, we believe that, under the revised USPI, approximately 1,300 patients will be eligible for Iclusig therapy. Our ability to successfully compete with these other products in the United States, Europe and any other markets where Iclusig is approved will depend on, among other factors, the impact of updated clinical and safety data and a revised indication statement in the United States for Iclusig, the results of on-going reviews of Iclusig data by regulatory authorities in Europe and other countries, the effectiveness of our commercial strategy for marketing Iclusig in each of these jurisdictions, including pricing and reimbursement strategies, the impact of changes to prescribing information and the implementation of a risk management strategy, and the acceptance of Iclusig by patients, the medical community and third-party payors in the United States and Europe, as well as other risks described in the "Risk Factors" set forth in Part I, Item 1A of this Annual Report.

Pipeline

Our product pipeline currently consists of three product candidates – Iclusig (for which we plan to seek approval in additional cancer indications and in additional countries), AP26113 and ridaforolimus.

Iclusig (for Additional Indications and Regions)

In July 2012, we initiated a randomized Phase 3 clinical trial of ponatinib, referred to as the EPIC (**E**valuation of **P**onatinib versus **I**matinib in **C**hronic Myeloid Leukemia) trial, in adult patients with newly diagnosed CML in the chronic phase. We believed that approval in newly diagnosed patients, if achieved, would significantly expand the patient population and associated revenues from sales of Iclusig in CML patients. The trial was 50% enrolled in September 2013. However, on October 18, 2013, based upon the assessment of the clinical trial data discussed above and further discussions with the FDA, we announced the discontinuation of this trial. Patients in the EPIC trial were removed from treatment in the trial and transferred to the care of their physician. Other clinical trials of Iclusig remain on partial clinical hold by the FDA, and we intend to address the FDA's clinical hold concerns in order to enable additional patient enrollment in these studies.

In August 2012, we initiated a multi-center Phase 1/2 clinical trial in Japan of Iclusig in Japanese patients with CML who have failed treatment with dasatinib or nilotinib or who have Ph+ ALL and have failed prior treatment with TKIs. This trial is designed to establish the recommended dose for Iclusig and confirm its anti-leukemic activity in Japanese patients. We expect that this trial should provide the incremental data needed for regulatory approval of Iclusig in resistant or intolerant patients in Japan. The trial is fully enrolled. The primary endpoint for chronic-phase CML patients is MCyR. The primary endpoint for accelerated and blast phase CML patients and for Ph+ ALL patients is MaHR.

In January 2013, we announced an agreement with Newcastle University, U.K., on behalf of the U.K. National Cancer Research Institute, or NCRI, to collaborate on a multi-center, randomized Phase 3 trial, named SPIRIT 3, to assess the impact of switching patients with CML being treated with a first-line TKI, upon suboptimal response or treatment failure, to Iclusig. The SPIRIT 3 trial is designed as a randomized, two-arm, multi-center trial that compares MMR at three years in newly diagnosed patients treated with imatinib to those treated with nilotinib, when patients are "rescued" with Iclusig upon suboptimal response at three or 12 months or treatment failure. Based upon our announcements and actions in October 2013 concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States, this trial has been delayed.

In June 2013, we initiated a Phase 2 clinical trial of Iclusig in adult patients with metastatic and/or resectable gastrointestinal stromal tumors, or GIST. This trial is designed to provide initial clinical data evaluating the efficacy and safety of Iclusig in patients with GIST following failure of prior TKI therapy. The trial is an open label, multicenter trial that will enroll approximately 45 patients. This trial remains on partial clinical hold by the FDA. We are currently addressing, with the FDA, the lifting of the partial clinical hold and expect to resume and complete enrollment in this trial in 2014.

In addition, Iclusig is being studied in various investigator-sponsored trials in settings including first line and second line CML, acute myeloid leukemia or AML, non-small cell lung cancer or NSCLC, and medullary thyroid cancer or MTC. The FDA's partial clinical hold has been lifted on the MTC trial and we expect the clinical hold will be lifted on the other trials in 2014. We expect to initiate additional investigator-sponsored clinical trials in 2014 in indications including Ph+ ALL, blast phase CML, AML and endometrial cancer.

AP26113

AP26113 is an investigational inhibitor of anaplastic lymphoma kinase, or ALK. In non-clinical studies, AP26113 also demonstrated that it can inhibit epidermal growth factor receptor, or EGFR, and c-ros oncogene-1, or ROS1. All of these kinases are clinically validated targets in NSCLC.

We initiated patient enrollment in a Phase 1/2 clinical trial of AP26113 in the third quarter of 2011. The protocol is designed to enroll approximately 50 to 60 patients in the Phase 1 portion of the trial and approximately 125 patients in the Phase 2 portion of the trial. We began enrollment in the Phase 2 portion of the trial in the second quarter of 2013. In September 2013, we announced updated clinical results from the ongoing Phase 1/2 clinical trial. The study results show robust anti-tumor activity in patients with TKI-naïve and crizotinib-resistant ALK-positive NSCLC, including in patients with brain metastases after crizotinib treatment. Crizotinib is the currently available first-generation ALK inhibitor. We plan to commence a pivotal trial of AP26113 in the first quarter of 2014 in ALK-positive NSCLC patients who are resistant to crizotinib, following confirmation of the safety and efficacy profile of the selected dose of AP26113 in the ongoing phase 1/2 clinical trial. We have decided to focus our development efforts on ALK-positive NSCLC patients, both treatment naïve and resistant, and those with CNS activity. We will no longer enroll EGFR, ROS1, or other patients in the ongoing Phase 1/2 clinical trial.

We estimate that currently there are approximately 14,200 ALK-positive patients with advanced and metastatic NSCLC in the United States, Europe and Japan, based on healthcare information providers, who would be potentially eligible for treatment with AP26113, if it were approved.

Ridaforolimus

Ridaforolimus is an investigational inhibitor of the mammalian target of rapamycin, or mTOR, that we discovered and developed internally and later licensed in 2010 to Merck & Co., Inc., or Merck, for oncology applications. Under the license agreement, Merck is responsible for all activities and funds all of the costs related to the development, manufacturing and commercialization of ridaforolimus in oncology. In the third quarter of 2011, Merck filed in the United States and Europe for regulatory approval of ridaforolimus as a maintenance therapy for patients with metastatic soft-tissue and bone sarcomas who had a favorable response to chemotherapy. In June 2012, the FDA issued a complete response letter regarding the New Drug Application, or NDA, filed by Merck, stating that the FDA could not approve the application in its present form and that additional clinical trial(s) would need to be conducted to further assess safety and efficacy of ridaforolimus in this indication. In November 2012, Merck announced that it had formally notified the EMA of Merck's decision to withdraw the marketing authorization application, or MAA, for ridaforolimus, because the data available to date and provided in the MAA were not sufficient to permit licensure of ridaforolimus in the European Union for the maintenance treatment of patients with soft tissue sarcoma or primary malignant bone tumor. In its announcement, Merck stated that it was studying ridaforolimus in combination with other drugs in other tumor types and that it is committed to the ongoing clinical trials of ridaforolimus. On February 20, 2014, we received notice from Merck that it is terminating the license agreement. Per the terms of the license agreement, this termination will become effective nine months from the date of the notice at which time all rights to ridaforolimus in oncology licensed to Merck will be returned to us.

Potential Cardiovascular Indications of Ridaforolimus

As an mTOR inhibitor, ridaforolimus has also been shown in preclinical studies to block the proliferation and migration of vascular smooth muscle cells, the primary cause of narrowing and blockage of injured arteries, and is an analog of sirolimus, another mTOR inhibitor that has been approved for use in drug-eluting stents. Clinical studies have found lower reblockage rates in patients treated with stents that deliver small-molecule drugs, such as sirolimus, everolimus or paclitaxel, a cytotoxic agent, locally to the site of vascular injury. Such stents have become the standard of care for many patients undergoing interventional procedures to open narrowed coronary arteries.

We entered into a non-exclusive license agreement with Medinol Ltd., or Medinol, a leading innovator in stent technology, in January 2005, pursuant to which Medinol agreed to develop and commercialize stents and other medical devices to deliver ridaforolimus to prevent restenosis, or reblockage, of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. In January 2014, we and Medinol announced the initiation of two registration trials in the United States and other countries of Medinol's NIRsupreme ™ Ridaforolimus-Eluting Coronary Stent System incorporating ridaforolimus. The two NIRsupreme clinical trials are randomized, single-blind, global studies which will take place in the United States, Europe, Israel and Canada and plan to enroll approximately 2,200 patients with coronary artery disease. Drug-eluting stents are now implanted in over 425,000 patients yearly in the United States.

The commencement of patient enrollment in Medinol's clinical trials, along with the submission of an investigational device exemption, or IDE, to the FDA, triggers milestone payments to us of $3.8 million, expected in 2014. We are eligible to receive additional regulatory, clinical and commercial milestones of up to $34.8 million, if two products are developed, plus royalties on worldwide sales of approved products. We are responsible for supplying ridaforolimus to Medinol, and Medinol is responsible for the development and commercialization of the medical devices delivering ridaforolimus.

We also entered into a license agreement with ICON Medical Corp., or ICON, an emerging medical device company, in October 2007, to also develop and commercialize stents and other medical devices to deliver ridaforolimus to prevent restenosis, or reblockage, of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. We have retained the right to enter into one additional non-exclusive license agreement, in addition to the licenses granted to Medinol and ICON, to develop and commercialize medical devices delivering ridaforolimus for use in vascular disease. ICON is still involved in the preclinical stages of development of these medical devices. There can be no assurance that we will receive any additional payments under these agreements.

Our Discovery Programs

Our research and development programs are focused on discovering and developing small-molecule drugs that regulate cell signaling for the treatment of cancer. Many of the critical functions of cells, such as cell growth, differentiation, gene transcription, metabolism, motility and survival, are dependent on signals carried back and forth from the cell surface to the nucleus and within the cell through a system of molecular pathways. When disrupted or over-stimulated, such pathways may trigger diseases such as cancer. Our research focuses on exploring cell-signaling pathways, identifying their role in specific cancers and cancer subtypes, and discovering drug candidates to treat those cancers by interfering with the aberrant signaling pathways of cells. The specific cellular proteins blocked by our product candidates have been well characterized and validated as cancer targets. Iclusig and our product candidates, AP26113 and ridaforolimus, have been developed in-house through the integrated use of structure-based drug design and computational chemistry, and their targets have been validated with techniques such as functional genomics, proteomics, and chemical genetics.

Our Intellectual Property

Patents and other intellectual property rights are essential to our business. In general, we file patent applications to protect our technology, inventions and improvements to our inventions that we consider to be patentable and important to our business.

We solely own the following patents and patent applications for our product candidates:

- Iclusig, our pan BCR-ABL inhibitor, is protected by composition of matter claims of U.S. Patent No. 8,114,874, which expires on December 22, 2026, and corresponding international counterparts;
- AP26113, our dual ALK/EGFR kinase inhibitor, is covered by composition of matter claims of a pending U.S. patent application, which, if granted, is expected to expire in 2029, and corresponding international counterparts; and
- Ridaforolimus, our mTOR inhibitor licensed to Merck, is protected by composition of matter claims of U.S. Patent No. 7,091,213, which expires on February 3, 2023, and corresponding international counterparts.

In addition to the composition of matter patents and patent applications mentioned above, we also own other patents and patent applications covering manufacturing processes, formulations and uses that may provide additional protection of the respective product or product candidate.

The remainder of our patent portfolio is focused primarily on inventions involving additional classes of chemical compounds, the mTOR gene, and the components, configurations and use of our ARGENT regulation technologies, which we out-licensed in 2011 and are no longer pursuing internally.

We also rely on unpatented trade secrets and proprietary know-how, some of which is not believed to be adequately protectable through patents. In order to protect our trade secrets, we enter into confidentiality agreements with our employees, consultants, investigators, clinical trial sites, contractors, collaborators and other third parties to whom we disclose confidential information, although protection of trade secrets is generally recognized as challenging.

Our Licenses to Third Parties

Our Collaboration and License Agreements with Merck

In July 2007, we entered into a collaboration agreement with Merck for the joint global development, manufacture and commercialization of ridaforolimus for use in cancer, referred to as the Collaboration Agreement. In May 2010, we entered into an amended and restated agreement with Merck, referred to as the License Agreement, which replaced the Collaboration Agreement, and a related supply agreement.

Under the terms of the License Agreement, we granted Merck an exclusive license to develop, manufacture and commercialize ridaforolimus in oncology, and Merck assumed responsibility for all activities related to the development, manufacture and commercialization of ridaforolimus and agreed to fund 100 percent of all ridaforolimus costs incurred after January 1, 2010. The License Agreement provided that Merck would develop ridaforolimus in multiple oncology indications. If ridaforolimus received regulatory approval, Merck would be responsible for selling ridaforolimus worldwide and would pay us tiered double-digit royalties on global net sales.

Under the License Agreement, Merck paid us an initial up-front fee of $50 million in the second quarter of 2010 and a $25 million milestone payment in the third quarter of 2011, for acceptance of an MAA in Europe, which was subsequently withdrawn by Merck in November 2012. On February 20, 2014, we received notice from Merck that it is terminating the license agreement. Per the terms of the license agreement, this termination will become effective nine months from the date of the notice at which time all rights to ridaforolimus in oncology licensed to Merck will be returned to us.

Our Stent Collaborations

In January 2005, we entered into a license agreement with Medinol and in October 2007 we entered into a license agreement with ICON, to develop and commercialize ridaforolimus-eluting stents and other medical devices to prevent restenosis, or reblockage, of injured vessels following interventions in which stents are used in conjunction with balloon angioplasty. Under these agreements, we granted to each of Medinol and ICON a non-exclusive, world-wide, royalty-bearing license, under our patents and technology relating to ridaforolimus, to develop, manufacture and sell the stents and certain other medical devices that deliver ridaforolimus. We are responsible for supplying Medinol and ICON with, and they have agreed to purchase from us, certain quantities of ridaforolimus for use in its development, manufacture and sale of the stents and other medical devices.

The agreement with Medinol provides for the payment by Medinol to us of up to $39.3 million, which includes an upfront license fee and payments based upon achievement of development, regulatory and commercial milestones, if two products are developed. Through December 31, 2013, we have received $750,000 under the agreement. With the initiation of two registration trials and the filing of an IDE with the FDA announced in January 2014, we expect to receive, during 2014, $3.8 million in milestone payments under the agreement. In addition, we are eligible to receive tiered single-digit royalties based on various minimum levels of stents or other medical devices sold under the agreement. As of December 31, 2013, no products have been approved by regulatory authorities for sale under this agreement.

The agreement with ICON provides for the payment by ICON to us of up to $27.4 million based upon achievement of certain clinical, regulatory and commercial milestones, if two products are developed. Through December 31, 2013, we have received no such payments under the agreement. In addition, we are eligible to receive single-digit royalties based on net sales of stents or other medical devices sold under the agreement. As of December 31, 2013, no products have been approved by regulatory authorities for sale under this agreement. Concurrent with the execution of the license agreement with ICON, we received shares of ICON common stock equal to an ownership interest in ICON of less than 10 percent and certain other rights, including maintenance, anti-dilution and registration rights.

The terms of both the Medinol and ICON agreements extend to the later to occur of the expiration of our patents relating to the rights licensed to Medinol or ICON under the agreement or 15 years after the first commercial sale of a product. The agreements may be terminated by either party for breach following the failure to cure after a 90-day cure period. In addition, Medinol or ICON may terminate their respective agreements upon 30 days' notice to us upon certain events, including if it determines, in its reasonable business judgment, that it is no longer in its business interest to continue the development of a medical device to deliver ridaforolimus. We may terminate the agreements upon 30 days' notice to Medinol or ICON, if we determine that it is no longer in our business interest to continue our development and regulatory approval efforts with respect to ridaforolimus.

Licenses Related to ARGENT Technology

In 2011, we executed three exclusive out-license agreements for separate aspects of our ARGENT cell-signaling regulation technology, which we are no longer pursuing internally. The licenses to these non-core assets provide us with a combination of equity ownership in the licensees, upfront payments, ongoing fees for supply of certain research reagents, and potential milestone and royalty payments linked to clinical, regulatory and sales achievements of the licensees. These out-license arrangements allow us to focus primarily on the development and commercialization of our core compounds, and we do not currently believe that these license agreements are material to our business or that any payments that could be received under these agreements would be material to our results of operations or financial position.

The ARGENT technology platform combines chemistry and genetics to allow specific cell-signaling and gene-expression events to be chemically activated in whole animals and cultured cells. The

technology platform includes a portfolio of distinct small-molecule “dimerizer” compounds optimized for specific applications. Dimerizers bring specific proteins together in cells. The technology allows intracellular processes to be controlled with small molecules, which may be useful in the development of therapeutic vaccines and gene and cell therapy products, and which provide versatile tools for applications in cell biology, functional genomics and drug-discovery research. The technology is being developed to treat human disease through cancer vaccines, cell therapy and gene therapy, in each case featuring small-molecule regulation of cellular activation.

Initial clinical proof of concept has already been demonstrated by the licensees for two product candidates, which utilize our small-molecule dimerizer drug AP1903, in patients with prostate cancer and in patients with hematologic malignancies who have undergone hematopoietic stem cell transplants. AP1903 was discovered and developed by ARIAD scientists.

Research and Development Spending

During each of the three years ended December 31, 2013, 2012 and 2011, we spent approximately $162.9 million, $144.7 million and $77.7 million, respectively, on our research and development activities.

Manufacturing

Iclusig and our drug candidates and preclinical compounds are small molecules that can be readily synthesized by processes that we have developed. We are able to manufacture in-house the quantities of our product candidates necessary for certain preclinical studies. We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of Iclusig or our product candidates. We contract with third-party manufacturers to assist in the development and optimization of our manufacturing processes and methods and to supply our product candidates in sufficient bulk quantities and in suitable dosage forms for use in our clinical trials. We also expect to continue to depend on third-party manufacturers for the supply of our products for commercialization in the United States, Europe and other territories in which we may sell Iclusig.

Iclusig and AP26113 are produced by an established manufacturing process using conventional organic chemical synthesis. The production of Iclusig and AP26113 is based on technology that we believe is proprietary to us. We have established relationships with third parties for the manufacture of Iclusig clinical and commercial supply and have existing agreements for our supply of drug substance, drug product and distribution.

Ridaforolimus is produced by an established manufacturing process using conventional synthetic and natural-product fermentation techniques. The production of ridaforolimus is based in part on technology that we believe is proprietary to us. Pursuant to our License Agreement with Merck, Merck is responsible for supplying the active pharmaceutical ingredient used in ridaforolimus drug product and the finished drug product. Merck may sub-license this technology to contract manufacturers to enable them to manufacture ridaforolimus for Merck’s and our use, including use by our medical device collaborators. Upon termination of the license agreement in November 2014, all rights to ridaforolimus will be returned to us and we will be responsible for all manufacturing required for any continued development of the drug candidate.

Contract manufacturers are subject to extensive governmental regulation and we depend on them to manufacture Iclusig and our product candidates in accordance with the FDA’s current good manufacturing practice regulations, or cGMPs. We have an established quality assurance program designed to ensure that our contract manufacturers produce our compounds in accordance with cGMPs, and other applicable domestic and foreign regulations. We believe that our current contractors comply with such regulations.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. We compete directly and indirectly with other pharmaceutical companies, biotechnology companies and academic and research

organizations, many of whom have greater resources than us. We compete with companies who have products on the market or in development in the same class or for the same indications as our product candidates. We may also compete with organizations that are developing similar technology platforms.

In the area of oncology, pharmaceutical and biotechnology companies such as Amgen Inc., AstraZeneca PLC, Bristol-Myers Squibb Company, Celgene Corporation, Eli Lilly and Company, the Roche Group, GlaxoSmithKline plc, Johnson & Johnson, Merck, Merck KGaA, Novartis AG, Pfizer, Inc., Sanofi-Aventis, Takeda Pharmaceutical Co., Ltd., and Teva Pharmaceutical Industries Ltd. are developing and marketing drugs to treat cancer.

Bristol-Myers Squibb, Novartis and Pfizer are currently marketing TKIs for the treatment of patients with CML that compete with Iclusig. Novartis' imatinib is marketed in the first-line setting, and Bristol-Myers Squibb's dasatinib and Novartis' nilotinib are marketed for patients in the first-line setting, as well as in those who have failed imatinib therapy. These drugs generated nearly $6 billion in revenues during 2013, according to reported results from Bristol-Myers Squibb and Novartis. In the resistance/intolerance market, Teva's omacetaxine mepesuccinate, a non-TKI, was recently approved in the United States and Pfizer's bosutinib was recently approved in the United States and the European Union. These products compete with Iclusig. In Asia, Il-Yang Pharmaceutical recently gained approval in South Korea for radotinib, a locally developed TKI for the treatment of CML patients. We cannot be certain that Iclusig will be commercially successful. In addition to the other challenges related to a company launching its first commercial drug, we will face competition from these other TKIs that are currently approved for the treatment of CML patients and any new products that may be approved. While we believe that Iclusig has a competitive commercial profile compared to the existing TKI therapies on the market, our current estimates of the potential competitiveness of Iclusig compared to existing TKI therapies and the revenues that Iclusig could generate in future periods are subject to various risks and uncertainties, including those set forth in "Risk Factors" in Part I, Item 1A of this Annual Report under the caption "Risks relating to the development and commercialization of our products and product candidates."

Several companies have ALK inhibitors in various stages of development that could compete with AP26113. Pfizer has obtained approval for and is currently marketing crizotinib for patients with ALK-positive non-small cell lung cancer. Novartis, Chugai Pharmaceutical Co., the Roche Group, Tesaro, Xcovery and Astellas also have ALK inhibitors in development.

Pfizer and Novartis are developing mTOR inhibitors for use in cancer that could compete with ridaforolimus. Pfizer's mTOR inhibitor, temsirolimus, and Novartis' mTOR inhibitor, everolimus, are both approved to treat patients with advanced kidney cancer. In addition, everolimus is approved to treat patients with several additional types of cancer, including advanced neuroendocrine tumors of pancreatic origin, subependymal giant cell astrocytoma associated with tuberous sclerosis, and advanced hormone receptor-positive, HER2-negative breast cancer in postmenopausal women in combination with exemestane, after failure of treatment with letrozole or anastrozole.

We may also experience competition from companies that have acquired or may acquire technology from companies, universities, and other research institutions. As these companies develop their technologies, they may develop proprietary positions that may materially and adversely affect us.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as Iclusig and those we are developing. Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the EMA through the MAA process before they may be legally marketed in Europe. Our product candidates will be subject to similar requirements in other countries prior to marketing in

those countries. The process of obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, requires the expenditure of substantial time and financial resources.

United States Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on the applicant. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters;
- product seizures;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLPs, or other applicable regulations;
- submission to the FDA of an Investigational New Drug Application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCPs, and other applicable requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practices, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

As part of the IND, an IND sponsor must submit to the FDA the results of preclinical tests, which may include laboratory evaluations and animal studies, together with manufacturing information and analytical data, and the proposed clinical protocol for the first phase of the clinical trial of the drug. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a "clinical hold" because of safety concerns or perceived procedural deficiencies. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials may begin. A clinical hold may be imposed by the FDA at any time during the life of an IND, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP's. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, must also review and approve each new clinical protocol and patient informed consent form prior to commencement of the corresponding clinical trial at

each institution where a trial is to be performed. Protocols detail, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor patient safety.

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

- *Phase 1:* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2:* Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3:* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution 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.

During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the end-of-Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

If a drug is intended to treat a serious or life threatening condition for which there is an unmet medical need, a company may request that the FDA consider the drug for a fast track development program at the time of submitting its IND or at any time prior to receiving marketing approval. The fast track program is designed to facilitate the development and expedite the review of a new drug for the treatment of specific conditions. If the FDA agrees that the drug meets the criteria for fast track development for treatment of one or more conditions, it will grant fast track status.

Orphan Drug Designation and Approval

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition which is defined as one affecting fewer than 200,000 individuals in the United States or more than 200,000 individuals where there is no reasonable expectation that the product

development cost will be recovered from product sales in the United States. Orphan drug designation must be requested before submitting an NDA and does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If an orphan drug-designated product subsequently receives the first FDA approval for the disease for which it was designed, the product will be entitled to seven years of product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years. Early in 2013, we received orphan drug exclusivity approval of Iclusig for the treatment of adult patients with chronic, accelerated or blast phase CML, who are resistant or intolerant to prior TKI therapy, and the treatment of adult patients with Ph+ ALL who are resistant or intolerant to prior TKI therapy. This seven year exclusivity period began on December 14, 2012, the date of approval of our NDA.

United States Drug Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product.

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth and substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may seek advice and a recommendation from an external advisory committee as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require submission of additional clinical or other data and information which, upon agency review and interpretation, may or may not be deemed by the FDA to satisfy the criteria for approval. The FDA may also issue a “complete response” letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA.

NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. In such a situation, a drug may be approved based on a Phase 2 pivotal trial, as was the case with Iclusig. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Priority review and accelerated approval do not change the standards for approval, but may expedite the approval process.

Expedited Review and Approval

The FDA has various programs, including Fast Track, Breakthrough Therapy designation, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs,

and/or provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months.

Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval, which is described in Subpart H of 21 Code of Federal Regulations Part 314, provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical trials.

In the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was signed into law in July 2012, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. In June 2013, the FDA published a draft Guidance for Industry entitled, "Expedited Programs for Serious Conditions—Drugs and Biologics" which provides guidance on FDA programs that are intended to facilitate and expedite development and review of new drugs as well as threshold criteria generally applicable to concluding that a drug is a candidate for these expedited development and review programs. In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on a new program for Breakthrough Therapy designation. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND. The FDA has already granted this designation to over 30 new drugs. We filed for Breakthrough Therapy designation for AP26113 in ALK-positive NSCLC. Due to the relatively short follow-up of many of the ALK-positive patients treated with AP26113 at that time, our request was not granted by the FDA.

Risk Evaluation and Mitigation Strategy

The Food and Drug Administration Amendments Act of 2007, or FDAAA, created a new section of the FDCA which authorizes the FDA to require a risk evaluation and mitigation strategy, or REMS, when necessary to ensure that the benefits of a drug outweigh the risks. The FDA may require, among other things, that an applicant develop a Medication Guide for distribution to each patient when the drug is dispensed, a communication plan to health care providers, and other elements to insure safe use, or ETASUs. Medication Guides may be safety-related, addressing serious risk(s) (relative to benefits) of which patients should be made aware, and/or efficacy-related, when patient adherence to directions for use is crucial to the drug's effectiveness. Since the enactment of FDAAA, the FDA has considered any new Medication Guide (or safety-related changes to an existing Medication Guide) to be part of a REMS. However, the FDA has the authority to determine, based on the risks of a drug and public health concern, whether a Medication Guide should be required as part of a REMS and may decide the Medication Guide should be required as labeling but not part of a REMS if the FDA determines that a REMS is not necessary to ensure the benefits of the drug outweigh its risks. Depending on the known or anticipated risks, the ETASU may require prescribers to have specific experience, pharmacies, practitioners or healthcare settings that dispense the drug to be specially certified and patients receiving the drug to be regularly monitored or enrolled in a registry. In addition, the drug's sponsor may be required to take reasonable steps to monitor and evaluate those in the healthcare system responsible for implementing ETASU measures. All REMS include a timetable for assessments and may be modified as necessary.

As part of our discussions with the FDA in December 2013 to allow us to resume marketing and commercial distribution of Iclusig in the United States, we have implemented a REMS for Iclusig.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of Iclusig and our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, or BPCA, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling

if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements. We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, biologics license applications and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must address the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, to keep a deferral current or to submit a request for approval of a pediatric formulation.

As part of the FDASIA, Congress made a few revisions to BPCA and PREA, which were slated to expire on September 30, 2012, and made both laws permanent.

Approval or Clearance of Medical Devices

The basic regulatory requirements that manufacturers of medical devices distributed in the United States must comply with are:

- 510(k) premarket notification, unless exempt, or premarket approval application, or PMA
- Establishment registration
- Medical device listing
- Quality system regulation
- Labeling requirements
- Medical Device Reporting

The FDA classifies medical devices into one of three classes based on the perceived level of associated risk. Regulatory control and related requirements increase from Class I to Class III. Before most new devices can be introduced, their manufacturers must obtain marketing clearance through either a premarket notification under Section 510(k) of the FDCA or approval of a PMA.

Drug-eluting stents are classified as Class III devices and must be the subject of an approved PMA before they may be marketed. A PMA must be supported by more detailed scientific evidence including clinical data to demonstrate the safety and efficacy of the device. If the device is determined to present a significant risk, the manufacturer must submit an investigational device exemption, or IDE, prior to commencing clinical trials. If the FDA approves the IDE and the institutional review boards, or IRBs, at the institution at which the clinical trials will be performed approve the clinical protocol and related materials, clinical trials may begin. Upon completion of the clinical trials, and assuming that the results indicate that the product is safe and effective for its intended purpose, the sponsor will then submit a PMA.

PMA approval requires, among other things, the submission of valid scientific evidence in the form of preclinical and clinical data, and a preapproval inspection to determine if the manufacturing facility complies with quality systems/current good manufacturing practices, or QS/cGMP, under the regulation that governs the design and all elements of the manufacture, control and documentation of devices.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

As in the United States, the EMA may grant orphan drug status for specific indications if the request is made before an MAA is made. The EMA considers an orphan medicinal product to be one that affects less than five of every 10,000 people in the European Union. A company whose application for orphan drug designation in the European Union is approved is eligible to receive, among other benefits, regulatory assistance in preparing the marketing application, protocol assistance and reduced application fees. Orphan drugs in the European Union also enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication, unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

ATU

In 2012, the French Health Products Safety Agency, or Afssaps, granted us an Autorisation Temporaire d'Utilisation, or Temporary Authorization for Use, or ATU, for Iclusig in France for the treatment of patients with CML and Ph+ ALL under a nominative program on a patient-by-patient basis. Under an ATU, the Afssaps allows the use of a drug in France before marketing approval has been obtained in France in order to treat serious or rare diseases for which no other treatment is available in that country. Afssaps will only grant an ATU where the benefit of the product outweighs the risk. An ATU is granted for one year and may be renewed. An ATU may be modified, suspended, or withdrawn for reasons of public health or if the conditions under which the ATU was granted are no longer met. The ATU for Iclusig automatically concluded on September 30, 2013, three months following the grant of marketing authorization of Iclusig by the EC. We continue to distribute Iclusig to patients in France under regulatory provisions that allow such use prior to pricing and reimbursement approval.

Reimbursement

Sales of Iclusig and any of our product candidates, if approved, 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 such as Medicare and Medicaid, commercial health insurers and managed care organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign 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. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposes requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part

D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides for funding for the federal government to compare the effectiveness of different treatments for the same illness. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, such a result is a likely outcome of the law and thus it is unclear what if any effect the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study.

The Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the Affordable Care Act or ACA, enacted in March 2010, are expected to have a significant impact on the health care industry. ACA is expected to expand coverage for the uninsured while at the same time contain overall healthcare costs. With regard to pharmaceutical products, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of ACA on pharmaceutical companies as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which are currently being drafted. In addition, although the United States Supreme Court recently upheld the constitutionality of most of the ACA, some states have indicated that they intend to not implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. These challenges add to the uncertainty of the legislative changes enacted as part of ACA.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. At the present time, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. The adoption of other legislative or regulatory proposals could have a material adverse effect on our business, financial condition and profitability.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other United States Regulations

Pharmaceutical companies also are subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws, and the reporting of payments to physicians and teaching hospitals.

Anti-Kickback Laws

U.S. federal laws prohibit fraud and abuse involving state and federal health care programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including the Centers for Medicare & Medicaid Services, or CMS, the Department of Justice, the Office of Inspector General for the Department of Health and Human Services and various state agencies. These anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program. Remuneration is broadly defined to include anything of value, such as cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies or equipment. The anti-kickback laws are broad and prohibit many arrangements and practices that are lawful in businesses outside of the health care industry.

The penalties for violating the anti-kickback laws can be severe. The sanctions include criminal and civil penalties, and possible exclusion from the federal health care programs. Many states have adopted laws similar to the federal anti-kickback laws, and some apply to items and services reimbursable by any payor, including third-party payors.

State and Federal Prohibitions on False Claims

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. Under the False Claims Act, a person acts knowingly if he has actual knowledge of the information or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the information. Specific intent to defraud is not required. Provisions of the False Claims Act allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. The number of filings under these provisions has increased significantly in recent years. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each false claim. Conduct that violates the False Claims Act may also lead to exclusion from the federal health care programs. Given the number of claims likely to be at issue, potential damages under the False Claims Act for even a single inappropriate arrangement could be significant. In addition, various states have enacted similar laws modeled after the False Claims Act that apply to items and services reimbursed under Medicaid and other state health care programs, and, in several states, such laws apply to claims submitted to all payors.

Federal Prohibitions on Health Care Fraud and False Statements Related to Health Care Matters

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and state laws, there are numerous regulations for protecting the privacy and security of protected health information. Additional administrative simplification provisions created the following new federal crimes: health care fraud, false statements relating to health care matters, theft or embezzlement in connection with a health benefit program and obstruction of criminal investigation of health care offenses. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including a private insurer. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for health care benefits, items, or services. The theft or embezzlement statute prohibits knowingly and willfully

embezzling, stealing or otherwise converting or misapplying the money or property of a health care benefit program. The obstruction of criminal investigations of health care offenses statute prohibits willfully preventing, obstructing, misleading or delaying the communication of information and records relating to a violation of a federal health care offense to a criminal investigator. A violation of any of these laws is a felony and may result in fines, or exclusion from the federal health care programs.

The Physician Payment Sunshine Act

The Physician Payment Sunshine Act, or Sunshine Act, which was enacted as part of ACA, requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program, to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals, or to third parties on behalf of physicians or teaching hospitals, during the course of the preceding calendar year. The Final Rule implementing the Sunshine Act, published on February 8, 2013, requires data collection on payments to begin on August 1, 2013. The first annual report, comprised of data collected from August 1, 2013 to December 31, 2013, is due March 31, 2014. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1 million). We are required to collect data on these payments and report such payments.

Our Employees

As of December 31, 2013, we had 307 employees, of whom more than half held post-graduate professional, medical or science degrees. Of these employees, 227 were based in the United States and 80 were based in Europe. During 2013, we hired new employees across the Company to support the commercial launch of Iclusig in the United States and Europe and expanded research and development activities. In November 2013, we eliminated approximately 155 positions in the United States as a consequence of the temporary suspension of marketing and commercial distribution of Iclusig in the United States. In January 2014, in connection with the resumption of marketing and commercial distribution of Iclusig in the United States, we began to hire additional personnel necessary to support commercial activities in the United States. We also expect to hire additional personnel in 2014 in Europe to support the expanding marketing and distribution of Iclusig in selected countries throughout Europe. We have entered into confidentiality, assignment of inventions and non-disclosure agreements with all of our employees and non-competition agreements with all of our senior level employees. None of our employees are covered by a collective bargaining agreement, and we consider relations with our employees to be good.

Our Company

ARIAD was organized as a Delaware corporation in April 1991. Our principal executive offices are located at 26 Landsdowne Street, Cambridge, Massachusetts 02139-4234, and our telephone number is (617) 494-0400. We maintain an internet website at http://www.ariad.com, the contents of which are not incorporated herein. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and all amendments to such reports are made available free of charge through www.sec.gov and the Investor Relations section of our website as soon as reasonably practicable after they have been electronically filed with or furnished to the United States Securities and Exchange Commission, or SEC.

ITEM 1A: RISK FACTORS

THE RISKS AND UNCERTAINTIES DESCRIBED BELOW ARE THOSE THAT WE CURRENTLY BELIEVE MAY MATERIALLY AFFECT OUR COMPANY. IF ANY OF THE FOLLOWING RISKS ACTUALLY OCCUR, THEY MAY MATERIALLY HARM OUR BUSINESS, OUR FINANCIAL CONDITION AND OUR RESULTS OF OPERATIONS.

Risks relating to the development and commercialization of our products and product candidates

We depend heavily on the commercial success of our first new cancer medicine, Iclusig ® (ponatinib), which was approved for sale in the United States in December 2012 and the European Union in July 2013. Marketing and commercial distribution of Iclusig was temporarily suspended in the United States during the fourth quarter of 2013 as a result of safety concerns. Marketing and commercial distribution of Iclusig resumed in January 2014 with revised prescribing information and an updated boxed warning. If we do not achieve commercial success with Iclusig, our business, results of operations and financial condition will suffer, and we will be dependent on the success of our other product candidates.

We obtained accelerated approval from the U.S. Food and Drug Administration, or FDA, on December 14, 2012, to sell our first new cancer medicine, Iclusig, for the treatment of adult patients with chronic, accelerated or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) that is resistant or intolerant to prior TKI therapy. When Iclusig was approved by the FDA, its United States prescribing information, or USPI, included a boxed warning concerning arterial thrombosis, hepatotoxicity and other precautions. We commenced sales and marketing of Iclusig in the United States in January 2013.

In October 2013, we suspended marketing and commercial distribution of Iclusig in the United States based on the FDA's concerns about updated safety data from the pivotal PACE trial of Iclusig. In addition, our clinical trials for Iclusig were placed on partial clinical hold and we discontinued our Phase 3 EPIC trial of Iclusig in adult patients with newly diagnosed CML in the chronic phase. In December 2013, the FDA approved revised USPI, a risk evaluation and mitigation strategy, and a revised box warning, allowing us to resume marketing and commercial distribution, which we commenced in January 2014. Iclusig is now indicated for adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL, and chronic phase, accelerated phase, or blast phase CML or Ph+ ALL for whom no other TKI therapy is indicated.

Iclusig has also been approved for marketing and commercial distribution in the European Union. On July 2, 2013, we announced that the European Commission had granted marketing authorization for Iclusig in the European Union, and we commenced sales efforts in certain European countries in 2013. In November 2013, the European Medicines Agency, or EMA, announced the continued availability of Iclusig for certain adult patients with CML and Ph+ ALL with revised authorized indications and recommendations on measures to reduce safety risk, including the risk of occlusive vascular events. In addition, the EMA has commenced an in-depth review of the benefits and risks of Iclusig, and we expect the results of this review in mid-2014.

Prior to the approval of Iclusig, we had not marketed a therapeutic product. We had no significant revenues from product sales in 2012 and $45.2 million in revenues from product sales in 2013. We expect that a majority of our total revenues in the next several years will be attributable to sales of Iclusig. We cannot be certain that Iclusig will be commercially successful. In addition to the other challenges related to a company launching its first commercial drug, we have faced the challenges of having Iclusig removed from the market in the United States in the fourth quarter of 2013 and re-launching the drug in the first quarter of 2014 with revised prescribing information that reduces the addressable patient population and an updated box warning. In addition, we face intense competition from other TKIs that are currently approved for the treatment of patients with CML, such as nilotinib marketed by Novartis, dasatinib marketed by Bristol-Myers Squibb, bosutinib marketed by Pfizer and omacetaxine mepesuccinate

marketed by Teva Pharmaceutical Industries. Moreover, the FDA, EMA or other regulatory authorities could take additional actions in the future that could further reduce the commercial potential of Iclusig. If we do not achieve commercial success with Iclusig, our business, results of operations and financial condition will suffer, and we will be dependent on the success of our other product candidates.

The commercial success of Iclusig depends on numerous factors, some of which are outside our control. If one or more of these factors negatively affects sales of Iclusig, our business, results of operations and financial condition will be materially harmed.

Our future sales of Iclusig depend on numerous factors, including:

- the impact of the changes required by the FDA in the USPI that reduce the addressable patient population and any changes that may be required by the EMA following its review of the risks and benefits of Iclusig, along with any additional changes that may be required in the future;
- the safety profile of Iclusig, including whether previously unknown side-effects or increased incidence or severity of known side-effects, as compared to those seen during development, are identified with the increased use of Iclusig after approval, such as we announced in the fourth quarter of 2013;
- competition from other TKIs, which compete with Iclusig on the basis of, among other things, efficacy, cost, breadth of approved use and the safety and side-effect profile;
- competition from any additional products for the treatment of CML that are approved by the FDA, the EMA and other regulatory authorities in the future;
- the effectiveness of our commercial strategy for marketing Iclusig and our execution of that strategy, including our pricing strategy and the effectiveness of our efforts to obtain adequate third-party reimbursements;
- receipt of regulatory approvals for Iclusig, and any applicable pricing and reimbursement approvals, in Europe, Japan and other countries or territories outside of the United States and the European Union;
- the acceptance of Iclusig by patients, the medical community and third-party payors, particularly following the temporary suspension of commercial distribution in the fourth quarter of 2013 and the updated prescribing information, including a revised boxed warning;
- results from clinical trials and the receipt of regulatory approvals in any other indications that we may decide to pursue in blood cancers and solid tumors; and
- our ability to meet the demand for commercial supplies of Iclusig and to maintain and successfully monitor commercial manufacturing arrangements for Iclusig with third-party manufacturers to ensure they meet our standards and those of regulatory authorities, which extensively regulate and monitor pharmaceutical manufacturing facilities.

While we believe that Iclusig is an important medicine for patients with resistant or intolerant Philadelphia-positive leukemias, our current estimates of the revenues that Iclusig could generate in future periods have changed as a result of our announcements in the fourth quarter of 2013 concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States and may change further based upon the above factors, and could be wrong. If our revenues, market share and/or other indicators of market acceptance for Iclusig do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline, as occurred in October 2013, when our stock price declined by 87%, from $17.14 per share before our announcements to a low of

$2.15 per share following the announcements. In addition, if one or more of the factors above negatively affects sales of Iclusig, our business, results of operations and financial condition will be materially harmed.

We have never marketed a drug prior to Iclusig, and if we are unable to maintain an effective and specialized sales force and marketing infrastructure, we will not be able to commercialize Iclusig successfully.

In order to successfully commercialize Iclusig, we built a marketing organization and a specialized sales force for Iclusig and commenced marketing and commercial distribution of Iclusig in the United States in January 2013. In addition, in Europe, we have established operations with headquarters in Switzerland and have commenced sales efforts in certain European countries. However, in November 2013, we implemented a significant reduction in workforce, amounting to approximately 40% of our employees in the United States, including commercial sales force positions and other commercial positions in the United States, following the suspension of marketing and commercial distribution of Iclusig in the United States. As we begin to resume these activities, we have recruited and hired additional personnel to commercialize Iclusig in the United States.

Factors that may hinder our ability to successfully market and commercially distribute Iclusig include:

- inability to recruit, retain and effectively manage adequate numbers of effective sales and marketing personnel, particularly in light of our workforce reduction in the fourth quarter of 2013;
- inability to maintain relationships with the single specialty pharmacy with whom we have contracted for distribution of Iclusig in the United States and our other distributors, suppliers and manufacturers;
- inability of sales personnel to obtain access to or convince adequate numbers of physicians to prescribe our products, particularly following the suspension of marketing and commercial distribution of Iclusig in the United States in the fourth quarter of 2013 and the resumption in the first quarter of 2014 with revised prescribing information and a revised boxed warning;
- lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies that have more extensive product lines; and
- unforeseen delays, costs and expenses associated with maintaining our international capabilities, including our international sales and marketing organization and international supply chain and pricing and reimbursement capabilities.

If we are unable to rebuild our sales force and marketing capability for Iclusig in the United States and further build and sustain our sales force for Iclusig in the European Union, we may not be able to generate sufficient product revenue, may generate increased expenses and may never become profitable.

We will need to continue to expend significant time and resources to train our Iclusig sales forces in the United States and the European Union to be credible, persuasive and compliant in discussing Iclusig with the specialists treating the patients indicated under the product's label. We will also need to continue to train our sales force to ensure that a consistent and appropriate message about Iclusig is being delivered to our potential customers, including new information in response to the developments that we announced in the fourth quarter of 2013. In addition, if we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of Iclusig and its proper administration, our ability to successfully commercialize Iclusig could be diminished, which would have a material adverse effect on our business, results of operations and financial condition.

If Iclusig and any of our product candidates are not accepted by patients, physicians and third-party payors, we will not be successful.

Our success is dependent on the commercial acceptance of Iclusig and any of our other product candidates that may be approved. Iclusig and any other approved product candidates may not achieve market acceptance among patients, physicians or third-party payors, even if we have obtained necessary regulatory and any applicable pricing and reimbursement approvals. Physicians and health care payors may conclude that Iclusig or our product candidates are not as safe and/or effective as competing therapies or are not as attractive based on a cost and risk/benefit analysis as alternative treatments. For example, physicians may elect not to prescribe our drugs, and patients may elect not to request or take them for a variety of reasons, including lower demonstrated or perceived clinical safety and efficacy compared to other drugs; prevalence and severity of adverse events or other side effects; lack of cost-effectiveness; lack of reimbursement availability from third-party payors; a decision to wait for the approval of other therapies that are believed to have significant advantages over our drugs and drug candidates; convenience and ease of administration; other potential advantages of alternative treatment methods; or ineffective marketing and distribution support. We expect that the revised prescribing information for Iclusig and our announcements in the fourth quarter of 2013 concerning Iclusig's safety, marketing and commercial distribution may cause physicians and other health care providers to reduce the recommended use of Iclusig.

We believe that recommendations by physicians and acceptance by health care payors will be essential for market acceptance of Iclusig and our product candidates. If Iclusig fails to achieve market acceptance, or our product candidates are approved and fail to achieve market acceptance, we will not be able to generate revenues sufficient to be successful.

Competing drugs or technologies may render some or all of our products or future products noncompetitive or obsolete.

Many well-known pharmaceutical, healthcare and biotechnology companies, which have substantially greater capital, research and development capabilities and experience, are presently engaged in one or more of the following activities:

- developing products based on computational and structure-based drug design;
- conducting research and development programs focused on the same biological targets or for the treatment of the various disease indications on which we are focused; and
- manufacturing, marketing and selling pharmaceutical or medical device products for treatment of diseases in all of the various disease indications in which we or our current or possible future collaborators are focused.

Some of these entities already have competitive products on the market or product candidates in clinical trials or in more advanced preclinical studies than we do. Many of these entities also have substantially greater research, development, manufacturing and marketing resources and experience than us.

For example, Iclusig currently competes with existing therapies that are approved for the treatment of patients with CML who are resistant or intolerant to prior TKI therapies, such as nilotinib marketed by Novartis, dasatinib marketed by Bristol-Myers Squibb, bosutinib marketed by Pfizer and omacetaxine mepesuccinate marketed by Teva Pharmaceutical Industries. Based on the revised USPI for Iclusig approved by the FDA in December 2013, Iclusig may only be promoted for treatment of adult patients with T315I-positive CML and Ph+ ALL and patients for whom no other TKI therapy is indicated, which we expect will result in lower revenues from sales of Iclusig in future periods than we initially anticipated when the drug was approved in December 2012.

Competing drugs or technologies may render some or all of our products or future products noncompetitive or obsolete, and we may not be able to make the enhancements to our products necessary to compete successfully with newly emerging drug products. Competing products on the market or in development may also lead us and our collaborators to revise or cease development of our product candidates in one or more indications for commercial reasons, even where clinical data may be promising. If we are unable to successfully compete in our chosen markets, we will not become profitable.

In order to execute our business plan and achieve the full commercial potential of Iclusig, we intend to seek regulatory approval to commercialize Iclusig outside of the United States and the European Union and to seek approval of additional therapeutic indications and lines of therapy. If we are not successful in these efforts, our business, results of operations and financial condition could be materially harmed.

Based on sales of existing TKIs for the treatment of CML, we believe that there are commercial opportunities for the use of Iclusig globally in additional therapeutic indications and in additional lines of therapy, and we are pursuing these opportunities. We have filed marking authorization applications for Iclusig in Switzerland (which was approved in February 2014), Canada and Australia and plan to file for marketing authorization for Iclusig with regulatory authorities in Japan. However, we are in discussions with the regulatory authorities regarding our announcements in the fourth quarter of 2013 concerning the safety of Iclusig, which could delay, limit or even potentially prevent the approval of Iclusig in these countries.

We also believe that Iclusig has potential applications beyond CML in other blood cancers and solid tumors, such as gastrointestinal stromal tumors, or GIST, acute myeloid leukemia and certain forms of non-small cell lung cancer, or NSCLC. In June 2013, we announced the initiation of a Phase 2 open-label, multicenter trial to evaluate the efficacy and safety of Iclusig in adult patients with metastatic and/or unresectable GIST, following failure of prior TKI therapy. However, this trial remains on partial clinical hold following our announcements in the fourth quarter of 2013 regarding additional safety data.

If we are not successful in obtaining regulatory approval of Iclusig in additional foreign countries and in additional indications and lines of therapy, our business, results of operations and financial condition could be materially harmed.

We may not succeed in developing, receiving regulatory approval and generating product revenues from our product candidate AP26113 or any other product candidates, which would materially harm our business, results of operations and financial condition.

As with all scientific endeavors, we face much trial and error, and we and our collaborators may fail at numerous stages along the way, which could prevent us and our collaborators from successfully developing, obtaining approval for and marketing our product candidate AP26113 and any other product candidates. Factors that could affect the timing and the ability to obtain additional regulatory approvals and to achieve market acceptance and gain market share for AP26113 and any other product candidates include, among others:

- product formulation;
- dose and dosage regimen;
- the ability to obtain timely and sufficient patient enrollment in clinical trials;
- the risk of occurrence of adverse events and other side effects in patients participating in clinical trials;
- the attainment of clinical data that is sufficient to support regulatory approval;
- the ability to manufacture sufficient quantities of product candidates at commercially reasonable costs;
- the ability to fund commercial development and to build or access a sales force in the marketplace for that product candidate;
- the ability to successfully differentiate product candidates from competitive products;

- the ability to educate physicians and build awareness about our product candidates; and
- the ability to sell, market and distribute such product candidates.

We may not receive regulatory approvals within the timeframes we anticipate, or at all, and ultimately we may not succeed in developing or commercializing additional products which will generate revenues for our company. If we are not successful in developing our product candidates, obtaining regulatory approvals and marketing any approved products, our business, results of operations and financial condition will be materially harmed.

Positive results from earlier stage clinical trials may not be replicated in later-stage clinical trials, increased adverse events or safety issues could arise, or regulatory authorities may conclude that clinical data from later-stage clinical trials are not sufficient to support approval or that data from post-approval clinical trials are not sufficient to support broader use of drugs after approval. Regulatory authorities may require changes in the permitted usage of any approved products.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials or following regulatory approval even after achieving promising results in earlier-stage development. Accordingly, the results to date from preclinical studies and clinical trials for Iclusig and AP26113 may not be predictive of the results to be obtained from ongoing or future clinical trials. In addition, regulatory authorities may conclude that data generated from later-stage clinical trials are not sufficient to support approval, or that data obtained following approval may require changes to be made in the permitted usage of any approved products. For example, although we were able to obtain accelerated approval for Iclusig on the basis of data from our pivotal Phase 2 PACE trial without conducting a Phase 3 trial, and we believe that similar prospects for regulatory approval exist for AP26113, we may be required to conduct more clinical trials for AP26113 than we currently anticipate. Moreover, we announced in October 2013 updated data from the PACE trial, in which it was observed that with a median follow up of 24 months, serious arterial thrombosis occurred in 11.8% of Iclusig-treated patients, compared to 8% after 11 months of follow-up reflected in the then-current USPI. Based on this and other follow-up data, marketing and commercial distribution of Iclusig was suspended in October 2013 and, following discussions with the FDA, was permitted to resume in December 2013 with revised prescribing information and a revised boxed warning. The updated prescribing information for Iclusig reduces the addressable patient population for whom Iclusig is indicated, which we expect will negatively impact future revenues associated with Iclusig compared to revenues anticipated based on the label that was initially approved in December 2012.

If positive results from earlier stage trials are not replicated in later-stage trials, if increased adverse events or safety issues arise, if we or our collaborators are required to conduct additional clinical trials or other testing of our product candidates beyond those currently contemplated, or if the permitted usage of Iclusig or any of our other product candidates that are approved is constrained or withdrawn by the FDA or other regulatory authorities, we or our collaborators may be delayed in obtaining, or may not be able to obtain or maintain, marketing approval for these products, and we may lose the opportunity to generate product revenues or to earn additional development or regulatory milestones or royalties. Furthermore, potential competitive commercial factors and our resources may influence future decisions and directions by us or our collaborators on which clinical indications to pursue and when.

Risks relating to our financial position and capital requirements

We have incurred significant losses to date and may never be profitable.

We have incurred significant losses since our formation in 1991, and had an accumulated deficit of $1.1 billion at December 31, 2013. Our losses have resulted principally from costs incurred in research and development of Iclusig and our product candidates AP26113 and ridaforolimus (prior to our license agreement with Merck), from our discovery research activities and from general and administrative costs, including costs incurred to prosecute and protect our intellectual property. In addition, we have incurred

significant expenses in building a commercial organization to market, sell and distribute Iclusig and our other products upon potential regulatory approval in the United States, Europe and other select markets, worldwide. It is likely that we will incur significant operating losses for the foreseeable future, as we continue our research and development activities and re-build our sales and marketing organization to market Iclusig and in anticipation of obtaining regulatory approval to market AP26113, which approval may never occur. If our losses continue and we and our existing collaborators or potential future collaborators are unable to successfully develop, commercialize, manufacture and market Iclusig, AP26113, ridaforolimus and any other product candidates and/or we are unable to enter into additional collaboration agreements or licenses for our intellectual property, we may never generate sufficient revenues to achieve profitability. Even if we and our collaborators are able to commercialize products and we are able to enter into collaboration agreements or licenses in the future, we may never generate sufficient revenues to have profitable operations.

Insufficient funding may jeopardize our research and development programs and may require us to reduce our operations or prevent commercialization of our products and technologies.

We have funded our operations to date primarily through sales of equity securities and, to a lesser extent, by the incurrence of debt from commercial lenders, the receipt of upfront and milestone payments from Merck since July 2007, and product revenues generated by sales of Iclusig beginning in 2013.

As of December 31, 2013, we had cash and cash equivalents totaling $237.2 million. Of this amount, $15 million is maintained as minimum balance requirements related to our bank term loan and $17.1 million was in accounts held by our international subsidiaries. We expect that our cash and cash equivalents as of December 31, 2013 will be sufficient to fund our operations to mid-2015. We will, however, require substantial additional funding for our research and development programs (including pre-clinical development and clinical trials), for the pursuit of regulatory approvals and for establishing or maintaining manufacturing, distribution, marketing and sales capabilities related to Iclusig, AP26113 and any other product candidates that may be approved. We will also require funding for our other operating expenses (including intellectual property protection and enforcement and litigation) as well as capital expenditures to maintain and improve our facilities, equipment and systems and provide for our business.

We may from time to time access funding by issuing common stock or other securities in private placements or public offerings. We are currently a “well-known seasoned issuer,” or WKSI, pursuant to rules of the U.S. Securities and Exchange Commission, or SEC, and have an active registration statement that allows us to sell additional shares of our common stock and other securities. We may also from time to time seek additional funding from technology licensing, or the issuance of debt or other structured funding alternatives. However, such additional funding may not be available at all, or on terms acceptable to us.

If we are not able to secure the significant funding which is required to maintain our operations or continue to fund current or future research and development programs at their current levels or at levels that may be required in the future, we may be required to reduce our operations or to delay, scale back, eliminate or terminate commercialization or further clinical development of Iclusig or clinical trials for one or more of our product candidates. In addition, we may be required to enter into licenses, settlements or other arrangements with third parties on terms that may be unfavorable to us or to sell, license or relinquish rights to develop or commercialize our product candidates, approved products, technologies or intellectual property.

Our ability to use net operating loss and tax credit carryforwards to offset future taxable income may be limited in the future if we do not have sufficient taxable income or due to ownership changes that have occurred or may occur in the future.

As of December 31, 2013, we had tax assets, including net operating loss carryforwards, or NOLs, of $498.7 million in the United States and $122.0 million in foreign territories and U.S. federal research tax credits of $25.9 million, which could be used in certain circumstances to offset our future taxable income or

otherwise payable taxes and therefore reduce our federal and state income tax liabilities. Based on current income tax rates, if fully utilized, our NOLs and other carryforwards could provide a benefit to us of significant future tax savings. However, our ability to use these tax benefits in future years will depend upon our ability to comply with the rules relating to the preservation and use of NOLs and the amount of our otherwise taxable income. If we do not have sufficient taxable income in future years to use the tax benefits before they expire, we will lose the benefit of these NOLs permanently. Consequently, our ability to use the tax benefits associated with our NOLs will depend significantly on our success in generating income from Iclusig and any other product candidates that may be approved.

Additionally, if we undergo an ownership change, the NOLs and tax credit carryforwards would be subject to an annual limit on the amount of the taxable income that may be offset by our NOLs generated prior to the ownership change, and we may be unable to use a significant portion or all of our NOLs to offset taxable income. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period (generally three years). An ownership change could limit our ability to utilize our NOL and tax credit carryforwards for taxable years including or following such "ownership change". Since our October 2013 announcements concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States, there has been an extremely high volume of trading of our stock, and a significant drop in the value of our stock. As a result of the high trading volume, there may be a shift of ownership amongst certain of our stockholders that could result in an ownership change, under Section 382 of the Internal Revenue Code. Limitations imposed on the ability to use NOLs and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would otherwise be required if such limitations were not in effect and could cause such NOLs and tax credits to expire unused, in each case reducing or eliminating the benefit of such NOLs and tax credits. Similar rules and limitations may apply for state income tax purposes. We have adopted a shareholder rights plan in the form of a Section 382 Rights Plan with the intention of reducing the likelihood of an ownership change. However, we cannot be sure that these measures will be effective in deterring or preventing such an ownership change.

Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may seek to raise the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaboration and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect our stockholders' rights or, in the case of debt securities, require us to pay interest that would reduce our cash flows from operations or comply with certain covenants that could restrict our operations. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Forecasting sales of Iclusig may be difficult and revenue recognition may be deferred. If our revenue projections are inaccurate or revenue is deferred, our business may be harmed and our future prospects may be adversely affected.

Iclusig may not be adopted rapidly, or at all, by physicians. Factors that can affect the rate of adoption and that can increase the difficulty of forecasting sales include the following:

- cautionary prescribing behavior, confusion or other concerns regarding the safety and risk-benefit of Iclusig, particularly following our announcements in the fourth quarter of 2013 concerning the safety, marketing and commercial distribution of Iclusig in the United States and the revised prescribing information and boxed warning for Iclusig approved by the FDA in December 2013;

- decisions that may be made by physicians regarding dosing of patients with Iclusig in response to safety concerns or adverse events;
- difficulty in identifying appropriate patients for treatment with Iclusig;
- the cost and availability of reimbursement for the product;
- other aspects of physician education;
- treatment guidelines issued by government and non-government agencies;
- types of cancer for which the product is approved;
- timing of market entry relative to competitive products;
- availability of alternative therapies;
- price of our product relative to alternative therapies, including generic versions of our product, or generic versions of innovative products that compete with our product;
- patients' reliance on patient assistance programs, under which we provide free drug;
- rates of returns and rebates;
- uncertainty of launch trajectory;
- the ability of our third-party manufacturers to manufacture and deliver Iclusig in commercially sufficient quantities;
- the ability of our single specialty pharmacy distributor to process orders in a timely manner and satisfy its other obligations to us;
- the extent of marketing efforts by us and any third-party agents retained by us; and
- side effects or unfavorable publicity concerning our products or similar products.

The extent to which any of these or other factors individually or in the aggregate may impact future sales of Iclusig is uncertain and difficult to predict. Our management must make forecasting decisions regarding future revenue in the course of business planning despite this uncertainty, and actual results of operations may deviate materially from projected results. This may lead to inefficiencies and increased difficulties in operational planning. If our revenues from Iclusig sales are lower than we anticipate or revenue is deferred, we will incur costs in the short term that will result in losses that are unavoidable. A shortfall in our revenue would have a direct impact on our cash flow and on our business generally. In addition, fluctuations in our quarterly results can adversely and significantly affect the market price of our common stock.

Our financial results depend on management's selection of accounting methods and certain assumptions and estimates.

Our accounting policies and methods are fundamental to how we record and report our financial condition and results of operations. Our management must exercise judgment in selecting and applying

many of these accounting policies and methods so they comply with generally accepted accounting principles and reflect management's judgment of the most appropriate manner to report our financial condition and results. In some cases, management must select the accounting policy or method to apply from two or more alternatives, any of which may be reasonable under the circumstances, yet may result in our reporting materially different results than would have been reported under a different alternative.

Certain accounting policies are critical to the presentation of our financial condition and results of operations. The preparation of our financial statements requires us to make significant estimates, assumptions and judgments that affect the amounts of assets, liabilities, revenues and expenses and related disclosures. Significant estimates that may be made by us include assumptions used in the determination of revenue recognition, accrued product development expenses, inventory, leased buildings under construction and stock-based compensation. Although we base our estimates and judgments on historical experience, our interpretation of existing accounting literature and on various other assumptions that we believe to be reasonable under the circumstances, if our assumptions prove to be materially incorrect, actual results may differ materially from these estimates.

Significant additional losses or insufficient funding may cause us to default on certain covenants of our loan documents.

At December 31, 2013, we had $9.1 million outstanding under a term loan agreement with a bank. Pursuant to this loan agreement, we are required to maintain certain financial and non-financial covenants, including minimum cash, cash equivalents and investments of $15 million, a default of any of which would allow the bank to demand payment of its loan. We currently have sufficient liquidity to fund payment of this loan if demand for payment were made. However, if we do not receive sufficient revenues from our collaborations and licenses or from any sales of our products, or if we are unable to raise adequate financing to fund continuing operations or otherwise to refinance our loan, we may not be able to maintain compliance with loan covenants, may be required to pay off the loan and may be required to reduce our spending on operations.

Risks relating to our reliance on third parties

We depend on third-party manufacturers, including sole source suppliers, to manufacture Iclusig and our product candidates and the materials we require for our clinical trials. We may not be able to maintain these relationships and could experience supply disruptions outside of our control.

We rely on a network of third-party manufacturers to manufacture and supply Iclusig for commercial sale and post-approval clinical trials, and our drug candidates for clinical trials and any commercial sales if they are approved. As a result of our reliance on these third-party manufacturers and suppliers, including sole source suppliers of certain components of Iclusig and our product candidates, we could be subject to significant supply disruptions. Our supply chain for sourcing raw materials and manufacturing drug product ready for distribution is a multi-step endeavor. Third-party contract manufacturers supply us with raw materials, and contract manufacturers in the United States convert these raw materials into drug substance and convert the drug substance into final dosage form. Establishing and managing this supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships. Although we attempt to effectively manage the business relationships with companies in our supply chain, we do not have control over their operations.

We require a supply of Iclusig for sale in the United States and Europe, and we will require a supply of Iclusig for sale in other markets if we obtain additional marketing approvals. We currently rely, and expect to continue to rely, on sole source third-party manufacturers to produce starting materials, drug substance, and final drug product, and to package and label Iclusig and our product candidates, until we enter into arrangements with additional or alternative suppliers. While we have identified and expect to qualify and engage back-up third-party manufacturers as additional or alternative suppliers for the commercial supply of Iclusig, we currently do not have such arrangements in place. Moreover, some of these alternative manufacturers will have to be approved by the FDA before we can use them for

manufacturing Iclusig. It is also possible that supplies of materials that cannot be second-sourced can be managed with inventory planning. There can be no assurance, however, that failure of any of our original sole source third party manufacturers to meet our commercial demands for Iclusig in a timely manner, or our failure to engage qualified additional or back-up suppliers for the commercial supply of Iclusig, would not have a material adverse effect on commercialization of Iclusig and our business.

Supply disruptions may result from a number of factors, including shortages in product raw materials, labor or technical difficulties, regulatory inspections or restrictions, shipping or customs delays or any other performance failure by any third-party manufacturer on which we rely. Any supply disruptions could disrupt sales of Iclusig and/or the timing of our clinical trials, which could have a material adverse impact on our business. Furthermore, we may be required to modify our production methods to permit us to economically manufacture our drugs for sale and our drug candidates for clinical trials. These modifications may require us to re-evaluate our resources and the resources of our third-party manufacturers, which could result in abrupt changes in our production methods and supplies.

In the course of providing its services, a contract manufacturer may develop process technology related to the manufacture of our products or drug candidates that the manufacturer owns, either independently or jointly with us. This would increase our reliance on that manufacturer or require us to obtain a license from that manufacturer in order to have Iclusig or our drug candidates manufactured by other suppliers utilizing the same process.

The failure of our third party manufacturers to meet our commercial demands for Iclusig in a timely manner, or our failure to engage qualified additional or back-up suppliers for the commercial supply of Iclusig, would have a material adverse effect on our business, results of operations and financial position.

We rely on a sole specialty pharmacy for distribution of Iclusig in the United States, and the loss of that specialty pharmacy or its failure to distribute Iclusig effectively would adversely affect sales of Iclusig.

In January 2014 we announced that Biologics, Inc. will serve as the sole specialty pharmacy for distribution of Iclusig in the United States. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications for complex or chronic conditions, which often require a high level of patient education and ongoing management. The use of specialty pharmacies involves certain risks, including, but not limited to, risks that these specialty pharmacies will:

- not provide us accurate or timely information regarding their inventories, the number of patients who are using our products or complaints about our products;
- reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support our products;
- not devote the resources necessary to sell our products in the volumes and within the time frames that we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

In addition, our agreement with Biologics may be terminated by either party on 30 days' notice. If our sole specialty pharmacy does not fulfill its contractual obligations to us, or refuses or fails to adequately serve patients, or the agreement is terminated without adequate notice, shipments of Iclusig, and associated revenues, would be adversely affected. In addition, we expect that it may take a significant amount of time if we were required to change our specialty pharmacy.

We have limited experience in conducting clinical trials and are dependent upon the ability of third parties, including contract research organizations, collaborative academic groups, clinical trial sites and investigators, to conduct or to assist us in conducting clinical trials for our product candidates.

Notwithstanding our successful development of Iclusig to date, we have limited experience compared to many other biopharmaceutical companies in designing, initiating, conducting and monitoring the clinical trials necessary to obtain regulatory approval of our product candidates. We are currently conducting clinical trials of Iclusig and of AP26113. We are dependent upon our ability and/or the ability of our collaborators, licensees, contract research organizations, clinical trial sites and investigators to successfully design, initiate, conduct and monitor clinical trials. Failure by us or any of these parties to timely and effectively initiate, conduct and monitor our clinical trials could significantly delay or materially impair our ability to complete clinical trials and/or obtain regulatory approval of our product candidates and, consequently, could delay or materially impair our ability to generate revenues from them.

If any collaborator or licensee terminates its agreement with us or fails to perform its obligations under its agreement with us, or fails to comply with applicable law, the development and commercialization of our product candidates could be delayed or terminated.

Our current or future collaborations and licenses may not result in product candidates that are scientifically or commercially successful or result in the development or commercialization of any product candidates. In addition, disputes may arise in the future with respect to the ownership of rights to technology or product candidates developed with collaborators and licensees, which could have an adverse effect on our ability to develop and commercialize any affected product candidate.

Our current collaboration and license agreements allow, and we expect that any future collaborations and licenses will allow, either party to terminate the agreement for specified material breaches by the other party. If a collaborator or licensee terminates its agreement with us, for breach or otherwise, it may be difficult for us to attract new collaborators or licensees and could adversely affect how we are perceived in the business and financial communities. In addition, a collaborator or licensee could determine that it is in its financial interest to:

- pursue alternative technologies or develop alternative products, either on its own or jointly with others, that may be competitive with the products on which it is collaborating with us or has licensed from us, which could affect its commitment to us;
- pursue higher-priority programs or change the focus of its development programs, which could affect the collaborator's or licensee's commitment to us; or
- choose to devote fewer resources to the marketing of our product candidates, if any are approved for marketing, than it does for product candidates of its own development.

If any of these events occur, the development and commercialization of one or more of our product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

Risks relating to our intellectual property

If our patents do not protect Iclusig or our product candidates, our exclusive commercial rights in the product or product candidate could be compromised, and if any of our approved drugs or product candidates infringe third-party patents, we could be subject to litigation and substantial liabilities.

We have numerous issued patents and patent applications pending in the United States, as well as counterparts in other countries. Our success will depend, in significant part, on our ability to obtain and maintain United States and foreign patent protection for Iclusig and our product candidates, their manufacture and uses; to preserve our trade secrets; and to operate without infringing the proprietary

rights of third parties. In particular, we believe that composition-of-matter claims are the most significant patent claims for companies in our segment of the pharmaceutical industry that focus on small molecule drug candidates that are new chemical compounds. While we have patents or patent applications with composition-of-matter claims for Iclusig and each of our product candidates, only a portion of these patents have been granted to date. We cannot be certain that any patents will issue from our patent applications or, even if patents issue or have issued, that the issued claims will provide us with any significant protection against competitive products or otherwise be valuable commercially.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. U.S. and foreign patent applications typically are maintained in confidence for a period of time after they initially are filed with the applicable patent office. Similarly, publication of discoveries in the scientific literature often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications covering Iclusig, our product candidates or their manufacture or use.

Third parties, including a number of our competitors, have developed competing and/or complementary technologies upon which patent applications have been filed and patents have been granted. These third-party technologies concern in part compounds, compositions, methods of use and production of such compounds and compositions, targets, genes and gene mutations, and the use of such targets, genes and gene mutations to identify drug candidates and develop companion diagnostic methods and corresponding kits. Third-party intellectual property protecting such technologies that are related to our business may cover or conflict with our patent applications, technologies or product candidates as well as those of complementary businesses which our business relies upon. Such conflicts could limit the scope of the patents that we may be able to obtain or may result in the denial of our patent applications. If a third party were to obtain intellectual property protection for any of the foregoing, we may be required to challenge such protection, terminate or modify our programs impacted by such protection or obtain licenses from such third parties, which might not be available on acceptable terms. Also, if a third party were to introduce a product into the market which we believe infringes our patents, we may be required to enforce our patent rights or seek to obtain an injunction or other relief, which could be time-consuming and expensive.

Our patents may be challenged by third parties, in connection with a third party's Abbreviated New Drug Application, or ANDA, or otherwise, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, which could compromise the scope or duration of our exclusive rights in the relevant product. An ANDA can be filed as early as four years after FDA approval of a drug. Other challenges to a patent may be mounted without regard to the date of an FDA approval. Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents as issued or as subsequently limited by any litigation might not contain claims that are sufficiently broad to prevent others from circumventing our patent protection and utilizing our technologies. For instance, the issued patents relating to Iclusig and our product candidates may be limited to a particular molecule or molecules and may not cover similar molecules that have similar clinical properties. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and other companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business could be substantially harmed.

Because of the extensive time required for development, testing and regulatory review of a drug candidate, it is possible that, before any of our drug candidates can be commercialized, any related patent

may expire or remain in force for only a short period following commercialization of our drug candidates, thereby reducing any advantages of the patent. To the extent our approved drugs or drug candidates are not commercialized significantly ahead of the expiration date of any applicable patent, or to the extent we have no other patent protection on such approved drugs or drug candidates, those drugs and drug candidates would not be protected by patents, and we would then need to rely solely on other types of exclusivity, such as orphan drug exclusivity and other types of regulatory exclusivity available under the Food, Drug and Cosmetic Act.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also have entered into confidentiality and invention or patent assignment agreements with our employees and our consultants. Any of these parties may breach the agreements and disclose our proprietary information, and we may not have adequate remedies for any such breach. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position could be harmed.

Risks relating to our operations

Our cost-reducing measures may not result in anticipated savings, could disrupt our business and could yield unintended consequences, which could have a material adverse effect on our business, results of operations and financial condition.

We have implemented significant cost savings measures to mitigate the financial impact of our announcements in the fourth quarter of 2013 concerning the safety, marketing and commercial distribution of, and revised prescribing information for, Iclusig. These measures included a substantial reduction of our workforce in November 2013, amounting to approximately 40% of our employees in the United States, and an ongoing realignment of our cost structure. As part of our reduction in workforce, we eliminated commercial sales force positions for Iclusig and also eliminated positions in research and development and support functions. Although we have recruited additional personnel to commercialize Iclusig in the United States in connection with our resumption of marketing and commercial distribution in January 2014, the earlier reduction in our workforce may limit our ability to complete all of our corporate objectives. In addition, we could be required to implement further workforce and expense reductions in the future. Further workforce and expense reductions could result in reduced progress on our internal programs.

The cost-reducing measures taken by us could yield unintended consequences, such as distraction of our management and employees, the inability to retain and attract new employees, business disruption, a negative impact on morale among remaining employees, attrition beyond our planned reduction in workforce and reduced employee productivity, any of which could have a material adverse effect on our business, results of operations and financial condition. In addition, employees, whether or not directly affected by a reduction, may seek future employment with our business partners or our competitors. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing Iclusig and our product candidates in the future. In addition, our reductions in personnel may subject us to risks of litigation, which could result in substantial cost. We cannot guarantee that the cost reduction measures, or other measures we may take in the future, will result in the expected cost savings, or that any cost savings will be unaccompanied by these or other unintended consequences.

If we fail to manage the size of our workforce and other resources effectively, our business may suffer.

The number of our employees more than doubled in the past two years as we built out the commercial organization that is responsible for the commercialization of Iclusig in the United States and Europe, but was then reduced by approximately 40% of our employees in the United States in the fourth quarter of 2013 in connection with our announcements concerning the updated safety, marketing and commercial distribution and further clinical development of Iclusig.

We have also entered into a new lease to move our corporate headquarters and laboratory facilities to two buildings being constructed by the landlord at 75 Binney Street and 125 Binney Street in Cambridge, Massachusetts. We had planned to move into the new buildings in early 2015. However, in light of our announcements in the fourth quarter of 2013 concerning Iclusig, we are re-assessing our occupancy plans related to this and our other properties. As a result, plans and drawings for the tenant improvements for the Binney Street facility have not been approved by us and have not, at this time, been completed and submitted in accordance with the timelines specified in the lease. If delay of submission of plans and drawings in accordance with the timelines specified in the lease results in a delay in the occupancy date for the facility, we may be required to commence rent payments for the facility prior to occupancy. We are currently in discussions with the landlord regarding revisions to our plans, the timelines related to submission of such plans and other matters in the lease.

In addition, because our drug discovery and development activities are highly technical in nature, we require the services of highly qualified and trained scientists who have the skills necessary to conduct these activities. We need to attract and retain employees with experience in these fields. We face intense competition for our personnel from our competitors, our collaborators and other companies throughout our industry. The growth of local biotechnology companies and the expansion of major pharmaceutical companies into the Cambridge, Massachusetts area have increased competition for the available pool of skilled employees, especially in technical fields, and the high cost of living in the Cambridge area makes it difficult to attract employees from other parts of the country to these areas.

We must respond effectively to these demands and manage our internal organization to accommodate our anticipated needs. If we are unable to manage the size of our workforce and our other resources effectively, there could be a material adverse effect on our business, results of operations and financial condition.

We are currently subject to securities class action litigation and derivative litigation and may be subject to similar or other litigation such as products liability litigation in the future.

The market price of our common stock declined significantly following our October 2013 announcements concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States. Class action lawsuits have been filed alleging, among other things, that we and certain of our officers violated federal securities laws by making allegedly material misrepresentations and/or omissions of material fact regarding clinical and safety data for Iclusig in our public disclosures. The plaintiffs seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees.

In addition, in November and December 2013, purported derivative lawsuits were filed alleging that our directors and certain of our officers breached their fiduciary duties related to the clinical development and commercialization of Iclusig and by making misrepresentations regarding the safety and commercial marketability of Iclusig. The lawsuits also assert claims for unjust enrichment and corporate waste, and for misappropriation of information and insider trading by the officers named as defendants. The plaintiffs seek unspecified monetary damages, changes in our corporate governance policies and internal procedures, restitution and disgorgement from the individually named defendants, and an award of costs and expenses, including attorney's fees.

While we believe we have meritorious defenses, we cannot predict the outcome of these lawsuits. We believe that there may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve these matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we have insurance, coverage could be denied or prove to be insufficient. We are not currently able to estimate the possible cost to us from these lawsuits, as they are currently at an early stage and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. We have not established any reserves for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on these actions could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition. In addition, the uncertainty of the currently pending lawsuits could lead to more volatility in our stock price.

Likewise, if product liability lawsuits are brought against us for injuries or deaths allegedly due to patients' adverse reactions to Iclusig, we may be subject to additional liability. In any event, a potential product liability lawsuit would require significant financial and management resources. Regardless of the outcome, product liability claims may result in injury to our reputation, withdrawal of clinical trial participants, significant costs, diversion of management's attention and resources, substantial monetary awards, loss of revenue, and additional distractions from our efforts to resume marketing and commercial distribution of Iclusig in the United States. Although we have product liability insurance, coverage could be denied or prove to be insufficient. We may not be able to renew or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims, which could also impact the resumption of marketing and commercial distribution of Iclusig in the United States.

Our business has a substantial risk of product liability claims. If we are unable to obtain appropriate levels of insurance, product liability claims could adversely affect our business.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. Prior to obtaining regulatory approval to market our products, we or our collaborators are required to test such products in human clinical trials at health care institutions pursuant to agreements which indemnify such institutions in case of harm caused to patients by our products. We may not be able to avoid significant product liability exposure resulting from use of our products. We have product liability insurance and clinical trial insurance in amounts that we believe are adequate to cover this risk. However, our insurance may not provide adequate coverage against potential liabilities. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as pay uncovered damages awards resulting from a claim brought successfully against us and these damages could be significant and have a material adverse effect on our financial condition. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

Risks associated with operating in foreign countries could materially adversely affect our business.

We have expanded our operations into Europe in order to market Iclusig internationally. In addition, we have manufacturing, collaborative and clinical trial relationships outside the United States. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries;

- changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations could materially adversely affect our business.

In addition, our international operations are subject to regulation under United States law. For example, the Foreign Corrupt Practices Act prohibits United States companies and their representatives from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad. In many countries, the health care professionals we regularly interact with may meet the definition of a foreign government official for purposes of the Foreign Corrupt Practices Act. We are also subject to import and export control laws. Failure to comply with domestic or foreign laws could result in various adverse consequences, including the possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, the imposition of civil or criminal sanctions, the prosecution of executives overseeing our international operations and corresponding adverse publicity and negative perception of our company in foreign countries.

The loss of key members of our scientific and management staff could delay and may prevent the achievement of our research, development and business objectives.

We are substantially dependent on our key officers and members of our staff responsible for areas such as drug development, clinical trials, regulatory affairs, drug discovery, manufacturing, commercial operations, business development and intellectual property protection and licensing. As we continue to expand our capabilities in connection with the launch of Iclusig and in anticipation of the possible launch of any additional commercial products, a loss of key personnel or a failure to properly integrate new personnel could be disruptive. While we have entered into employment agreements with all of our executive officers, these officers may terminate their employment with us at any time. The value to employees of stock-related benefits that vest over time, such as options and restricted stock units, will be significantly affected by movements in our stock price that we cannot control, and may at any point in time be insufficient to counteract more lucrative offers from other companies. The loss of, and failure to promptly replace, any member of our management team could significantly delay and may prevent the achievement of our research, development and business objectives.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development efforts involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and

disposing of these materials comply with the standards prescribed by state, federal and foreign regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We maintain insurance to cover pollution conditions or other extraordinary or unanticipated events relating to our use and disposal of hazardous materials that we believe is appropriate based on the small amount of hazardous materials we generate. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

A breakdown or breach of our information technology systems could subject us to liability or interrupt the operation of our business.

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy breaches by employees and others who access our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. There can be no assurance that our management or diligence efforts will prevent breakdowns or breaches in our systems that could adversely affect our business.

Risks relating to regulatory approvals, pricing and reimbursement

The manufacture, distribution and sale of Iclusig are subject to significant regulatory oversight and restrictions. Regulatory authorities may require the use of a risk mitigation strategy such as the Risk Evaluation and Mitigation Strategy (REMS) required by the FDA for Iclusig. These restrictions and requirements subject us to increased risks and uncertainties, any of which could negatively impact sales of Iclusig.

In connection with the approval to resume marketing and commercial distribution of Iclusig in the United States in December 2013, the FDA required us to implement a Risk Evaluation and Mitigation Strategy, or REMS. The objective of the REMS program is to inform prescribers of the risk of vascular occlusion associated with Iclusig and of the revised USPI. The REMS program includes letters to physicians and professional societies, a fact sheet and information that will be communicated through professional journals and displayed at scientific meetings. In addition, we have agreed to fulfill a series of post-marketing requirements beginning in 2014 to better understand the risks of vascular occlusion and to further explore various doses of Iclusig, including enhanced assessment and prospective observation of patients with vascular occlusive events, continued follow-up monitoring of patients from our Iclusig trials, and a randomized multi-arm trial to characterize a range of Iclusig doses and safe use.

Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of Iclusig, all of which could lead to lower sales volume and revenue. As required by the FDA and other regulatory agencies, the information that we collect while implementing our REMS could result in further required changes to the Iclusig label and prescribing information or require us to take other actions that could have an adverse effect on Iclusig's commercial success, which would have a material adverse effect on our business, financial condition and results of operations.

Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcome is uncertain.

We and our collaborators are currently conducting multiple clinical trials for our clinical product candidates, and we and our collaborators expect to commence additional trials of Iclusig and our product candidates in the future. Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays attributable to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay in or failure to obtain IRB approval to conduct a clinical trial at a prospective site, shortages of available drug supply, or the imposition of a clinical hold by regulatory agencies, such as the partial clinical hold the FDA imposed on additional patient enrollment in all clinical trials of Iclusig in October 2013. Patient enrollment is a function of many factors, including the size of the target patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative established or investigational treatments.

We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with FDA and other applicable requirements and guidelines, often referred to as Good Clinical Practices, and to the extent they fail to enroll patients for our clinical trials, are delayed for a significant time in achieving full enrollment, or fail to follow proper procedures, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the need to engage foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, different standards of medical care, and fluctuating foreign currency exchange rates.

Clinical trials must be conducted in accordance with Good Clinical Practices and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices, or cGMP, conditions. We, the FDA, the EMA or other foreign governmental agencies could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks, such as was reflected in our announcement in October 2013 that the FDA had imposed a partial clinical hold on all clinical trials for Iclusig following our review of additional clinical data from the PACE trial showing that a higher percentage of patients taking Iclusig had experienced serious arterial thrombosis and serious venous occlusion after a median of 24 months of follow-up;
- the time required to determine whether the product candidate is effective may be longer than expected;
- the product candidate may not be more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards;
- our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;

- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- our inability to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- our inability to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events, including patient fatalities that may be attributable to our product candidates, during a clinical trial could cause it to be redone or terminated. Further, some of our clinical trials may be overseen by an independent data monitoring committee, or DMC, and a DMC may recommend a delay or suspension in one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

If clinical trials of any of our product candidates fail, we or our collaborators may not be able to obtain marketing approval for the product candidate that is the subject of the failed clinical trials. The FDA and foreign regulatory agencies could also require additional clinical trials before or after granting of marketing approval for any products, which could result in increased costs and significant delays in the development and commercialization of such products and could result in the withdrawal of such products from the market after initially obtaining marketing approval. Our failure, or the failure of our collaborators, to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent obtaining marketing approval of the product candidate and, after obtaining marketing approval, data from post-approval studies could result in the product being withdrawn from the market, either of which would likely have a material adverse effect on our business.

Iclusig and each of our product candidates will remain subject to ongoing regulatory review even if they receive marketing approval. If we or our collaborators or contractors fail to comply with applicable regulations, we or they may be subject to enforcement action that could adversely affect us.

We and our collaborators and contractors will continue to be subject to extensive regulation by the FDA and other regulatory authorities even after our product candidates are approved. We and our collaborators and contractors will continue to be subject to FDA requirements governing, among other things, the manufacture, packaging, sale, promotion, adverse event reporting, storage and recordkeeping of our approved products. For example, in October 2013, the FDA placed a partial clinical hold on all clinical trials of Iclusig and, at the request of the FDA, we suspended marketing and commercial distribution of Iclusig in the United States following our review of additional clinical data from the pivotal PACE trial of Iclusig. The FDA has also issued Drug Safety Communications concerning Iclusig and is investigating the drug to further understand its risks and potential patient populations in which the benefits of the drug may outweigh the risks. Additionally, the EMA and FDA announced in November 2013 and December 2013, respectively, that the approved indications for Iclusig should be narrowed and its product information should be updated to include strengthened warnings.

If we or any of our collaborators fails to comply with the requirements of the FDA and other U.S. or foreign governmental or regulatory authorities with jurisdiction over our products or operations or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we or our collaborator could be subject to administrative or judicially imposed sanctions, including warning letters; civil or criminal penalties; fines; injunctions; product seizures or detentions; import bans; voluntary or mandatory product recalls; suspension or withdrawal of regulatory approvals; total or partial suspension of production; and refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

We may not be able to obtain government regulatory approval to market our product candidates.

Other than Iclusig, none of our product candidates has been approved for commercialization in any country. Prior to commercialization, each product candidate will be subject to an extensive and lengthy review process in the United States and in other countries. We or our collaborators may not be able to obtain regulatory approval for any product candidates, or even if approval is obtained, the labeling for such products may place restrictions on their use that could materially impact the marketability and profitability of those products. Satisfaction of regulatory requirements, which includes satisfying the FDA and foreign regulatory authorities that the product is both safe and effective for its intended uses, typically takes several years or more depending upon the type, complexity, novelty and safety profile of the product and requires the expenditure of substantial resources. Uncertainty with respect to meeting the regulatory requirements governing our product candidates may result in excessive costs or extensive delays in the regulatory review process.

We will not be able to sell our product candidates if we or our third-party manufacturers fail to comply with current good manufacturing practice requirements.

Before approving any of our product candidates, the FDA will inspect the facility or facilities at which the drug product is manufactured and will not approve the drug candidate unless it is satisfied with our or our third-party manufacturer's compliance with cGMPs. The manufacturing of our product candidates must comply with cGMP requirements of the FDA and similar requirements of regulatory agencies in other countries. These requirements govern, among other things, manufacturing, quality control and documentation procedures. We, or any third-party manufacturer of our product candidates, may not be able to comply with these requirements, which would prevent us from obtaining approval for commercialization of our products. Material changes to the manufacturing processes or a change in manufacturer of products after approvals have been granted are also subject to review and approval by the FDA or other regulatory agencies. Following approval, such facilities are subject to continuing FDA and foreign regulatory requirements including inspections and failure to comply with cGMPs or similar regulations could result in regulatory action including market withdrawals and recalls.

Government and other third-party payors seek to contain costs of health care through legislative and other means. If they fail to provide coverage and adequate reimbursement rates for our products, our revenues will be harmed.

In both domestic and foreign markets, sales of products depend in part upon the availability of reimbursement from third-party payors. Third-party payors include government health programs such as Medicare and Medicaid, managed care providers, and private health insurers. Governments and other third-party payors continually try to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. The Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the Affordable Care Act or ACA, will require discounts under the Medicare drug benefit program and increases the rebates paid by pharmaceutical companies on drugs covered by Medicaid. In addition, the ACA imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers. The financial impact of these discounts, increased rebates and fees and the other provisions of the ACA on our business is unclear, and there can be no assurance that our business will not be materially harmed by future implementation of the ACA.

In addition, third-party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of drugs that they will cover and the amounts that they will pay for drugs. As a result, they may not cover or provide adequate payment for our products. We may have to conduct post-marketing studies in order to demonstrate the cost-effectiveness of Iclusig or any other of our future drugs to such payors' satisfaction.

Such studies might require us to commit a significant amount of management's time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that already are reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products are often reduced by mandatory discounts or rebates required by government health care programs or by privately-negotiated discounts. Moreover, the United States federal government, state governments and private payors frequently pursue actions against pharmaceutical companies alleging that the companies have overstated prices in order to inflate reimbursement rates. Any such action could adversely affect the pricing of and the commercial success of our products.

Any legislation or regulatory changes or relaxation of laws that restrict imports of drugs from other countries also could reduce the net price we receive for our products.

If we market any of our products in a manner that violates federal or state health care laws, including fraud and abuse laws, laws prohibiting off-label promotion, disclosure laws or other similar laws, we may be subject to civil or criminal penalties.

We are subject to health care "fraud and abuse" laws, such as the federal False Claims Act and the anti-kickback provisions of the federal Social Security Act, laws prohibiting off-label product promotion and other similar state and federal laws and regulations. While we have a corporate compliance program designed to actively identify, prevent and mitigate risk through the implementation of compliance policies and systems and the promotion of a culture of compliance, if we are found not to be in full compliance with these laws our business could be materially harmed.

The federal anti-kickback law prohibits knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the ordering, furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program, such as Medicare or Medicaid. The federal statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, patients, purchasers and formulary managers on the other hand, and therefore constrains our marketing practices and our various service arrangements with physicians, including physicians who make clinical decisions to use our products. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as "off-label" uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated "best price" information to the Medicaid Rebate Program.

Although physicians are permitted to, based on their medical judgment, prescribe products for indications other than those cleared or approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses. We market Iclusig for the treatment of adult patients with T315I-positive

CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL and chronic phase, accelerated phase, or blast phase CML or Ph+ ALL for whom no other TKI therapy is indicated, and provide promotional materials to physicians regarding the use of Iclusig in these patient populations. If the FDA determines that our promotional materials or other activities constitute off-label promotion, it could request that we modify our promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It also is possible that other federal, state or foreign enforcement authorities might take action if they believe that the alleged improper promotion led to the submission and payment of claims for an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

Also applicable to some of our practices is the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, certain states have laws governing the privacy of certain health information, which may differ from each other in significant ways and often are not preempted by HIPAA, complicating compliance efforts. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a pharmaceutical manufacturer's products from reimbursement under government programs and criminal fines. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business.

In recent years, several states and localities, including California, the District of Columbia, Maine, Minnesota, Nevada, New Mexico, Vermont and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, health care provider, or HCP payments and other activities. Similar legislation is being considered in other states. Additionally, as part of the ACA, the federal government has enacted the Physician Payment Sunshine provisions. The Physician Payment Sunshine provisions which were enacted in February 2013 and require pharmaceutical manufacturers to publicly report gifts and payments made to physicians and teaching hospitals beginning in March 2014. Many of these requirements are new and the penalties for failure to comply with these requirements will be significant. If we are found not to be in full compliance with these laws, we could face enforcement action, fines and other penalties, and could receive adverse publicity.

The ACA also includes various provisions designed to strengthen significantly fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal health care fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.

If our past or present operations are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal health care programs and/or the curtailment or restructuring of our operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

The sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Future health care reform measures could hinder or prevent commercial success of our drugs and drug candidates.

The U.S. federal government and other governments have shown significant interest in pursuing health care reform. Any government-adopted reform measures could adversely affect the pricing of health care products, including our approved product and/or any future product candidates approved for sale. The continuing efforts of governments, insurance companies, managed care organizations and other payors for health care products to contain or reduce health care costs may adversely affect our ability to set prices we believe are fair for our products or any drugs we may develop and commercialize.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, relating to health care availability, methods of delivery or payment for drugs, or sales, marketing or pricing, may limit our potential revenues, and we may need to revise our research and development or commercialization programs. The pricing and reimbursement environment may change in the future and become more challenging for any of several reasons, including policies advanced by the U.S. government, new health care legislation or fiscal challenges faced by government health administration authorities. Specifically, in the United States and in some foreign jurisdictions there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell products. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our current or future products, which would adversely affect our business, operations and financial results. As discussed above, the recently enacted ACA may have far reaching consequences for companies like us. As a result of this new legislation, substantial changes could be made to the current system for paying for health care in the United States, including changes made in order to extend medical benefits to those who currently lack health insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursement. If reimbursement for our products is substantially less than we expect in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely affected.

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

Risks relating to our common stock

Results of our operations, new clinical and safety data, FDA actions, general market conditions for biotechnology stocks and other factors could result in a sudden change in the value of our stock.

As a biopharmaceutical company, we continue to experience significant volatility in the price of our common stock. In the twelve months ended December 31, 2013, our stock price ranged from a high of $23.00 per share to a low of $2.15 per share. In connection with our October 2013 announcements concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States, our stock price declined by 87%, from $17.14 per share before the announcements to a low of $2.15 per share following the announcements. Some of the many factors that could contribute to such volatility include:

- actual or anticipated results of our commercialization and development of Iclusig in light of our announcements in the fourth quarter of 2013 concerning the revised prescribing information and safety, marketing and commercial distribution and further clinical development of Iclusig;
- our plans for seeking marketing approval and the expected timing of any regulatory approvals of our product candidates, including approval of Iclusig outside of the United States and the European Union;
- additional actual or anticipated actions taken by regulatory agencies that may impact Iclusig and our product candidates;
- evidence of the safety or efficacy of Iclusig and our product candidates, including additional data on serious arterial thrombosis and serious venous occlusion of CML patients being treated with Iclusig or the occurrence of other serious adverse events;
- litigation, including the securities class action and derivative lawsuits pending against us and certain of our officers;
- announcements regarding results and timing of preclinical studies and clinical trials for our product candidates;
- announcements of financial results and other operating performance measures, including product revenues;
- our funding resources and requirements, including announcements of new equity or debt financings;
- the timing of our receipt of, or our failure to receive, future milestones under our license agreements with our stent collaborators;
- announcements regarding existing collaborations or new collaborations or our failure to enter into collaborations;
- announcements regarding product developments or regulatory approvals obtained by companies developing competing products;
- announcements of technological innovations or new therapeutic product candidates;
- developments relating to intellectual property rights, including licensing, litigation and governmental regulation;
- healthcare or cost-containment legislation and public policy pronouncements;
- sales of our common stock by us, our insiders or our other stockholders;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

The stock markets, and the markets for biotechnology stocks in particular, have experienced volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. Investors may not be able to sell when they desire due to insufficient buyer demand and may realize less than, or lose all of, their investment.

Anti-takeover provisions of Delaware law, provisions in our charter and bylaws and our shareholder rights plan could delay, discourage or make more difficult a third-party acquisition of control of us.

Because we are a Delaware corporation, the certain provisions of Delaware law could delay, discourage or make more difficult a third-party acquisition of control of us, even if the change in control would be beneficial to stockholders or the stockholders regard it as such. We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits certain "business combination" transactions (as defined in Section 203) with an "interested stockholder" (defined in Section 203 as a 15 percent or greater stockholder) for a period of three years after a stockholder becomes an "interested stockholder", unless the attaining of "interested stockholder" status or the transaction is pre-approved by our board of directors, the transaction results in the attainment of at least an 85 percent ownership level by an acquirer or the transaction is later approved by our board of directors and by our stockholders by at least a 66 2/3 percent vote of our stockholders other than the "interested stockholder", each as specifically provided in Section 203.

In addition, because our board of directors is a classified board, as described below, Section 141(k)(1) of the DGCL provides that directors may only be removed by the stockholders and then only for "cause". Further, Section 242(b)(1) of the DGCL provides that amendment of our certificate of incorporation requires that the amendment be determined by the board of directors to be advisable and be submitted by our board of directors to our stockholders for action by them and then approved by our stockholders holding a majority of the outstanding shares of our common stock.

Our certificate of incorporation and our bylaws, each as currently in effect, also contain certain provisions that may delay, discourage or make more difficult a third-party acquisition of control of us:

- a classified board of directors, with three classes of directors, each serving for a staggered three-year term, such that not all members of the board of directors may be elected at one time;
- the authorized number of directors may be changed only by resolution of the board of directors;
- any vacancies on the board of directors may only be filled by a majority of the directors then serving, although not a quorum, and not by the stockholders;
- the ability of the board of directors to issue preferred stock that could dilute the stock ownership of a potential unsolicited acquirer and so possibly hinder an acquisition of control of us that is not approved by our board of directors, including through the use of preferred stock in connection with a shareholder rights plan which we could adopt by action of the board of directors;
- record date-setting provisions for annual and special meetings of stockholders and actions by written consent, provisions regulating the conduct of meetings of stockholders and action by written consent, and "advance notice" timing and informational requirements for stockholder nominations to our board of directors at stockholder meetings or for stockholder proposals that can be acted on at stockholder meetings or by written consent; and
- the inability of our stockholders to call a special meeting of stockholders, the limitation of matters to be acted upon at an annual meeting of stockholders to those matters proposed by the Company or properly brought before the meeting and the limitation of matters to be acted upon at a special meeting of stockholders to matters which we place on the agenda for the meeting.

We have adopted a shareholder rights plan in the form of a Section 382 Rights Plan, designed to help protect and preserve our substantial tax attributes primarily associated with our NOLs and research tax credits under Sections 382 and 383 of the Internal Revenue Code and related U.S. Treasury regulations. Although this is not the purpose of the Section 382 Rights Plan, it could have the effect of making it uneconomical for a third party to acquire us on a hostile basis.

These provisions of the DGCL, our certificate of incorporation and bylaws, and our Section 382 Rights Plan may delay, discourage or make more difficult certain types of transactions in which our stockholders might otherwise receive a premium for their shares over the current market price, and might limit the ability of our stockholders to approve transactions that they think may be in their best interest.

ITEM 1B: UNRESOLVED STAFF COMMENTS

None.

ITEM 2: PROPERTIES

We have leased approximately 100,000 square feet of laboratory and office space at 26 Landsdowne Street, Cambridge, Massachusetts through July 2019, with two five-year renewal options. In May 2012, we entered into a three-year operating lease agreement for an additional 26,000 square feet of office space in Cambridge, Massachusetts. We also have a short-term lease for approximately 4,500 square feet of office space in Lausanne, Switzerland.

We have entered into a long-term lease for approximately 386,000 square feet of laboratory and office space in two adjacent, connected buildings under construction in Cambridge, Massachusetts, which is expected to be available for occupancy in early 2015. The lease has a term of 15 years with options to renew for three terms of five years each. In connection with this lease, the landlord is providing a tenant improvement allowance for the costs associated with the design, engineering, and construction of tenant improvements for the leased facility. The tenant improvements will be in accordance with our plans and include fit-out of the buildings to construct appropriate laboratory and office space, subject to approval by the landlord. Given our involvement in the design of tenant improvements for the leased facility, the lease establishes dates by which we are required to submit plans and drawings for tenant improvements consistent with the timeline for completion of the construction, including tenant improvements, and readiness of the facility for occupancy. In connection with the partial clinical hold of Iclusig imposed by the FDA and the temporary suspension of marketing and commercial distribution of Iclusig in the United States in October 2013, plans and drawings for the tenant improvements for this facility have not been approved by us and have not, at this time, been completed and submitted in accordance with the timelines specified in the lease. If delay of submission of plans and drawings in accordance with the timelines specified in the lease results in a delay in the occupancy date for the facility, we may be required to commence rent payments for the facility prior to occupancy. We are currently in discussions with the landlord regarding revisions to our plans, the timelines related to submission of such plans and other matters in the lease.

We have also entered into a long-term lease for approximately 22,000 square feet of office space in a building in Lausanne, Switzerland, which we occupied in early 2014 and will serve as our European headquarters. We believe that any additional space we may require will be available on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

On October 10, 2013, October 17, 2013, December 3, 2013 and December 6, 2013, purported shareholder class actions, styled *Jimmy Wang v. ARIAD Pharmaceuticals, Inc., et al.*, *James L. Burch v. ARIAD Pharmaceuticals, Inc., et al.*, *Greater Pennsylvania Carpenters' Pension Fund v. ARIAD Pharmaceuticals, Inc., et al*, and *Nabil Elmachtoub v. ARIAD Pharmaceuticals, Inc., et al*, respectively, were filed in the United States District Court for the District of Massachusetts (the District Court), naming us and certain of our officers as defendants. The lawsuits allege that we made material misrepresentations and/or omissions of material fact regarding clinical and safety data for Iclusig in our public disclosures during the period from December 12, 2011 through October 8, 2013 or October 17, 2013, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. On January 9, 2014, the District Court consolidated the actions and appointed lead plaintiffs. On February 18, 2014, the

lead plaintiffs filed an amended complaint as contemplated by the order of the District Court. The amended complaint extends the class period for the Securities Exchange Act claims through October 30, 2013. In addition, plaintiffs allege that certain of our officers, present and former directors and certain underwriters made material misrepresentations and/or omissions of material fact regarding clinical and safety data for Iclusig in connection with our January 24, 2013 follow-on public offering of common stock in violation of Sections 11 and 15 of the Securities Act of 1933, as amended. The plaintiffs seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees.

On November 6, 2013, a purported derivative lawsuit, styled *Yu Liang v. ARIAD Pharmaceuticals, Inc., et al.,* was filed in the United States District Court for the District of Massachusetts (the District Court), on behalf of us naming our directors and certain of our officers as defendants. On December 6, 2013, an additional purported derivative lawsuit, styled *Arkady Livitz v. Harvey J. Berger, et al*, was filed in the District Court. The lawsuits allege that our directors and certain of our officers breached their fiduciary duties related to the clinical development and commercialization of Iclusig and by making misrepresentations regarding the safety and commercial marketability of Iclusig. The lawsuits also assert claims for unjust enrichment and corporate waste, and for misappropriation of information and insider trading by the officers named as defendants. On January 23, 2014, the District Court consolidated the actions. On February 3, 2014, plaintiffs designated the *Yu Liang* complaint as the operative complaint as contemplated by the order of the District Court. The plaintiffs seek unspecified monetary damages, changes in our corporate governance policies and internal procedures, restitution and disgorgement from the individually named defendants, and an award of costs and expenses, including attorney fees.

Additional complaints may be filed against us and our directors and officers related to our disclosures and announcements concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States.

We believe that these actions are without merit. At this time, no assessment can be made as to the likely outcome of these lawsuits or whether the outcome will be material to us.

ITEM 4: MINE SAFETY DISCLOSURES

None.

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 "ARIA". The following table sets forth the high and low sales prices of our common stock as quoted on this market for the periods indicated.

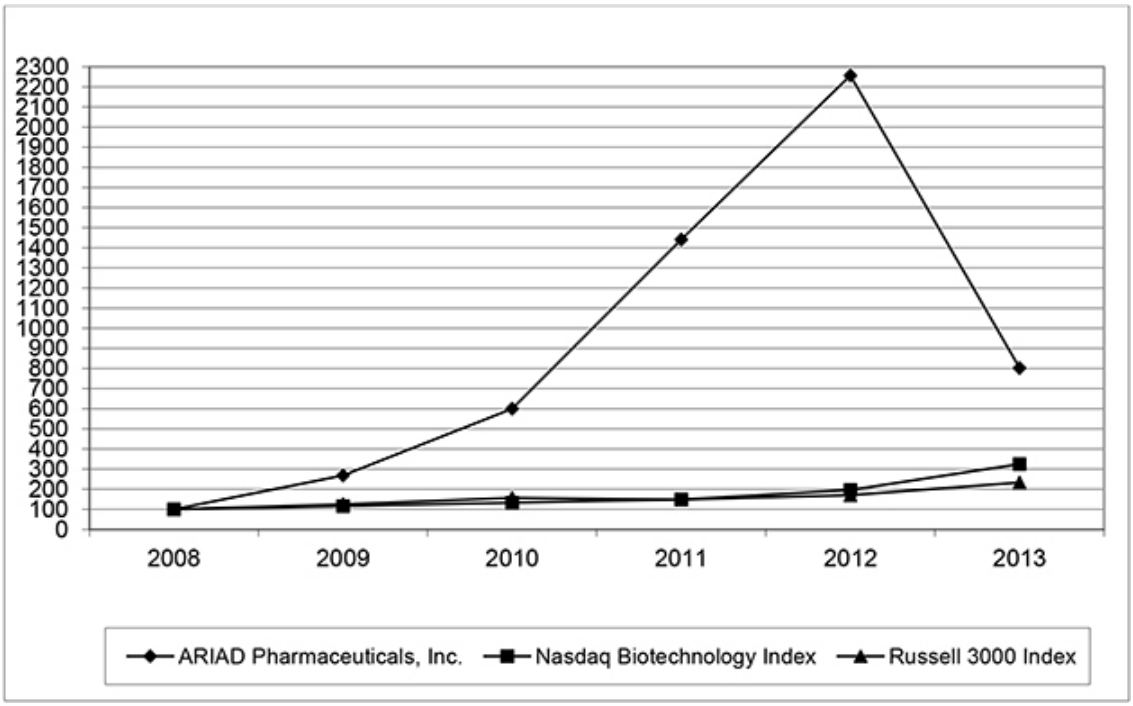
	High	Low
2013:		
First Quarter	$ 22.49	$ 17.15
Second Quarter	20.32	15.35
Third Quarter	23.00	16.95
Fourth Quarter	19.18	2.15
2012:		
First Quarter	$16.76	$ 12.26
Second Quarter	18.10	14.10
Third Quarter	24.36	16.61
Fourth Quarter	25.40	18.83

On February 24, 2014, the last reported sale price of our common stock was $8.63 per share.

Stock Performance Graph

The following graph compares the yearly percentage change in the cumulative total stockholder return on our common stock since December 31, 2008, with the total cumulative return of the NASDAQ Biotechnology Index and the Russell 3000 ® Index, in each of which ARIAD is listed. The Russell 3000 Index measures the stock performance of the largest 3,000 U.S. companies representing approximately 98 percent of the investable U.S. equity market. Since the Russell 3000 Index is specifically designed to provide a comprehensive, unbiased and stable barometer of the broad stock market, we believe it is a meaningful index against which to compare our stock price performance.

The price of a share of common stock is based upon the closing price per share as quoted on NASDAQ on the last trading day of the year shown. The graph lines merely connect year-end values and do not reflect fluctuations between those dates. The comparison assumes $100 was invested on December 31, 2008 in our common stock and in each of the foregoing indices. We did not declare or pay any dividends during the comparison period. The stock price performance as shown in the graph below is not necessarily indicative of future stock price performance.



	2008	2009	2010	2011	2012	2013
ARIAD Pharmaceuticals, Inc.	100.00	268.24	600.00	1,441.18	2,256.47	802.35
Nasdaq Biotechnology Index	100.00	115.63	132.98	148.69	196.12	324.80
Russell 3000 Index	100.00	125.22	156.90	148.35	170.06	232.98

The performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

Stockholders

As of February 24, 2014, the approximate number of holders of record of our common stock was 333.

Dividends

We have not declared or paid dividends on our common stock in the past and do not intend to declare or pay such dividends in the foreseeable future. Our long-term debt agreement prohibits the payment of cash dividends.

Unregistered Sales of Securities

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 6: SELECTED FINANCIAL DATA

The selected financial data set forth below as of December 31, 2013, 2012, 2011, 2010 and 2009 and for each of the years then ended have been derived from the audited consolidated financial statements of the Company, of which the financial statements as of December 31, 2013 and 2012 and for the years ended December 31, 2013, 2012 and 2011 are included elsewhere in this Annual Report on Form 10-K. The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited consolidated financial statements, and the notes thereto, and other financial information included herein.

	Years Ended December 31,				
In thousands, except per share data	2013	2012	2011	2010	2009
Consolidated Statements of Operations Data:					
Revenue:					
Product revenue, net	$ 45,238	$ —	$ —	$ —	$ —
License and collaboration revenue [1]	296	514	25,189	174,460	8,302
Service revenue [1]	27	44	111	4,520	—
Total revenue	45,561	558	25,300	178,980	8,302
Operating expenses:					
Cost of product revenue	9,612	—	—	—	—
Research and development expense	162,900	144,709	77,743	57,985	63,447
Selling, general and administrative expense	146,615	60,909	24,380	16,095	16,888
Total operating expenses	319,127	205,618	102,123	74,080	80,335
Income (loss) from operations	(273,566)	(205,060)	(76,823)	104,900	(72,033)
Other income (expense):					
Interest income (expense), net	(23)	41	(65)	(120)	(171)
Revaluation of warrant liability [2]	—	(15,924)	(46,715)	(19,532)	(7,804)
Foreign exchange gain (loss)	(130)	71	—	—	—
Other income (expense), net	(153)	(15,812)	(46,780)	(19,652)	(7,975)
Provision for income taxes	439	—	—	—	—
Net income (loss)	$ (274,158)	$ (220,872)	$ (123,603)	$ 85,248	$ (80,008)
Net income (loss) per share - basic	$ (1.49)	$ (1.34)	$ (0.93)	$ 0.75	$ (0.86)
- diluted	$ (1.49)	$ (1.34)	$ (0.93)	$ 0.74	$ (0.86)
Weighted average number of shares of common stock outstanding - basic	183,575	164,964	132,375	113,020	93,330
- diluted	183,575	164,964	132,375	114,734	93,330

	As of December 31,				
In thousands	2013	2012	2011	2010	2009
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 237,179	$ 164,414	$ 306,256	$ 103,630	$ 40,362
Working capital	172,769	119,484	282,195	88,775	8,212
Total assets	370,894	180,193	320,712	120,030	65,010
Long-term debt, capital lease and facility lease obligations	104,312	9,100	11,215	8,294	142
Warrant liability [2]	—	—	58,639	28,815	11,363
Accumulated deficit	(1,051,993)	(777,835)	(556,963)	(433,360)	(518,608)
Stockholders' equity (deficit)	185,517	112,851	220,141	64,076	(89,016)

[1] During 2010, we modified our collaboration agreement with Merck and entered into a license agreement, as described in Note 2 to the consolidated financial statements. As a result of this modification, additional payments were received and deferred revenue was recognized. Pursuant to the license agreement, we provided services to Merck, recognized as service revenue.

(2) In 2009, we issued warrants that were accounted for as a derivative liability. The change in fair value of outstanding warrants was recorded in our consolidated statements of operations. Upon exercise of all remaining warrants in January and February 2012, the balance of the warrant liability was credited to stockholders' equity and the liability was eliminated. See Note 11 to the consolidated financial statements.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information set forth below should be read in conjunction with the audited consolidated financial statements, and the notes thereto, and other financial information included herein.

Overview

ARIAD is a global oncology company whose vision is to transform the lives of cancer patients with breakthrough medicines. Our mission is to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest unmet medical need – aggressive cancers where current therapies are inadequate.

Our first approved cancer medication, Iclusig® (ponatinib), and our product candidates, AP26113 and ridaforolimus, were discovered internally by our scientists based on our expertise in computational and structure-based drug design. Ridaforolimus is being developed for cardiovascular indications by Medinol, Ltd., or Medinol, and ICON Medical Corp., or ICON, pursuant to license agreements entered into in 2005 and 2007, respectively.

Iclusig (ponatinib)

United States

On December 14, 2012, we obtained accelerated approval from the U.S. Food and Drug Administration, or FDA, to sell our first new cancer medicine, Iclusig. Iclusig is a tyrosine kinase inhibitor, or TKI, that was initially approved in the United States for the treatment of adult patients with chronic, accelerated or blast phase chronic myeloid leukemia, or CML, who were resistant or intolerant to prior TKI therapy, and the treatment of adult patients with Philadelphia chromosome-positive acute lymphoblastic leukemia, or Ph+ ALL, who were resistant or intolerant to prior TKI therapy. The approved United States prescribing information, or USPI, included a boxed warning specifying that arterial thrombosis and hepatoxicity had occurred in some patients during clinical trials of Iclusig. We commenced sales and marketing of Iclusig in the United States in the first quarter of 2013 through a limited number of specialty pharmacies and specialty distributors and we charged approximately $115,000, on a wholesale basis, for an annual supply of the approved dose of Iclusig.

On October 9, 2013, we announced results of our review of updated clinical data from the pivotal PACE (**P**onatinib Ph+ **A**LL and **C**ML **E**valuation) clinical trial of Iclusig and our actions following consultations with the FDA. In the review of the clinical data, with a median follow up of 24 months, serious arterial thrombosis occurred in 11.8% of Iclusig-treated patients, compared to 8% after 11 months of follow-up reflected in the previously approved USPI. In addition, at 24 months, serious venous occlusion occurred in 2.9% of Iclusig-treated patients, compared to 2.2% in the previously approved USPI. Based upon our review and the FDA consultations, we paused patient enrollment in all clinical trials of Iclusig and the FDA placed a partial clinical hold on all additional patient enrollment in clinical trials of Iclusig.

On October 31, 2013, in response to a request by the FDA, we announced that we temporarily suspended the marketing and commercial distribution of Iclusig in the United States while we negotiated updates to the USPI for Iclusig and the implementation of a risk mitigation strategy with the FDA.

On December 20, 2013, we announced that the FDA had approved revised USPI and a Risk Evaluation and Mitigation Strategy, or REMS, that allowed for the immediate resumption of the marketing and commercial distribution of Iclusig. Iclusig is now approved in the United States for the treatment of adult patients with:

- T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL, and

- Chronic phase, accelerated phase, or blast phase CML or Ph+ ALL for whom no other tyrosine-kinase inhibitor therapy is indicated.

The FDA granted approval of the revised USPI based on its review of the Iclusig clinical trial data, including 24-month follow-up of the PACE trial. The boxed warning has been revised to alert patients and healthcare professionals to the risk of vascular occlusive events and includes a new warning for heart failure. In addition, neuropathy and ocular toxicity have been added as warnings, and dose reduction recommendations have been strengthened. We also agreed to additional post-marketing requirements as described further below. The starting dose of Iclusig remains 45mg daily. On January 17, 2014, we announced that we had resumed marketing and distribution of Iclusig in the United States through an exclusive specialty pharmacy with a wholesale price of approximately $125,000 for an annual supply of the approved dose of Iclusig.

In addition to focusing our efforts on the re-launch of Iclusig in the United States, in 2014, we plan to invest in studies designed to better understand the safety profile of Iclusig in resistant and intolerant CML and Ph+ ALL patients, with the objective of improving the balance of benefit and risk for these patients as post-marketing commitments. We expect that these studies will include a randomized clinical trial of Iclusig in this patient population to evaluate multiple dose levels, and we expect to begin this trial in the second half of 2014. Our post-marketing commitments with regulatory authorities also include a pharmacovigilance study and a prospective observational study of safety events.

Except as noted below with respect to the EPIC clinical trial of Iclusig, patients receiving Iclusig in clinical trials continue on therapy and reductions in Iclusig dose from 45mg daily, the approved dosage, are being implemented or considered on a trial-by-trial basis for patients. Before being able to restart enrollment, we expect that the eligibility criteria for the various Iclusig trials will also need to be modified. On December 20, 2013, we announced that the partial clinical hold was lifted for a trial of Iclusig for the treatment of medullary thyroid cancer. We expect that the partial clinical hold will be lifted for other Iclusig trials in 2014.

In November 2013, following the decision to suspend the marketing and commercial distribution of Iclusig in the United States, we announced a reduction in our work force in the United States and other actions to significantly reduce operating expenses and extend our cash runway. We eliminated approximately 40 percent of the U.S. workforce. In addition to personnel-related expense reductions, we implemented reductions in expenses related to marketing and commercial distribution of Iclusig in the United States, development and manufacturing activities for Iclusig, including reductions related to the discontinuation of the EPIC clinical trial discussed below and certain other trials, as well as AP26113, and reductions in expenses for discovery research and general and administrative activities.

International Markets

In 2012, we established operations in Europe, with headquarters in Switzerland, in preparation for the European approval of Iclusig. We hired management and other key personnel in Switzerland and other selected countries in Europe. We established early-access programs for Iclusig in Europe, established the supply chain in key markets and implemented initial pricing and reimbursement activities in various countries.

On July 2, 2013, we announced the granting of our marketing authorization for Iclusig by the European Commission, or EC, as an orphan medicinal product for two indications:

- The treatment of adult patients with chronic phase, accelerated phase or blast phase CML who are resistant to dasatinib or nilotinib; who are intolerant to dasatinib or nilotinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation, and

- The treatment of adult patients with Ph+ ALL who are resistant to dasatinib; who are intolerant to dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or who have the T315I mutation.

We began to obtain pricing and reimbursement approvals in certain European countries in 2013 and began selling Iclusig in those countries. In 2013, the price charged for an annual supply of Iclusig in these European countries was approximately 80% of the price charged in the United States, on a wholesale basis.

Based upon the announcements and actions taken in October 2013 concerning the safety, marketing and commercial distribution, and further clinical development of Iclusig in the United States, we engaged in discussions with the European Medicines Agency, or EMA, regarding revised prescribing information for Iclusig. On November 8, 2013, the EMA announced that Iclusig's product information should be updated to include strengthened warnings for cardiovascular risk and guidance on optimizing the patient's cardiovascular therapy before starting treatment. In addition, the EMA has commenced an in-depth review, known as an Article 20 referral, of the benefits and risks of Iclusig to better understand the nature, frequency and severity of events obstructing the arteries or veins, the potential mechanism that leads to these side effects and whether there needs to be a revision in the dosing recommendation for Iclusig. We expect the results of this review in mid-2014.

We have also filed marketing authorization applications for Iclusig in Switzerland (which was approved in February 2014), Canada and Australia and plan to file for marketing authorization for Iclusig with regulatory authorities in Japan. Each of these regulatory authorities has its own processes and timelines for the review and approval of marketing authorization applications and such reviews are ongoing at this time. We are discussing the announcements regarding updated Iclusig clinical data with these other foreign regulatory agencies.

Other Development Matters

In July 2012, we initiated a randomized Phase 3 clinical trial, the EPIC trial, of ponatinib, in adult patients with newly diagnosed CML in the chronic phase. However, in October 2013, based upon the assessment of the clinical trial data discussed above and further discussions with the FDA, we announced the discontinuation of this trial.

In August 2012, we initiated a multi-center Phase 1/2 clinical trial in Japan of Iclusig in Japanese patients with CML who have failed treatment with dasatinib or nilotinib or who have Ph+ ALL and have failed prior treatment with TKIs. The trial is fully enrolled. In January 2013, we announced an agreement with Newcastle University, U.K., on behalf of the U.K. National Cancer Research Institute, or NCRI, to collaborate on a multi-center, randomized Phase 3 investigator sponsored trial, named SPIRIT 3. This trial is designed to assess the impact of switching CML patients treated with a first-line TKI to Iclusig, upon suboptimal response or treatment failure. Based upon our announcements and actions in October 2013 concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States, this trial has been delayed.

We are also developing Iclusig in other blood cancers and solid tumors, such as gastrointestinal stromal tumors, or GIST, acute myeloid leukemia and certain forms of non-small cell lung cancer, or NSCLC. In June 2013, we announced the initiation of a Phase 2 trial to evaluate the efficacy and safety of Iclusig in adult patients with metastatic and/or unresectable GIST, following failure of prior TKI therapy. This trial remains on partial clinical hold by the FDA and we intend to address the FDA's clinical hold concerns in order to initiate further enrollment.

In addition, Iclusig is being studied in various investigator-sponsored trials in indications including first line and second line CML, acute myeloid leukemia or AML, non-small cell lung cancer or NSCLC, and medullary thyroid cancer or MTC. The FDA's partial clinical hold has been lifted on the MTC trial and we expect the clinical hold will be lifted on the other trials in 2014. We expect to initiate additional investigator-sponsored clinical trials in 2014 in indications including Ph+ ALL, blast phase CML, AML and endometrial cancer.

AP26113

AP26113 is an investigational inhibitor of anaplastic lymphoma kinase, or ALK. In non-clinical studies, AP26113 also demonstrated that it inhibits epidermal growth factor receptor, or EGFR, and c-ros oncogene-1, or ROS1. All of these kinases are clinically validated targets in NSCLC.

We initiated patient enrollment in a Phase 1/2 clinical trial of AP26113 in the third quarter of 2011. The protocol was designed to enroll approximately 50 to 60 patients in the Phase 1 portion of the trial and approximately 125 patients in the Phase 2 portion of the trial. We began enrollment in the Phase 2 portion of the trial in the second quarter of 2013. In September 2013, we announced updated clinical results from the ongoing Phase 1/2 clinical trial. The study results show robust anti-tumor activity in patients with TKI-naïve and crizotinib-resistant ALK-positive NSCLC, including in patients with brain metastases after crizotinib treatment. Crizotinib is the currently available first-generation ALK inhibitor.

We plan to commence a pivotal trial of AP26113 in the first quarter of 2014 in ALK-positive NSCLC patients who are resistant to crizotinib, following confirmation of the safety and efficacy profile of the selected dose of AP26113 in the ongoing phase 1/2 clinical trial. We have decided to focus our development efforts on ALK-positive NSCLC patients, both treatment naïve and resistant, and those with CNS activity. We will no longer enroll EGFR, ROS1, or other patients in the ongoing Phase 1/2 clinical trial.

Ridaforolimus

Ridaforolimus is an investigational inhibitor of the mammalian target of rapamycin, or mTOR, that we discovered and developed internally and later licensed in 2010 to Merck & Co., Inc., or Merck. Under the license agreement, Merck was responsible for all activities related to the development, manufacture and commercialization of ridaforolimus and funds 100 percent of all ridaforolimus costs incurred after January 1, 2010. The agreement provided that Merck would develop ridaforolimus in multiple oncology indications. On February 20, 2014, we received notice from Merck that it is terminating the license agreement, which termination will become effective nine months from the date of the notice and at which time all rights to ridaforolimus in oncology licensed to Merck will be returned to us.

We also have license agreements with Medinol and ICON under which these companies are pursuing the development of stents and other medical devices to deliver ridaforolimus to prevent restenosis, or reblockage of injured vessels following interventions in which stents are used in connection with balloon angioplasty.

We are responsible for supplying Medinol and ICON with, and they have agreed to purchase from us, certain quantities of ridaforolimus for use in their development, manufacture and sale of the stents and other medical devices. Each of these licenses provide for potential milestone payments to us based on achievement of specified development, regulatory and/or sales objectives as well as royalty payments upon commercialization of products. There can be no assurance that any future payments will be received under these license agreements.

On January 14, 2014, we jointly announced with Medinol the initiation of two registration trials of Medinol's stent system that incorporates ridaforolimus. The two trials are randomized, single-blind, global studies. The studies will enroll approximately 2,200 patients with coronary artery disease. Under the terms of our agreement with Medinol, the commencement of enrollment in the clinical trials, along with the submission of an investigational device exemption, or IDE, with the FDA, will trigger milestone payments to us of $3.8 million, expected in 2014, with the potential for additional regulatory, clinical and sales milestones, as well as royalties on product sales.

Critical Accounting Policies and Estimates

Our financial position and results of operations are affected by subjective and complex judgments, particularly in the areas of revenue recognition, accrued product development expenses, inventory, leased buildings under construction and stock-based compensation.

Revenue Recognition

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria are met.

Product Revenue, net

We commercially launched Iclusig in the United States on January 3, 2013 and in certain European countries in the second half of 2013. As noted above, in the fourth quarter of 2013, we temporarily suspended the marketing and commercial distribution of Iclusig in the United States. In January 2014, we resumed marketing and commercial distribution of Iclusig in the United States under the revised USPI and the REMS program.

Through October 31, 2013, we sold Iclusig in the United States through a limited number of specialty distributors and specialty pharmacies. Title and risk of loss transferred upon receipt of Iclusig by these customers. Specialty pharmacies dispensed Iclusig directly to patients in fulfillment of prescriptions. Specialty distributors sold Iclusig to hospital pharmacies and community practice pharmacies, referred to as healthcare providers, for treatment of patients. We provided the right of return to customers in the United States for unopened product for a limited time before and after its expiration date. Iclusig's shelf-life in the United States is eighteen months for 15mg tablets and twelve months for 45mg tablets, measured from date of manufacture. In the United States, we deferred the recognition of revenue until Iclusig was sold to the healthcare providers or dispensed to the patients. Revenue recognition was deferred due to the inherent uncertainties in estimating future returns of Iclusig from our United States customers, due to factors such as estimated product demand and the limited shelf life of Iclusig. Upon the temporary suspension of marketing and commercial distribution in the United States in the fourth quarter of 2013, we terminated our existing contracts with these specialty distributors and specialty pharmacies and we accepted product returns of Iclusig from these customers. The majority of these product returns related to product held by specialty distributors and specialty pharmacies that had not yet been sold to patients or recognized as revenue. As a result, these returns were recorded as a reduction of accounts receivable and deferred revenue. For customers that had already paid for delivered product, a liability was recorded in other current liabilities. Upon receiving approval to resume marketing and commercial distribution in the United States, we revised our distribution strategy and plan to sell Iclusig through one exclusive specialty pharmacy who will distribute Iclusig to customers.

In Europe, we sell Iclusig to retail pharmacies and hospital pharmacies that dispense product directly to patients. These customers are provided with a limited right of return, such as instances of damaged product, and the criteria for revenue recognition is met at the time of shipment to these customers provided all other revenue recognition criteria are met.

Product revenues are recorded net of estimated gross to net deductions, including government-mandated rebates and chargebacks, distribution fees and other deductions. Reserves are established for these deductions and actual amounts incurred are offset against applicable reserves. We reflect these reserves as either a reduction in the related account receivable from the customer or as an accrued liability, depending on the nature of the deduction. These reserves are based on management's estimates that consider payor mix in target markets, industry benchmarks and experience to date. These estimates involve a high degree of judgment and are periodically reviewed and adjusted as necessary.

We have individual contracts or standard terms of sale with our customers and delivery occurs when a customer receives Iclusig. We evaluate the creditworthiness of each of our customers to determine whether collection is reasonably assured and have determined that all of our customers are creditworthy. In order to conclude that the price is fixed or determinable, we must be able to calculate our gross product revenues from our customers and reasonably estimate our net product revenues. Our gross product revenues are based on the fixed wholesale acquisition cost for Iclusig that we charge our customers. We estimate our net product revenues by deducting from our gross product revenues (i) trade allowances, such as invoice discounts for prompt payment and customer fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicare and Medicaid reimbursements in the United States, and (iii) estimated costs of incentives offered to certain indirect customers including patients. These gross to net deductions, and in particular the estimates for rebates, chargebacks and discounts, require us to make significant judgments that materially affect our recognition of net product revenues related to Iclusig.

Trade Allowances: We provide invoice discounts on Iclusig sales to certain of our customers for prompt payment and pay fees for certain services, such as fees for certain data that customers provide to us. We expect our customers to earn these discounts and fees, and therefore deduct these discounts and fees from our gross product revenues when revenue is recognized.

Rebates, Chargebacks and Discounts: In the United States, we contract with Medicare, Medicaid, other government agencies and various private organizations (collectively, payors) to make Iclusig, when commercially available, eligible for purchase by, or for partial or full reimbursement from, such payors. We estimate the rebates, chargebacks and discounts we will provide to payors and deduct these estimated amounts from our gross product revenue at the time the revenue is recognized. We estimate rebates, chargebacks and discounts based on (1) the contractual terms of agreements in place with payors, (2) the government-mandated discounts applicable to government-funded programs, and (3) the estimated payor mix. Government rebates that are invoiced directly to us are recorded in accrued liabilities on our consolidated balance sheet. For qualified programs that can purchase our product at a lower contractual government or commercial price, the customers charge back to us the difference between their acquisition cost and the lower contractual government or commercial price, which we record as an allowance against accounts receivable on our consolidated balance sheet. In Europe, we are subject to mandatory rebates and discounts in markets where government-sponsored healthcare systems are the primary payers for healthcare. These rebates and discounts are recorded when revenue is recognized and included in accrued liabilities on our consolidated balance sheet.

The value of the rebates, chargebacks and discounts provided to third-party payors per course of treatment vary significantly and are based on government-mandated discounts and our arrangements with other third-party payors. In the United States, typically, government-mandated discounts are significantly larger than discounts provided to other third-party payors. In order to estimate our total rebates, chargebacks and discounts, we estimate the percentage of prescriptions that will be covered by each third-party payor, which is referred to as the payor mix. In order to estimate the payor mix for Iclusig, we used both (i) information obtained from our customers and third parties regarding the payor mix for Iclusig and (ii) historical industry information regarding the payor mix for competitive products. We track available information regarding changes, if any, to the payor mix for Iclusig, to our contractual terms with third-party payors and to applicable governmental programs and regulations. If necessary, we adjust our estimated rebates, chargebacks and discounts based on new information, including information regarding actual rebates, chargebacks and discounts for Iclusig, as it becomes available. If we increased our estimate of the percentage of patients receiving Iclusig covered by third-party payors entitled to government-mandated discounts by five percentage points, our United States net product revenues would have decreased by approximately 1.2% in 2013. In the European countries where we currently sell Iclusig, rebates, as applicable, are fixed percentages of product sales.

Other Incentives: Other incentives that we offer include co-pay assistance for our patients and distribution fees offered to our customers. Our co-pay assistance programs assist commercially insured patients who have coverage for Iclusig and who reside in states that permit co-pay assistance programs. Our co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Iclusig's purchase price to a specified dollar amount. In each period, we record the amount of co-pay assistance provided to eligible patients based on the terms of the program.

Patients in Europe are also being treated with Iclusig in the framework of clinical trials and related studies and in named patient programs. In 2012, the French regulatory authority granted an *Autorisation Temporaire d'Utilisation* (ATU), or Temporary Authorization for Use, for Iclusig for the treatment of patients with CML and Ph+ ALL under a nominative program on a patient-by-patient basis. We began shipping Iclusig under this program during the year ended December 31, 2012. Until all revenue recognition criteria are met (including a fixed or determinable price), all amounts received under this program (approximately $8.8 million as of December 31, 2013) have not been recorded as revenue. This program concluded on September 30, 2013 and all outstanding amounts have been received. Upon completion of this program, we became eligible to ship Iclusig directly to customers in France as of October 1, 2013. These shipments have not met the criteria for revenue recognition as the price for these shipments is not yet fixed or determinable. These shipments totaled $4.1 million for the period from October 1, 2013 to December 31, 2013, of which $1.8 million was received as of December 31, 2013. We will record these shipments, as well as shipments under the ATU program, as revenue once the price is fixed or determinable.

Accrued Product Development Expenses

We accrue expenses for our product development activities based on our estimates of services performed or progress achieved pursuant to contracts and agreements with multiple vendors including research laboratories, contract manufacturers, contract research organizations and clinical sites. These estimates are recorded in research and development expenses in our consolidated statements of operations and are reflected in accrued product development expenses on our consolidated balance sheet. At December 31, 2013, we reported accrued product development expenses of $16.7 million on our consolidated balance sheet.

Our estimates of services performed or progress achieved are based on all available information we have from reports, correspondence and discussions with our vendors. Our estimates of accrued expenses based on such information require judgment. Actual costs may vary from such estimates. When such variances become known, we adjust our expenses accordingly.

Inventory

Inventory costs consist of costs related to the manufacturing of Iclusig, which are primarily the costs of contract manufacturing. We value our inventory at the lower of cost or market. We determine the cost of our inventory on a specific identification basis. If we identify excess, obsolete or unsalable items, inventory is written down to net realizable value in the period in which it is identified. Estimates of excess inventory consider inventory levels, our projected sales of the product for the foreseeable future and the estimated shelf-lives of our inventory components. At the time of launch in the United States, Iclusig 15mg tablets had a shelf-life of twelve months, which has subsequently been extended to eighteen months, and Iclusig 45mg tablets have a shelf-life of twelve months. In Europe, the shelf-life of both 15mg and 45mg tablets is twenty-four months. Inventory that is not expected to be used within one year is recorded as a non-current asset.

Prior to receiving approval from the FDA in December 2012 to sell Iclusig, we expensed all costs incurred related to the manufacture of Iclusig as research and development costs because of the inherent risks associated with the development of a drug candidate, the uncertainty about the regulatory approval process and the lack of history for our Company of regulatory approval of drug candidates. Accordingly,

the manufacturing costs for Iclusig included in our cost of product revenue for 2013 are significantly lower than full manufacturing cost, as most of these costs have been recorded as research and development expenses in prior periods.

As a result of the temporary suspension of Iclusig in the United States and the revised USPI, which reduces the addressable patient population for whom Iclusig is currently indicated, the current commercial opportunity for Iclusig has been reduced from what was expected under the previously approved USPI. Due to this expected decrease in demand for Iclusig, in the fourth quarter of 2013, we assessed the need for an inventory write-down for excess inventory for our inventory on hand at December 31, 2013. This review included all components of inventory, including raw materials, work-in-process and finished goods inventory. Inventory balances on hand were compared to the expected uses of inventory in the foreseeable future, taking into account the estimated future global demand for Iclusig as well as the estimated shelf-life of our inventory components. From this analysis, we determined that approximately $7.1 million of our inventory was excess at December 31, 2013 and we recorded a charge to cost of product revenue to write down inventory for this amount in the fourth quarter of 2013. In connection with this review, we also charged $1.3 million of vendor advances to cost of product revenue as the advances relate to future inventory production that will result in excess inventory. In addition, during 2013 we also wrote down finished goods that will expire and not be sold. Our total charges for 2013 for excess inventory, as well as finished goods inventory that will expire before it is sold, was approximately $8.9 million. Total inventory on hand at December 31, 2013 was approximately $3.4 million.

As we re-launch Iclusig in the United States in 2014, there is no assurance that we will be successful in commercializing Iclusig in the United States, in Europe or in other territories where we await regulatory approval or have yet to file for regulatory approval. In addition, the outcome of the EMA's review of Iclusig is uncertain. We expect that the developments announced in October 2013 concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States and the EMA's review will adversely impact our efforts to commercialize Iclusig in patients with CML and Ph+ ALL. Our ability to obtain product revenue from the sales of Iclusig will depend on our ability to continue to commercialize Iclusig in the United States and in Europe and other territories, as well as the success of our efforts to develop Iclusig in other patient populations and cancers. If we are not successful in generating sufficient levels of sales from Iclusig, additional inventory write-downs may be required. In addition, we may incur additional inventory costs as we complete planned production runs related to qualification of new manufacturing processes or vendors in the future.

Due to the inventory costs that were recorded as research and development expenses as well as the write-down of inventory, we expect that our cost of inventory sold in the future will be significantly less than full manufacturing cost. The time period over which this reduced-cost inventory is consumed will depend on a number of factors, including the amount of future sales of Iclusig in the United States and in Europe, the ultimate use of this inventory in either commercial sales, clinical development or other research activities and the ability to utilize inventory prior to its expiration date. We expect that as this reduced-cost inventory is used in the future, the cost of product revenue, before consideration of any future required inventory write-downs or reserves, will be in the low single digits as a percentage of net product revenue.

For 2013, our cost of product revenue would have been approximately $10.0 million, if the related costs were not previously expensed as research and development expenses prior to receiving FDA approval.

Leased Buildings Under Construction

In January 2013, we entered into a lease agreement for approximately 244,000 square feet of laboratory and office space in two adjacent, connected buildings which are under construction in Cambridge, Massachusetts. Construction is expected to be completed in early 2015. Under the terms of the original lease, we leased all of the rentable space in one of the two buildings and a portion of the available space in the second building. In September 2013, we entered into a lease amendment to lease all of the remaining space, approximately 142,000 square feet, in the second building, for an aggregate of 386,000 square feet in both buildings. The terms of the lease amendment were consistent with the terms of the original lease.

In connection with this lease, the landlord is providing a tenant improvement allowance for the costs associated with the design, engineering, and construction of tenant improvements for the leased facility. The tenant improvements will be in accordance with our plans and include fit-out of the building to construct appropriate laboratory and office space, subject to approval by the landlord. To the extent the stipulated tenant allowance provided by the landlord is exceeded, we are obligated to fund all costs incurred in excess of the tenant allowance. The scope of the planned tenant improvements do not qualify as "normal tenant improvements" under the lease accounting guidance. Accordingly, for accounting purposes, we are the deemed owner of the buildings during the construction period.

As construction progresses, we record the project construction costs incurred as an asset, which reflects estimated replacement cost, along with a corresponding facility lease obligation, on the consolidated balance sheet for the total amount of project costs incurred whether funded by us or the landlord. Upon completion of the buildings, we will determine if the asset and corresponding financing obligation should continue to be carried on our consolidated balance sheet under the accounting guidance. Based on the current terms of the lease, we expect to continue to be the deemed owner of the buildings upon completion of the construction period.

Given our involvement in the design of tenant improvements for the leased facility, the lease establishes dates by which we are required to submit plans and drawings for tenant improvements consistent with the timeline for completion of the construction, including tenant improvements, and readiness of the facility for occupancy. In connection with the partial clinical hold of Iclusig imposed by the FDA and the temporary suspension of marketing and commercial distribution of Iclusig in the United States in October 2013, plans and drawings for the tenant improvements for this facility have not been approved by us and have not at this time, been completed and submitted in accordance with the timelines specified in the lease. If delay of submission of plans and drawings in accordance with the timelines specified in the lease results in a delay in the occupancy date for the facility, we may be required to commence rent payments for the facility prior to occupancy. We are currently in discussions with the landlord regarding revisions to our plans, the timelines related to submission of such plans and other matters in the lease.

Stock-Based Compensation Expense

Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award if performance and service conditions are expected to be achieved. We use the Black-Scholes option-pricing model to estimate the fair value of stock options. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. Estimated volatility is based on a combination of historical and implied volatility. Expected life is based on our historical experience. The risk-free interest rate is based on U.S. Treasury interest rates with terms consistent with the expected life of the stock-based award. Expected dividend yield was not considered in the option pricing formula since we do not pay dividends and have no current plans to do so in the future. The forfeiture rate is based upon historical experience. We adjust the estimated forfeiture rate based upon our actual experience. In addition, we have performance based awards that are valued at the fair value of shares as of the grant date and compensation expense is recognized based on the number of shares expected to vest under the terms of the award under which they are granted, if performance conditions are expected to be met. The determination of whether the performance condition will be met requires significant judgment, including estimating the probability and timing of future events. Compensation cost for certain awards may increase by up to 60% of the cost estimated at target award levels based upon the eventual outcome of the performance conditions. We recognized stock compensation expense of $2.6 million as of December 31, 2013 for performance awards that are expected to vest in the future.

Results of Operations

For the Years Ended December 31, 2013 and 2012

Revenue

Our revenues for 2013, as compared to 2012, were as follows:

In thousands	Year Ended December 31, 2013	2012	Increase/ (decrease)
Product revenue, net	$ 45,238	$ —	$45,238
License revenue	296	514	(218)
Service revenue	27	44	(17)
	$45,561	$ 558	$ 45,003

The increase in product revenue, net reflects the commercial launch of Iclusig, our first approved cancer medicine, in the United States and in Europe in 2013. Prior to the temporary suspension of marketing and commercial distribution of Iclusig in the United States in the fourth quarter of 2013, we recognized revenue on a sell-through basis. In Europe, we generally recognize revenue upon shipment to our customers. Product revenue is reduced by certain gross to net deductions. In 2013, these gross to net deductions, as a percentage of gross revenue, were approximately 8.7% and related to reductions in the United States including government-related discounts, as well as government-mandated rebates in Europe.

We expect that our product revenue will increase in 2014 compared to 2013 due primarily to increasing sales of Iclusig in Europe as we obtain pricing and reimbursement approval in various countries in Europe during the year. Although we have resumed marketing and commercial distribution of Iclusig in the United States in January 2014, the revised USPI reduces the addressable patient population which we expect will adversely impact our sales of Iclusig in the United States. Our ability to obtain product revenue from sales of Iclusig will depend on the impact of the changes to the USPI and the implementation of a REMS program, the effectiveness of our commercial strategy for marketing Iclusig in the United States, including pricing and reimbursement strategies, the outcome of the EMA's review of Iclusig, the acceptance of Iclusig by patients, the medical community and third party payors in the United States and Europe, as well as the success of our efforts to develop Iclusig in other patient populations and cancers. There can be no assurance that we will be successful in our continuing commercialization of Iclusig in the United States or Europe or the receipt of satisfactory pricing and reimbursement approvals in Europe, or that we will be able to obtain additional regulatory approvals and new sources of product revenue.

We recognized $296,000 of license revenue in 2013, pursuant to a license agreement related to our ARGENT technology in accordance with our revenue recognition policy. Revenue in 2012 also consisted of $514,000 of license revenue related to our ARGENT technology.

Operating Expenses

Cost of Product Revenue

Our cost of product revenue relates to sales of Iclusig upon commercial launch in the United States commencing in January 2013 and in certain European countries in the second half of 2013. For 2013, our cost of product revenue totaled $9.6 million and included the following:

In thousands	Year Ended December 31, 2013
Inventory cost of Iclusig sold	$ 183
Shipping and handling costs	572
Inventory reserves/write-downs	8,857
	$ 9,612

Prior to receiving regulatory approval for Iclusig from the FDA in December 2012, we expensed as research and development costs all costs incurred in the manufacturing of Iclusig to be sold upon commercialization. For Iclusig sold in 2013, the majority of manufacturing costs incurred had previously been expensed. Therefore, the cost of inventory sold included limited manufacturing costs and the cost of packaging and labeling for commercial sales. If product-related costs had not previously been expensed as research and development prior to receiving FDA approval, the cost to produce the Iclusig sold would have been approximately $594,000 and total cost of product revenue would have been approximately $10.0 million in 2013.

Due to the temporary suspension of U.S. marketing and commercial distribution and the expected decrease in demand for Iclusig, we assessed the need for an inventory write-down for excess inventory for our inventory on hand at December 31, 2013. This review included all components of inventory, including raw materials, work-in-process and finished goods inventory. Inventory balances on hand were compared to the expected uses of inventory in the foreseeable future, taking into account the estimated future global demand for Iclusig as well as the estimated shelf-life of our inventory components. From this analysis, we determined that approximately $7.1 million of our inventory was excess at December 31, 2013 and we recorded a charge to cost of product revenue to write down inventory in the fourth quarter of 2013. In connection with this review, we also charged $1.3 million of vendor advances to cost of product revenue as the advances relate to future inventory production that will result in excess inventory. In addition, during 2013 we also wrote down finished goods that will expire and not be sold. Our total charges for 2013 for excess inventory, as well as finished goods inventory that will expire before it is sold, was approximately $8.9 million.

Research and Development Expenses

Research and development expenses increased by $18.2 million, or 13 percent, to $162.9 million in 2013, compared to $144.7 million in 2012, for the reasons set forth below.

The research and development process necessary to develop a pharmaceutical product for commercialization is subject to extensive regulation by numerous governmental authorities in the United States and other countries. This process typically takes years to complete and requires the expenditure of substantial resources. Current requirements include:

- preclinical toxicology, pharmacology and metabolism studies, as well as *in vivo* efficacy studies in relevant animal models of disease;
- manufacturing of drug product for preclinical studies and clinical trials and ultimately for commercial supply;
- submission of the results of preclinical studies and information regarding manufacturing and control and proposed clinical protocol to the FDA in an Investigational New Drug application, or IND (or similar filings with regulatory agencies outside the United States);
- conduct of clinical trials designed to provide data and information regarding the safety and efficacy of the product candidate in humans; and

- submission of all the results of testing to the FDA in a New Drug Application, or NDA (or similar filings with regulatory agencies outside the United States).

Upon approval by the appropriate regulatory authorities, including in some countries approval of product pricing, we may commence commercial marketing and distribution of the product.

We group our research and development, or R&D, expenses into two major categories: direct external expenses and all other R&D expenses. Direct external expenses consist of costs of outside parties to conduct and manage clinical trials, to develop manufacturing processes and manufacture product candidates, to conduct laboratory studies and similar costs related to our clinical programs. These costs are accumulated and tracked by product candidate. All other R&D expenses consist of costs to compensate personnel, to purchase lab supplies and services, to lease, operate and maintain our facility, equipment and overhead and similar costs of our research and development efforts. These costs apply to our clinical programs as well as our preclinical studies and discovery research efforts. Product candidates are designated as clinical programs once we have filed an IND with the FDA, or a similar filing with regulatory agencies outside the United States, for the purpose of commencing clinical trials in humans.

Our R&D expenses for 2013, as compared to 2012, were as follows:

In thousands	Year Ended December 31, 2013	2012	Increase/ (decrease)
Direct external expenses:			
Iclusig	$ 59,593	$ 54,588	$ 5,005
AP26113	17,439	6,034	11,405
All other R&D expenses	85,868	84,087	1,781
	$162,900	$144,709	$18,191

In 2013 and 2012, our clinical programs consisted of (i) Iclusig, our pan BCR-ABL inhibitor, and (ii) AP26113, our ALK inhibitor.

Direct external expenses for Iclusig were $59.6 million in 2013, an increase of $5.0 million, or 9%, as compared to 2012. The increase is due primarily to an increase in clinical trial costs of $13.6 million which was due to increases related to ongoing treatment of patients in existing and new trials, including the EPIC trial and the related comparator drug purchases, our Phase 2 GIST trial, our Phase 1/2 clinical trial of Iclusig in Japan, our pediatric trial of Iclusig, and increased costs associated with investigator-sponsored trials, offset by a decrease in costs related to our Phase 2 PACE clinical trial as treatment of patients and other related activities decreased in 2013 compared to 2012. As noted above, we announced the discontinuation of the EPIC trial in October 2013 and a pause on additional patient enrollment, as well as a partial FDA clinical hold, for all other Iclusig trials. The increase in the clinical trial costs was offset, in part, by a decrease in contract manufacturing costs of $5.9 million, and a decrease in other non-clinical support costs of $2.2 million. Contract manufacturing costs decreased as costs to manufacture Iclusig in 2013 are now being capitalized in inventory while such costs in 2012, prior to the FDA approval of Iclusig, were included in research and development expense. Non-clinical support costs decreased due primarily to the completion of the regulatory filings in support of the Iclusig NDA and in support of the initiation of the Phase 1/2 clinical trial in Japan.

Direct external expenses for AP26113 were $17.4 million in 2013, an increase of $11.4 million, or 189%, as compared to 2012. The increase in expenses for AP26113 was due primarily to an increase in clinical trial costs related to the initiation of additional trials and an increase in contract manufacturing costs due to the manufacture of additional material to supply the Phase 1/2 clinical trial and readiness to support additional trials.

All other R&D expenses increased by $1.8 million, or 2%, in 2013, as compared to 2012. This increase was primarily due to an increase in personnel costs of $7.4 million, due to higher compensation and related costs from an increase in the number of employees to support expanding R&D activities and costs associated with the employee workforce reduction in the fourth quarter of 2013, an

increase in lab expenses of $1.2 million, related to increased discovery efforts, and an increase in general and other expenses of $861,000 related to travel expenses and training costs. These increases were offset primarily by a decrease in professional fees of $3.9 million and a decrease in intellectual property costs of $3.6 million due primarily to an impairment charge recorded for ridaforolimus technology in 2012.

On November 7, 2013, we reduced our United States workforce, including personnel in research and development, following the temporary suspension of marketing and commercial distribution of Iclusig in the United States. As a result of these actions, our future research and development activities will focus on key research and development activities for Iclusig, AP26113 and discovery research. We expect that our direct external expenses for Iclusig will decrease in 2014 compared to 2013, primarily due to a reduction in clinical trial and manufacturing related costs. We expect direct external expenses for AP26113 will increase in 2014 compared to 2013 as we focus our resources primarily on the pivotal trial that is planned to begin in the first quarter of 2014. All other R&D expenses in 2014 compared to 2013 are expected to decrease due to the impact of our restructuring actions and as we focus our resources on key research and development activities and discovery research efforts.

The successful development of our product candidates is uncertain and subject to a number of risks. We cannot be certain that any of our products or product candidates will prove to be safe and effective or will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval. Data from preclinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or could result in label warnings related to or recalls of approved products. As noted above, in October 2013, we announced the results of our review of updated clinical data from the pivotal PACE trial of Iclusig and actions that we took following consultations with the FDA, including a pause in patient enrollment, a partial clinical hold by the FDA, product label changes, and the discontinuation of the EPIC trial. We expect that these developments will adversely impact our efforts to further develop and commercialize Iclusig in CML and Ph+ ALL patients, and our ability to obtain sources of product revenue from the successful development our product candidates will depend on, among other things, our efforts to develop Iclusig in other patient populations and cancers, as well as the success of AP26113 and any other product candidates. Other risks associated with our products and product candidates are described in the section entitled “Risk Factors” in this report.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $85.7 million, or 141 percent, to $146.6 million in 2013, compared to $60.9 million in 2012. This increase was due primarily to an increase in personnel costs of $43.4 million related primarily to compensation and related costs associated with an increase in the number of employees, including sales and marketing related personnel to support the commercial launch of Iclusig, expanding business activities in the United States and in Europe during 2013 and costs associated with the employee workforce reduction that occurred in the fourth quarter of 2013; an increase in professional services of $23.5 million due to corporate and commercial development initiatives supporting the launch of Iclusig; an increase in general expenses of $10.4 million primarily related to increases in technology costs and travel costs in support of the launch of Iclusig; and an increase in overhead and other expenses of $6.1 million primarily related to increased office, overhead and administrative expenses incurred to support the commercial operations associated with the launch of Iclusig.

On November 7, 2013, as a consequence of our announcements and events in October 2013, as discussed above, we reduced our United States workforce including United States sales force positions and additional selling, general and administrative positions. We expect that selling, general and administrative costs will decrease in 2014 compared to 2013 as a result of the restructuring actions taken and other cost reduction initiatives, offset by costs that we will incur related to the re-launch of Iclusig.

We expect that operating expenses in total, will decrease in 2014 compared to 2013 as a result of these restructuring actions and other cost reduction initiatives. The actual amount of operating expenses will

depend on, among other things, costs related to the re-launch of Iclusig in the United States, the outcome of the EMA's review of Iclusig, discussions with other regulatory agencies regarding our review of the PACE clinical data, the status of regulatory reviews and timing of potential pricing and reimbursement approvals of Iclusig in Europe, costs related to commercialization of Iclusig in Europe, cost savings from our restructuring efforts, the progress of our product development programs, including on-going and planned clinical trials, results of continuing non-clinical studies and the costs of product and process development activities and product manufacturing.

Other Income (Expense)

Interest Income/Expense

Interest income decreased to $130,000 in 2013 from $240,000 in 2012, as a result of a lower average balance of funds invested in 2013.

Interest expense decreased to $153,000 in 2013 from $199,000 in 2012 as a result of lower average borrowings in 2013.

Foreign Exchange Gain (Loss)

We recognized net foreign exchange transaction losses of $130,000 in 2013 compared to net foreign exchange gains of $71,000 in 2012. The gains and losses are a result of our expansion into Europe as we carry accounts denominated in foreign currencies.

Provision for Income Taxes

Our provision for income taxes for 2013 was $439,000 and reflects estimated taxes for state taxes and taxable income associated with certain foreign subsidiaries. There was no provision for income taxes in 2012.

Operating Results

We reported a loss from operations of $273.6 million in 2013 compared to a loss from operations of $205.1 million in 2012, an increase of $68.5 million, or 33 percent. We also reported a net loss of $274.2 million in 2013, compared to a net loss of $220.9 million in 2012, an increase in net loss of $53.3 million or 24 percent, and a net loss per share of $1.49 and $1.34, respectively. The increase in net loss is largely due to the increase in our operating expenses described above offset in part by product revenue related to the commercial launch of Iclusig in January 2013. Our results of operations for 2014 will vary from those of 2013 and actual results will depend on a number of factors, including our ability to successfully re-launch and commercialize Iclusig in the United States, the outcome of the EMA's review of Iclusig, our discussions with other regulatory agencies regarding our review of the PACE clinical data, the status of pricing and reimbursement approvals and commercialization in Europe, the progress of our product development programs, ongoing employee and related personnel costs, the progress of our discovery research programs, the impact of any commercial and business development activities and other factors. The extent of changes in our results of operations will also depend on the sufficiency of funds on hand or available from time to time, which will influence the amount we will spend on operations and capital expenditures and the development timelines for our product candidates.

For the Years Ended December 31, 2012 and 2011

Revenue

We recorded total revenue of $558,000 for the year ended December 31, 2012, compared to $25.3 million for the year ended December 31, 2011. Total revenue in 2012 consisted primarily of license revenue pursuant to a license agreement related to our ARGENT technology. Total revenue in 2011 consisted

primarily of a $25 million milestone payment received pursuant to our license agreement with Merck for the acceptance of an application for regulatory approval in Europe of ridaforolimus for the treatment of patients with sarcoma, which was subsequently withdrawn by Merck in November 2012.

Operating Expenses

Research and Development Expenses

Our R&D expenses for 2012 as compared to 2011 were as follows:

In thousands	Year ended December 31, 2012	2011	Increase / (decrease)
Direct external expenses:			
Iclusig	$ 54,588	$32,392	$ 22,196
AP26113	6,034	4,120	1,914
All other R&D expenses	84,087	41,231	42,856
	$144,709	$ 77,743	$66,966

In 2012 and 2011, our clinical programs consisted of (i) Iclusig, and (ii) AP26113, for which we filed an IND in June 2011 and commenced a Phase 1/2 clinical trial in the third quarter of 2011.

Direct external expenses for Iclusig were $54.6 million in 2012, an increase of $22.2 million, or 69 percent, compared to 2011 expenses of $32.4 million. The increase was due to an increase in clinical trial costs of $13.3 million, contract manufacturing costs of $3.3 million and supporting non-clinical costs of $5.6 million. Clinical trial costs increased primarily due to ongoing treatment of patients in our pivotal Phase 2 PACE clinical trial and increased enrollment and treatment of patients in our Phase 3 EPIC clinical trial in newly diagnosed CML patients, including purchases of the comparator drug, imatinib, for use in this trial, as well as costs related to initiation of a Phase 1/2 clinical trial of Iclusig in Japan, offset in part by a decrease in costs of our on-going Phase 1 clinical trial as treatment of patients and other activities in this trial decreased over this time period. Contract manufacturing costs increased due primarily to the conduct of product and process development and qualification initiatives to support regulatory filings for Iclusig, as well as the production of Iclusig for use in our clinical trials and provided for initial commercial supply in anticipation of regulatory approval of Iclusig. Supporting non-clinical costs increased due primarily to increased quality and stability studies and initiatives to develop and commercialize a companion diagnostic test to identify patients with the T315I mutation of the BCR-ABL gene. We collaborated with MolecularMD Corp. to establish this companion diagnostic test and MolecularMD filed a PreMarketing Approval (PMA) application with the FDA. In September 2012, we and MolecularMD announced the voluntary withdrawal of the PMA following advice from the FDA that the FDA no longer considered this test to be a companion diagnostic test for ponatinib.

Direct external expenses for AP26113 were $6.0 million for 2012, an increase of $1.9 million, or 46 percent, compared to 2011 expenses of $4.1 million, of which $2.2 million were included in clinical programs and $1.9 million were included in preclinical programs. The increase in expenses for AP26113 was due to an increase in clinical trial costs of $0.5 million and an increase of $2.0 million in contract manufacturing cost, offset in part by a decrease in supporting non-clinical costs of $0.6 million. The increase in clinical trial costs was due to costs of the Phase 1/2 clinical trial initiated in the third quarter of 2011. The increase in contract manufacturing costs was due to the manufacture of additional material to supply the Phase 1/2 clinical trial and investment in product and process development. The decrease in supporting non-clinical costs was due primarily to the completion in 2011 of toxicology studies required for filing of the IND.

All other R&D expenses increased by $42.9 million, or 104 percent, to $84.1 million in 2012, as compared to $41.2 million in 2011. This increase was primarily due to an increase in personnel costs of $19.8 million, related primarily to an increase in the number of employees to support expanding R&D activities, overall increases in compensation for employees and an increase in recruiting costs; an increase in professional services of $6.2 million due primarily to initiatives to upgrade systems and technology used in our

business; an increase in stock-based compensation expense of $6.1 million as a result of the impact of a significant increase in the market value of our common stock on the value of stock-based compensation awards in 2011 and 2012, as well as the vesting of previously awarded performance share units triggered by the approval of Iclusig by the FDA in December 2012; an impairment charge related to ridaforolimus intangible assets of $4.8 million; an increase in rent expense of $2.2 million as a result of an amendment to our existing building lease and a new lease agreement for additional space; an increase in general expenses of $2.6 million, including technology support costs and travel costs associated with our expanded R&D workforce; and an increase in lab expenses of $1.6 million.

General and Administrative Expenses

General and administrative expenses increased by $36.5 million, or 150 percent, to $60.9 million in 2012, compared to $24.4 million in 2011. This increase was due primarily to an increase in personnel costs of $15.7 million related primarily to an increase in the number of employees, including sales related personnel, to support expanding business activities and to prepare for commercial launch of Iclusig, overall increases in compensation for existing employees and an increase in recruiting costs; an increase in professional services of $10.2 million as a result of an increase in corporate and commercial development initiatives to plan and prepare for the commercial launch of Iclusig; an increase in stock-based compensation expense of $6.6 million due to the impact of a significant increase in the market value of our common stock on the value of stock-based compensation awards in 2011 and 2012, as well as the vesting of previously awarded performance share units triggered by the approval of Iclusig by the FDA in December 2012; an increase in general expenses of $2.4 million primarily related to increased travel costs as we prepared for regulatory approval and commercial launch of Iclusig; and an increase in overhead and other expenses of $1.8 million primarily related to insurance costs, taxes and other miscellaneous costs.

Other Income/Expense

Interest Income

Interest income increased by 44 percent to $240,000 in 2012 from $167,000 in 2011, as a result of a higher average balance of funds invested in 2012.

Interest Expense

Interest expense decreased by 14 percent to $199,000 in 2012 from $232,000 in 2011, as a result of lower average borrowings in 2012.

Revaluation of Warrant Liability

In the first quarter of 2012, all 5,805,843 warrants that were outstanding at December 31, 2011 were exercised for proceeds to us of approximately $12.5 million. During the first quarter of 2012, the value of the warrant liability on our consolidated balance sheet was adjusted, resulting in a non-cash charge of $15.9 million for the year ended December 31, 2012, due primarily to the increase in the market price of our common stock from December 31, 2011 to the dates the warrants were exercised. The revaluation of our warrant liability in 2011 resulted in a non-cash charge of $46.7 million. Upon exercise of those remaining warrants, the balance of the warrant liability and the associated exercise proceeds were credited to stockholders' equity and the liability was eliminated.

Operating Results

We reported a loss from operations of $205.1 million in 2012 compared to a loss from operations of $76.8 million in 2011, an increase of $128.3 million, or 167 percent. We also reported a net loss of $220.9 million in 2012, compared to a net loss of $123.6 million in the corresponding period in 2011, an increase in net loss of $97.3 million or 79 percent, and a net loss per share of $1.34 for 2012 compared to $0.93 for 2011. The increase in net loss is largely due to the decrease in revenue and the increase in our operating expenses described above, offset in part by the decrease in charges related to the revaluation of our warrant liability of $30.8 million in 2012, as compared to 2011.

Selected Quarterly Financial Data

Summarized unaudited quarterly financial data are as follows:

	2013			
In thousands, except per share amounts	First	Second	Third	Fourth[a]
Total revenue	$ 6,464	$ 14,011	$ 16,732	$ 8,354
Gross profit (loss)	6,195	13,783	16,317	(346)
Net loss	(64,670)	(68,985)	(66,339)	(74,164)
Net loss per share – basic and diluted	(0.36)	(0.37)	(0.36)	(0.40)

	2012			
In thousands, except per share amounts	First	Second	Third	Fourth
Total revenue	$ 81	$ 318	$ 85	$ 74
Net loss	(55,894)	(51,312)	(53,213)	(60,453)
Net loss per share – basic and diluted	(0.35)	(0.31)	(0.32)	(0.36)

[a] Our results for the fourth quarter of 2013 include expenses related to the write-down of excess inventory and vendor advances of $8.5 million and restructuring charges of $4.8 million.

Liquidity and Capital Resources

We have financed our operations and investments to date primarily through sales of our common stock in public and private offerings, through the receipt of up-front and milestone payments from collaborations and licenses with pharmaceutical and biotechnology companies and, to a lesser extent, through issuances of our common stock pursuant to our equity incentive and employee stock purchase plans, supplemented by the borrowing of long-term debt from commercial lenders. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. We seek to balance the level of cash, cash equivalents and marketable securities on hand with our projected needs and to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. In October 2013, in connection with the temporary suspension of marketing and commercial distribution of Iclusig in the United States and other announcements that we made, our market capitalization declined significantly, by approximately $2.8 billion, or 87%. In the fourth quarter of 2013, we revised our operating plan and implemented steps to reduce our expenses in order to extend our existing cash and cash equivalents further than we had previously projected. These steps included a reduction in our United States workforce of approximately 40% that we announced on November 7, 2013. Positions were eliminated in our commercial, research and development and administrative functions. We also took actions to significantly lower our operating expenses in 2014 and in the future, including reductions in research and development expenses by focusing on key activities in the Iclusig and AP26113 development programs and discovery research, and reductions in general and administrative expenses associated with the reductions in commercial and research and development activities.

With the launch of Iclusig in 2013, we began generating product revenues that have contributed to our cash flows. However, our cash flows generated by sales of Iclusig are not currently sufficient to fund operations and we will need to seek additional sources to fund our operations.

For the purpose of the following discussion, our funds consist of cash, cash equivalents and marketable securities as follows:

In thousands	December 31, 2013	December 31, 2012
Cash and cash equivalents	$237,179	$119,379
Marketable securities	—	45,035
	$237,179	$ 164,414

We manage our marketable securities portfolio to maintain liquidity for payment of our obligations and to maximize yields. We purchase marketable securities to enhance our yield on invested funds and when such amounts are not needed for near-term payment of obligations. We generally hold our marketable securities to maturity. Upon maturity of such marketable securities, a portion may be retained as cash to provide for payment of current obligations while the remainder will be reinvested in accordance with our investment policy. During 2013, there were no purchases of marketable securities and proceeds from maturities of marketable securities were $45.0 million. During 2012, we purchased marketable securities in the amount of $89.6 million and realized proceeds of $44.5 million from maturities of marketable securities. A total of $17.1 million of our cash and cash equivalents as of December 31, 2013 is held by various international subsidiaries and $15.0 million is required to be held as a minimum balance under the loan agreement with our commercial lender.

Our balance sheet at December 31, 2013 includes property and equipment, net of $108.8 million, which represents an increase of $101.1 million from December 31, 2012. The increase is primarily due to the accounting, as described below, for our lease of new laboratory and office space in Cambridge, Massachusetts. In January 2013, we entered into a lease agreement for approximately 244,000 square feet of laboratory and office space in two adjacent, connected buildings which are under construction in Cambridge, Massachusetts, and construction is expected to be completed in early 2015. Under the terms of the original lease, we leased all of the rentable space in one of the two buildings and a portion of the available space in the second building. In September 2013, we entered into a lease amendment to lease all of the remaining space, approximately 142,000 square feet, in the second building, that was not previously committed to lease. The terms of the lease amendment were consistent with the terms of the original lease. Under the relevant accounting guidance, we are the deemed owner for the project during the construction period and accordingly, we record the project construction costs as an asset ($99.4 million at December 31, 2013) and a corresponding facility lease obligation. In connection with the lease, the landlord is providing a tenant improvement allowance for the costs associated with the design, engineering and construction of tenant improvements. To the extent that the related costs exceed the allowance, we will be responsible to fund such excess. We do not anticipate any funding requirements in 2014. Any future funding requirements will be dependent on design, engineering and construction work, which will develop over time. As construction continues on the facility, the asset and corresponding facility lease obligation will continue to increase. Given our involvement in the design of tenant improvements for the leased facility, the lease establishes dates by which we are required to submit plans and drawings for tenant improvements consistent with the timeline for completion of the construction, including tenant improvements, and readiness of the facility for occupancy. In connection with the partial clinical hold of Iclusig imposed by the FDA and the temporary suspension of marketing and commercial distribution of Iclusig in the United States in October 2013, plans and drawings for the tenant improvements for this facility have not been approved by us and have not, at this time, been completed and submitted in accordance with the timelines specified in the lease. If delay of submission of plans and drawings in accordance with the timelines specified in the lease results in a delay in the occupancy date for the facility, we may be required to commence rent payments for the facility prior to occupancy. We are currently in discussions with the landlord regarding revisions to our plans, the timelines related to submission of such plans and other matters in the lease.

Our balance sheet at December 31, 2013 includes other current assets of $6.0 million, an increase of $2.1 million from December 31, 2012, which was primarily due to an increase in prepaid costs for insurance due to the expansion of our business and commercial costs supporting the launch of Iclusig as well as advances to vendors related to clinical trial activities.

In connection with the commercial launch of Iclusig in 2013 in both the United States and Europe, we began to capitalize inventory, ship product to customers and recognize revenue from sales of Iclusig. As a result of these activities, at December 31, 2013, our accounts receivable balance increased to $1.3 million and inventory increased to $3.4 million, inclusive of the current and non-current portions of inventory.

Sources of Funds

During the years ended December 31, 2013, 2012 and 2011, our sources of cash were as follows:

In thousands	2013	2012	2011
Sales/issuances of common stock:			
In common stock offerings	$ 310,037	$ —	$243,058
Pursuant to warrant exercises	—	12,483	8,080
Pursuant to stock option and purchase plans	6,284	10,511	4,791
Proceeds from long-term borrowings	—	—	4,375
Reimbursement of amounts related to facility lease obligation	2,741	—	—
Milestone payment from Merck, included in cash used in operating activities	—	—	25,000
	$319,062	$22,994	$285,304

The amount of funding we raise through sales of our common stock or other securities depends on many factors, including, but not limited to, the status and progress of our product development programs, projected cash needs, availability of funding from other sources, our stock price and the status of the capital markets.

On February 25, 2009, we sold 14,378,698 shares of our common stock in a registered direct offering to institutional investors, at a purchase price of $1.69 per share, resulting in net proceeds after fees and expenses of $22.8 million. The investors also received warrants to purchase an additional 10,784,024 shares of our common stock exercisable at a price of $2.15 per share in cash or pursuant to the net exercise provisions of the warrants. During the year ended December 31, 2011, a total of 3,757,767 warrants were exercised for proceeds to us of approximately $8.1 million. During the three-month period ended March 31, 2012, all 5,805,843 warrants that remained outstanding at December 31, 2011 were exercised for proceeds to us of approximately $12.5 million.

On December 20, 2011, we sold 24,725,000 shares of our common stock in an underwritten public offering at a purchase price of $10.42 per share. Net proceeds of this offering, after underwriting discounts and commissions and expenses, were approximately $243.1 million.

On January 29, 2013, we sold 16,489,893 shares of our common stock in an underwritten public offering at a purchase price of $19.60 per share. Net proceeds of this offering, after underwriting discounts and commissions and expenses, were approximately $310.0 million.

We have filed shelf registration statements with the U.S. Securities and Exchange Commission, or SEC, from time to time, to register shares of our common stock and other securities for sale, giving us the opportunity to raise funding when needed or otherwise considered appropriate. Under SEC rules, we currently qualify as a “well-known seasoned issuer,” which allows us to file shelf registration statements to register an unspecified amount of securities that are effective upon filing. On December 14, 2011, we filed such a shelf registration statement with the SEC for the issuance of an unspecified amount of common stock, preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, from time to time at prices and on terms to be determined at the time of any such offering. This registration statement was effective upon filing and will remain in effect for up to three years from filing.

Uses of Funds

The primary uses of our cash are to fund our operations and working capital requirements and, to a lesser degree, to repay our long-term debt and to invest in our property and equipment as needed for our business. Our uses of cash during the years ended December 31, 2013, 2012 and 2011 were as follows:

In thousands	2013	2012	2011
Net cash used in operating activities	$221,882	$153,681	$53,262
Adjusted for milestone payment from Merck	—	—	25,000
Adjusted net cash used in operating activities	221,882	153,681	78,262
Repayment of long-term borrowings and capital leases	2,115	1,454	1,466
Change in restricted cash	10,319	289	—
Investment in intangible assets	—	633	671
Investment in property and equipment	8,543	4,424	1,452
Payment of tax withholding obligations related to stock compensation	3,363	4,336	827
	$246,222	$164,817	$82,678

The net cash used in operating activities is comprised of our net losses, adjusted for non-cash expenses and working capital requirements. As noted previously, our net loss for 2013 increased by $53.3 million as compared to 2012, due primarily to the overall increases in operating expenses offset in part by increases in revenue, due to the launch of Iclusig in 2013, and a reduction in the non-cash charge for revaluation of our warrant liability of $15.9 million in 2012. Our net cash used in operating activities increased by $68.2 million in 2013 as compared to 2012, reflecting overall increases in operating expenses, decreases in non-cash adjustments and a decrease in working capital items, offset in part by increased revenue due to the launch of Iclusig in 2013. Another significant use of cash in 2013 compared to 2012 was an increase in restricted cash held as collateral for a letter of credit associated with the lease we executed in January 2013, and amended in September 2013, for new laboratory and office space.

Off-Balance Sheet Arrangements

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities for financial partnerships, such as entities often referred to as structured finance or special purpose entities which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of December 31, 2013, we maintained outstanding letters of credit of $11.4 million in accordance with the terms of our existing leases for our office and laboratory space, our new lease for office and laboratory space under construction, and for other purposes.

Contractual Obligations

We have substantial fixed contractual obligations under our long-term debt agreement, lease agreements, employment agreements, purchase commitments and benefit plans. These non-cancellable contractual obligations were comprised of the following as of December 31, 2013:

		Payments Due By Period			
In thousands	Total	In 2014	2015 through 2017	2018 through 2019	After 2019
Long-term debt	$ 9,100	$ 4,200	$ 4,900	$ —	$ —
Lease agreements	493,305	7,848	60,934	72,629	351,894
Employment agreements	7,347	6,689	658	—	—
Purchase commitments	33,809	2,704	19,744	5,736	5,625
Other long-term obligations	4,613	2,585	2,028	—	—
Total fixed contractual obligations	$548,174	$24,026	$88,264	$ 78,365	$357,519

Long-term debt consists of scheduled principal payments on such debt. Interest on our long-term debt is based on variable interest rates. Assuming a constant interest rate of 1.42 percent, our average interest rate on our debt at December 31, 2013, over the remaining term of the debt, our interest expense would total approximately $148,000 in 2014 and 2015.

Leases consist of payments to be made on our building leases in Cambridge, Massachusetts and Lausanne, Switzerland, including future lease commitments related to leases executed for office and laboratory space in two buildings currently under construction in Cambridge and office space in a building in Lausanne that completed construction in early 2014. The minimum non-cancelable payments for the facility being constructed in Cambridge are included in the table above and include amounts related to the original lease and the lease amendment. We are the deemed owner for accounting purposes and have recognized a financing obligation associated with the cost of the buildings incurred to date for the buildings under construction in Cambridge, Massachusetts. In addition to minimum lease payments, the leases require us to pay additional amounts for our share of taxes, insurance, maintenance and operating expenses, which are not included in the above table. Employment agreements represent base salary payments under agreements with officers. Purchase commitments represent non-cancelable contractual commitments associated with certain clinical trial activities. Other long-term obligations are comprised primarily of our obligations under our deferred executive compensation plan and our liability for unrecognized tax positions, which is classified in 2016.

Liquidity

At December 31, 2013, we had cash and cash equivalents totaling $237.2 million and working capital of $172.8 million, compared to cash, cash equivalents and marketable securities totaling $164.4 million and working capital of $119.5 million at December 31, 2012. Of the $237.2 million of cash and cash equivalents at December 31, 2013, $15.0 million is maintained as a minimum balance requirement related to our bank term loan and $17.1 million was in accounts held by our international subsidiaries. For 2013, we reported a net loss of $274.2 million and cash used in operating activities of $221.9 million. Based on our recently revised operating plan and our restructuring activities announced on November 7, 2013, we believe that our cash and cash equivalents at December 31, 2013, together with anticipated sales of Iclusig, will be sufficient to fund our operations to mid-2015. This revised operating plan does not assume any capital-raising activities or other financing transactions.

During the past year, we have invested significant amounts in personnel, processes and systems related to the commercialization of Iclusig in the United States and Europe, including the hiring and training of an experienced sales force and other professional staff necessary for a product launch, the implementation of systems and processes to support the launch, the development of tools and materials being used in the launch and other activities. Due to the temporary suspension of Iclusig in the United States, we also incurred expenses related to a workforce reduction in the fourth quarter of 2013.

As noted above, in the fourth quarter of 2013, we temporarily suspended the marketing and commercial distribution of Iclusig in the United States. As we re-launch Iclusig in the United States in 2014, there is no

assurance that we will be successful in commercializing Iclusig in the United States, in Europe or in other territories where we await regulatory approval or have yet to file for regulatory approval. In addition, the outcome of the EMA's review of Iclusig is uncertain. We expect that the developments announced in October 2013 concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States and the EMA's review will adversely impact our efforts to commercialize Iclusig in CML and Ph+ ALL patients, and our ability to obtain product revenue will depend on our ability to continue to commercialize Iclusig in the United States, Europe and other territories, the success of our efforts to develop Iclusig in other patient populations and cancers, as well as the success of AP26113 and any other product candidates. If we are not successful in generating sufficient levels of sales from Iclusig and/or obtaining additional regulatory approvals, we will need to raise additional funding and/or further revise our operating plans in order to conserve cash to fund our operations.

We have historically incurred operating losses and net losses related to our research and development activities. Although we have discontinued the EPIC trial of Iclusig in CML patients and the majority of our Iclusig trials are on partial clinical hold, we are still currently conducting a number of clinical trials for Iclusig, including the Phase 2 clinical trial for Iclusig in adult patients with metastatic and/or unresectable GIST that we announced in June 2013 and we intend to initiate further enrollment if the partial clinical hold is lifted. For AP26113, we plan to commence a pivotal trial of AP26113 in ALK-positive NSCLC patients in the first quarter of 2014. We also plan to continue to invest in discovery research and add to our pipeline of product candidates through these activities. While we plan to continue these research and development activities, we expect that our total research and development activities will decrease in 2014 compared to 2013 due to the impact of the reduction in the size of our workforce and as we focus on key research and development activities and discovery research efforts. We also expect that our selling, general and administrative expenses will decrease in 2014 compared to 2013 as a result of the restructuring actions we have taken and other cost reduction initiatives. There are many factors that will affect our level of spending on these activities, our ability to successfully commercialize Iclusig in the United States and Europe, the results of the EMA's review of Iclusig, the impact of the FDA's partial clinical hold on Iclusig trials, the number, size and complexity of, and rate of enrollment of patients in our continued or future clinical trials for Iclusig and AP26113, the extent of other development activities for Iclusig and AP26113, the progress of our preclinical and discovery research programs, the status of regulatory reviews and timing of potential additional regulatory approvals and commercial launch of Iclusig in additional countries in Europe and other markets and of our other product candidates, the size of the workforce and required systems and infrastructure necessary to support commercialization of Iclusig and our product candidates in multiple markets and other factors.

Under our license agreements with Medinol and ICON, we are eligible to receive milestone payments based on achievement of specified development, regulatory and/or sales objectives as well as royalty payments upon commercialization of products. The commencement of patient enrollment in Medinol's clinical trials, along with the submission of an investigational device exemption, or IDE, with the FDA, will trigger milestone payments to us of $3.8 million, expected in 2014. There can be no assurance that future regulatory approvals will be obtained or that we will receive any additional milestone or other payments under these license agreements.

Until such time, if ever, that we generate revenues from sales of Iclusig and our product candidates sufficient to fund operations, we plan to continue to fund our operations by issuing common stock, debt or other securities in one or more public or private offerings, as market conditions permit, or through the incurrence of additional debt from commercial lenders or other financing transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends.

There can be no assurance that additional funds will be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to: (1) delay, limit, reduce or terminate our commercialization of Iclusig; (2) delay, limit, reduce or terminate preclinical studies, clinical trials or other clinical development activities for one or more of our approved products or product candidates; (3) delay, limit, reduce or terminate our discovery research or preclinical development activities; or (4) enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our product candidates, approved products, technologies or intellectual property.

Recently Adopted or Issued Accounting Pronouncements

In July 2013, the FASB issued ASU 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*. ASU 2013-11 requires, unless certain conditions exists, an unrecognized tax benefit or a portion of an unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar to a tax loss or a tax credit carryforward. We will apply this standard beginning January 1, 2014. The adoption of the standard is not expected to have a material impact on our consolidated financial statements.

ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our available funds in accordance with our investment policy to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment.

We invest cash balances in excess of operating requirements first in short-term, highly liquid securities, and money market accounts. Depending on our level of available funds and our expected cash requirements, we may invest a portion of our funds in marketable securities, consisting generally of corporate debt and U.S. government and agency securities. Maturities of our marketable securities are generally limited to periods necessary to fund our liquidity needs and may not in any case exceed three years. These securities are classified as available-for-sale.

At December 31, 2013, as our available funds are invested solely in cash and cash equivalents and we do not have significant market risk related to interest rate movements.

At December 31, 2013, we had $9.1 million outstanding under a bank term note which bears interest at prime or, alternatively, LIBOR + 1.25 percent to 2.25 percent. This note is sensitive to interest rate risk. In the event of a hypothetical 10 percent increase in the interest rate on which the loan is based (14 basis points at December 31, 2013), we would incur approximately $11,000 of additional interest expense per year based on expected balances over the next twelve months.

Certain Factors That May Affect Future Results of Operations

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Annual Report on Form 10-K contains such "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be made directly in this Annual Report, and they may also be made a part of this Annual Report by reference to other documents filed with the SEC, which is known as "incorporation by reference." Such statements in connection with any discussion of future operating or financial performance are identified by use of words such as "may," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," and other words and terms of similar meaning. Such statements are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties

include, but are not limited to, our ability to successfully commercialize and generate profits from sales of Iclusig; competition from alternative therapies and the acceptance of Iclusig by patients, physicians and third-party payors, particularly in light of changes to the product label in December 2013; our ability to obtain approval for Iclusig outside of the United States and in additional countries in Europe and in additional indications; difficulties in forecasting sales or recognizing revenues for Iclusig; our reliance on third-party manufacturers, including sole-source suppliers, and on specialty pharmacies and/or specialty distributors for the distribution of Iclusig; the impact of adverse events or additional safety data, such as our announcements in October 2013 concerning a partial clinical hold of trials of Iclusig, safety warnings from the FDA, discontinuation of the EPIC trial and the temporary suspension of marketing and commercial distribution of Iclusig in the United States; preclinical data and early-stage clinical data that may not be replicated in later-stage clinical studies or the receipt of additional adverse data as more patients are treated; the costs associated with our research, development, manufacturing and other activities; the conduct and results of preclinical and clinical studies of our product candidates; difficulties or delays in obtaining or maintaining regulatory approvals to market products; the timing of development and potential market opportunity for our products and product candidates; our reliance on our strategic partners, licensees and other key parties for the successful development, manufacturing and commercialization of our product candidates; the adequacy of our capital resources and the availability of additional funding; patent protection and third-party intellectual property claims; our failure to comply with extensive regulatory requirements; the occurrence of serious adverse events in patients being treated with Iclusig or our product candidates; the ability to manage our growth effectively; litigation, including our pending securities class action and derivative lawsuits; our operations in foreign countries; future capital needs; risks related to key employees, markets, economic conditions, health care reform, prices and reimbursement rates; and other factors. Please also see the discussion under “Risk Factors” in Part I, Item 1A appearing elsewhere in this Annual Report on Form 10-K for more details regarding these and other risks.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Annual Report or in any document incorporated by reference might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference in this Annual Report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
ARIAD Pharmaceuticals, Inc.
Cambridge, Massachusetts

We have audited the accompanying consolidated balance sheets of ARIAD Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of ARIAD Pharmaceuticals, Inc. and subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2013, based on the criteria established in *Internal Control—Integrated Framework* (*1992*) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 3, 2014 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 3, 2014

ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

In thousands, except share and per share data	December 31, 2013	December 31, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 237,179	$ 119,379
Marketable securities	—	45,035
Accounts receivable	1,305	—
Inventory	419	6
Other current assets	6,043	3,930
Total current assets	244,946	168,350
Restricted cash	11,357	1,038
Property and equipment, net	108,777	7,681
Intangible and other assets, net	5,814	3,124
Total assets	$ 370,894	$ 180,193
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,363	$ 8,267
Current portion of long-term debt and capital lease obligations	4,200	2,115
Accrued compensation and benefits	12,778	11,865
Accrued product development expenses	16,740	14,061
Other accrued expenses	8,977	8,096
Current portion of deferred executive compensation	2,511	3,533
Current portion of deferred revenue	472	231
Other current liabilities	15,136	698
Total current liabilities	72,177	48,866
Long term debt	4,900	9,100
Long-term facility lease obligation	99,412	—
Other long-term liabilities	8,580	6,870
Deferred revenue	308	538
Deferred executive compensation	—	1,968
Commitments (Note 10)		
Stockholders' equity:		
Preferred stock, $.01 par value, authorized 10,000,000 shares, none issued and outstanding		
Common stock, $.001 par value, authorized 450,000,000 shares in 2013 and 240,000,000 in 2012; shares issued and outstanding 185,896,080 shares in 2013 and 167,075,758 shares in 2012	186	167
Additional paid-in capital	1,238,859	890,499
Accumulated other comprehensive income (loss)	(1,535)	20
Accumulated deficit	(1,051,993)	(777,835)
Total stockholders' equity	185,517	112,851
Total liabilities and stockholders' equity	$ 370,894	$ 180,193

See notes to consolidated financial statements.

ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

In thousands, except per share data	Years Ended December 31, 2013	2012	2011
Revenue:			
Product revenue, net	$ 45,238	$ —	$ —
License and collaboration revenue	296	514	25,189
Service revenue	27	44	111
Total revenue	45,561	558	25,300
Operating expenses:			
Cost of product revenue	9,612	—	—
Research and development expense	162,900	144,709	77,743
Selling, general and administrative expense	146,615	60,909	24,380
Total operating expenses	319,127	205,618	102,123
Loss from operations	(273,566)	(205,060)	(76,823)
Other income (expense):			
Interest income	130	240	167
Interest expense	(153)	(199)	(232)
Revaluation of warrant liability	—	(15,924)	(46,715)
Foreign exchange gain (loss)	(130)	71	—
Other income (expense), net	(153)	(15,812)	(46,780)
Loss before provision for income taxes	(273,719)	(220,872)	(123,603)
Provision for income taxes	439	—	—
Net loss	$ (274,158)	$(220,872)	$(123,603)
Net loss per share – basic and diluted	$ (1.49)	$ (1.34)	$ (0.93)
Weighted-average number of shares of common stock outstanding – basic and diluted	183,575	164,964	132,375

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

In thousands	Years Ended December 31, 2013	2012	2011
Net loss	$(274,158)	$(220,872)	$(123,603)
Other comprehensive income (loss):			
Net unrealized gains (reclassification adjustment) on marketable securities	(20)	20	—
Cumulative translation adjustment	(40)	—	—
Defined benefit pension obligation	(1,495)	—	—
Other comprehensive income (loss)	(1,555)	20	—
Comprehensive loss	$(275,713)	$(220,852)	$(123,603)

See notes to consolidated financial statements.

ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

In thousands, except share data	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance, January 1, 2011	126,942,431	$ 127	$ 497,309	$ —	$ (433,360)	$ 64,076
Issuance of shares pursuant to ARIAD stock plans	2,183,504	2	4,789			4,791
Issuance of common stock, net of issuance costs	24,725,000	25	243,033			243,058
Issuance of common stock from warrant exercise	3,757,767	4	24,967			24,971
Stock-based compensation			7,675			7,675
Payments of tax withholding obligations related to stock compensation			(827)			(827)
Net loss					(123,603)	(123,603)
Balance, December 31, 2011	157,608,702	158	776,946	—	(556,963)	220,141
Issuance of shares pursuant to ARIAD stock plans	3,661,213	3	10,508			10,511
Issuance of common stock from warrant exercise	5,805,843	6	87,040			87,046
Stock-based compensation			20,341			20,341
Payments of tax withholding obligations related to stock compensation			(4,336)			(4,336)
Net loss					(220,872)	(220,872)
Other comprehensive income				20		20
Balance, December 31, 2012	167,075,758	167	890,499	20	(777,835)	112,851
Issuance of shares pursuant to ARIAD stock plans	2,330,429	2	6,282			6,284
Issuance of common stock, net of issuance costs	16,489,893	17	310,020			310,037
Stock-based compensation			35,421			35,421
Payments of tax withholding obligations related to stock compensation			(3,363)			(3,363)
Net loss					(274,158)	(274,158)
Other comprehensive loss				(1,555)		(1,555)
Balance, December 31, 2013	185,896,080	$ 186	$1,238,859	$ (1,535)	$(1,051,993)	$ 185,517

See notes to consolidated financial statements.

ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

In thousands	Years Ended December 31, 2013	2012	2011
Cash flows from operating activities:			
Net loss	$(274,158)	$ (220,872)	$(123,603)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation, amortization and impairment charges	4,136	8,307	4,614
Stock-based compensation	35,421	20,341	7,675
Deferred executive compensation expense	963	2,810	1,719
Revaluation of warrant liability	—	15,924	46,715
Increase (decrease) from:			
Accounts receivable	(1,305)	—	—
Inventory	(413)	—	—
Other current assets	(2,113)	(4,714)	228
Other assets	(2,714)	—	—
Accounts payable	2,478	2,664	2,394
Accrued compensation and benefits	913	10,656	82
Accrued product development expenses	2,679	2,113	3,759
Other accrued expenses	1,340	4,669	1,271
Other liabilities	14,834	5,714	1,660
Deferred revenue	10	(230)	999
Deferred executive compensation paid	(3,953)	(1,063)	(775)
Net cash used in operating activities	(221,882)	(153,681)	(53,262)
Cash flows from investing activities:			
Acquisitions of marketable securities	—	(89,554)	—
Proceeds from maturities of marketable securities	45,000	44,500	—
Change in restricted cash	(10,319)	(289)	—
Investment in property and equipment	(8,543)	(4,424)	(1,452)
Investment in intangible assets	—	(633)	(671)
Net cash provided by (used in) investing activities	26,138	(50,400)	(2,123)
Cash flows from financing activities:			
Proceeds from long-term borrowings	—	—	4,375
Repayment of long-term borrowings	(2,100)	(1,400)	(1,400)
Principal payments under capital lease obligations	(15)	(54)	(66)
Proceeds from issuance of common stock, net of issuance costs	310,037	—	243,058
Reimbursements of amounts related to facility lease obligation	2,741	—	—
Proceeds from issuance of common stock pursuant to warrants	—	12,483	8,080
Proceeds from issuance of common stock pursuant to stock option and purchase plans	6,284	10,511	4,791
Payment of tax withholding obligations related to stock compensation	(3,363)	(4,336)	(827)
Net cash provided by financing activities	313,584	17,204	258,011
Effect of exchange rates on cash	(40)	—	—
Net increase (decrease) in cash and cash equivalents	117,800	(186,877)	202,626
Cash and cash equivalents, beginning of year	119,379	306,256	103,630
Cash and cash equivalents, end of year	$ 237,179	$ 119,379	$306,256
Supplemental disclosures:			
Interest paid	$ 153	$ 206	$ 230
Income taxes paid	$ 17	$ —	$ —
Capitalization of construction-in-progress related to facility lease obligation	$ 96,671	$ —	$ —
Non-cash transaction – property and equipment included in accounts payable or accruals	$ 738	$ 579	$ 911

See notes to consolidated financial statements.

ARIAD PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Summary of Significant Accounting Policies

Nature of Business

ARIAD is a global oncology company whose vision is to transform the lives of cancer patients with breakthrough medicines. The Company's mission is to discover, develop and commercialize small-molecule drugs to treat cancer in patients with the greatest unmet medical need – aggressive cancers where current therapies are inadequate.

In addition to commercializing Iclusig® (ponatinib), the Company is developing Iclusig for approval in additional countries and cancer indications and has two other product candidates in development, AP26113 and ridaforolimus. AP26113 is being studied in patients with advanced solid tumors, including non-small cell lung cancer. Ridaforolimus is being developed for cardiovascular indications by Medinol, Ltd. and ICON Medical Corp. In addition to its clinical development programs, the Company has a focused drug discovery program centered on small-molecule therapies that are molecularly targeted to cell-signaling pathways implicated in cancer.

In December 2012, the Company obtained accelerated approval from the U.S. Food and Drug Administration ("FDA") to sell its first new cancer medicine, Iclusig, and commenced sales and marketing of Iclusig in the United States in January 2013. Iclusig is approved for the treatment of adult patients with chronic myeloid leukemia ("CML") and Philadelphia chromosome-positive acute lymphoblastic leukemia ("Ph+ ALL"). On July 2, 2013, the Company announced that the European Commission granted marketing authorization for Iclusig in the European Union. The Company commenced sales efforts in certain European countries in the second half of 2013. Accordingly, the Company's financial statements for 2013 include product revenue and other transactions related to commercialization that did not exist in prior years.

On October 9, 2013, the Company announced results of its review of updated clinical data from the pivotal PACE (**P**onatinib Ph+ **A**LL and **C**ML **E**valuation) trial of Iclusig and actions that it was taking following consultations with the FDA. Based upon its review and the FDA consultations, the Company paused patient enrollment in all clinical trials of Iclusig and the FDA placed a partial clinical hold on all additional patient enrollment in clinical trials of Iclusig. In response to a request by the FDA, on October 31, 2013, the Company announced that it temporarily suspended the marketing and commercial distribution of Iclusig in the United States. On December 20, 2013, the Company announced that the FDA approved revised U.S. prescribing information, or USPI, and a Risk Evaluation and Mitigation Strategy, or REMS, that allowed for the immediate resumption of marketing and commercial distribution of Iclusig. Sales of Iclusig in the United States resumed in January 2014.

The Company's current operating plan includes the impact of the re-launch of Iclusig in the United States. Based on this operating plan, the Company believes that its cash and cash equivalents at December 31, 2013, together with anticipated sales of Iclusig, will be sufficient to fund operations into 2015. The operating plan does not assume any capital-raising activities or other financing transactions. Until such time that revenue is sufficient to fund operations, the Company plans to continue to fund operations, as necessary, through capital raising or other financing transactions.

Principles of Consolidation

The consolidated financial statements include the accounts of ARIAD Pharmaceuticals, Inc. and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency

A subsidiary's functional currency is the currency of the primary economic environment in which the subsidiary operates; normally, that is the currency of the environment in which a subsidiary primarily generates and expends cash. In making the determination of the appropriate functional currency for a subsidiary, the Company considers cash flow indictors, local market indicators, financing indicators and the subsidiary's relationship with both the parent company and other subsidiaries. For subsidiaries that are primarily a direct and integral component or extension of the parent entity's operations, the U.S. dollar is the functional currency.

For foreign subsidiaries that transact in functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign exchange rate for the period. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net loss and are recorded in accumulated other comprehensive income (loss), a separate component of stockholders' equity. For foreign subsidiaries where the functional currency is the U.S. dollar, monetary assets and liabilities are re-measured into U.S. dollars at the current exchange rate on the balance sheet date. Nonmonetary assets and liabilities are re-measured into U.S. dollars at historical exchange rates. Revenue and expense items are translated at average rates of exchange prevailing during each period.

The net total of realized and unrealized transaction gains and losses was a loss of $194,000 in 2013.

Accounting Estimates

The preparation of the consolidated financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts and disclosure of assets and liabilities at the date of the consolidated financial statements and the reported amounts and disclosure of revenue and expenses during the reporting period. Significant estimates included in the Company's financial statements include estimates associated with revenue recognition and the related adjustments, research and development accruals, inventory, leased buildings under construction and stock-based compensation. Actual results could differ from those estimates.

Reclassifications

In the consolidated balance sheet as of December 31, 2012, inventory has been separately presented and amounts due under license agreement has been aggregated with other current assets in order to conform with current year presentation. In addition, amounts due under license and collaboration agreements and other current assets in the consolidated statement of cash flows for 2012 and 2011 have been aggregated. None of the reclassifications were significant.

Cash Equivalents

Cash equivalents include short-term, highly liquid investments, with remaining maturities at the date of purchase of 90 days or less, and money market accounts.

Restricted Cash

Restricted cash consists of cash balances held as collateral for outstanding letters of credit related to the lease of the Company's laboratory and office facilities, for a letter of credit related to the lease agreement entered into in January 2013, and amended in September 2013, for lab and office space in a new facility under construction in Cambridge, Massachusetts and for other purposes.

Marketable Securities

Marketable securities consist of United States government and agency-backed debt securities. The Company classifies these marketable debt securities as available-for-sale at fair value. The Company records the amortization of premium and accretion of discounts on marketable debt securities in the results of operations. The Company uses the specific identification method as a basis for determining cost and calculating realized gains and losses with respect to marketable debt securities.

Inventory

The Company outsources the manufacturing of Iclusig and uses contract manufacturers that produce the raw and intermediate materials used in the production of Iclusig as well as the finished product. The Company currently has one supplier qualified for each step in the manufacturing process and is in the process of qualifying additional suppliers for certain steps of the production process of Iclusig. Accordingly, the Company has concentration risk associated with its manufacturing process and relies on its currently approved contract manufacturers for supply of its product.

In connection with production of inventory, the Company may be required to provide payments to vendors in advance of production. These amounts are included in other current assets on the accompanying consolidated balance sheets.

Inventory is composed of raw materials, intermediate materials, which are classified as work-in-process, and finished goods, which are goods that are available for sale. The Company records inventory at the lower of cost or market. The Company determines the cost of its inventory on a specific identification basis. If the Company identifies excess, obsolete or unsalable items, it writes down its inventory to its net realizable value in the period it is identified. These adjustments are recorded based upon various factors, including the level of product manufactured by the Company, the level of product in the distribution channel, current and projected demand for the foreseeable future and the expected shelf-life of the inventory components. Inventory that is not expected to be used within one year is included in other assets, net, on the accompanying consolidated balance sheets.

Prior to receiving approval from the FDA on December 14, 2012 to sell Iclusig, the Company expensed all costs incurred related to the manufacture of Iclusig as research and development expense because of the inherent risks associated with the development of a drug candidate, the uncertainty about the regulatory approval process and the lack of history for the Company of regulatory approval of drug candidates.

Shipping and handling costs for product shipments are recorded as incurred in cost of product revenue along with costs associated with manufacturing the product sold and any inventory reserves or write-downs.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Leasehold improvements and assets under capital leases are amortized over the shorter of their useful lives or lease term using the straight-line method.

In connection with a lease for a facility being constructed in Cambridge, Massachusetts, the landlord is providing the Company with a tenant improvement allowance for the costs associated with the design, engineering, and construction of tenant improvements for the leased facility. The tenant improvements will be constructed in accordance with the Company's plans and include fit-out of the buildings to construct appropriate laboratory and office space, subject to approval by the landlord. To the extent the stipulated tenant allowance provided by the landlord is exceeded, the Company is obligated to fund all costs incurred in excess of the tenant allowance. The scope of the planned tenant improvements do not qualify as "normal tenant improvements" under the lease accounting guidance. Accordingly, for accounting purposes, the Company is the deemed owner of the buildings during the construction period.

As construction progresses, the Company records the project construction costs incurred as an asset, along with a corresponding facility lease obligation, on the consolidated balance sheet for the total amount of project costs incurred whether funded by the Company or the landlord. Upon completion of the buildings, the Company will determine if the asset and corresponding financing obligation should continue to be carried on its consolidated balance sheet under the accounting guidance. Based on the current terms of the lease, the Company expects to continue to be the deemed owner of the buildings upon completion of the construction period.

Intangible Assets

Intangible assets consist primarily of purchased technology and capitalized patent and license costs. The cost of purchased technology, patents and patent applications, costs incurred in filing patents and certain license fees are capitalized when recovery of the costs is probable. Capitalized costs related to purchased technology are amortized over the estimated useful life of the technology. Capitalized costs related to issued patents are amortized over a period not to exceed seventeen years or the remaining life of the patent, whichever is shorter, using the straight-line method. Capitalized license fees are amortized over the periods to which they relate. In addition, capitalized costs are expensed when it becomes determinable that the related patents, patent applications or technology will not be pursued.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, including the above-mentioned intangible assets, for impairment when events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

Accrued Rent

The Company recognizes rent expense for leases with increasing annual rents on a straight-line basis over the term of the lease. The amount of rent expense in excess of cash payments is classified as accrued rent. Any lease incentives received are deferred and amortized over the term of the lease. At December 31, 2013 and 2012, the amount of accrued rent is $5.1 million and $5.0 million, respectively. Of these amounts, at December 31, 2013 and 2012, $4.6 million and $4.7 million, respectively, are included in other long-term liabilities, with the remaining $0.5 million and $0.3 million as of December 31, 2013 and 2012, respectively, included in other current liabilities.

Revenue Recognition

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of each deliverable and the appropriate revenue recognition principles are applied to each unit.

Product Revenue, Net

Commencing in January 2013, the Company sold Iclusig in the United States to a limited number of specialty pharmacies, which dispensed the product directly to patients, and specialty distributors, which in turn sold the product to hospital pharmacies and community practice pharmacies (collectively, healthcare providers) for the treatment of patients. In Europe, the Company sells Iclusig to retail pharmacies and hospital pharmacies which dispense product directly to patients. These specialty pharmacies, specialty distributors, retail pharmacies and hospital pharmacies are referred to as the Company’s customers.

During 2013, the Company provided the right of return to customers in the United States for unopened product for a limited time before and after its expiration date. European customers are provided the right

to return product only in limited circumstances, such as instances of damaged product. Given the Company's limited sales history for Iclusig and the inherent uncertainties in estimating product returns, the Company determined that the shipments of Iclusig to its United States customers in 2013 did not meet the criteria for revenue recognition at the time of shipment. Accordingly, the Company recognized revenue when the product was sold through by its United States customers, provided all other revenue recognition criteria were met. The Company invoiced its United States customers upon shipment of Iclusig to them and recorded accounts receivable, with a corresponding liability for deferred revenue, equal to the gross invoice price. The Company then recognized revenue when Iclusig was sold through, either when the specialty distributors shipped product to healthcare providers or when specialty pharmacies dispensed product directly to the patient. Healthcare providers to whom specialty distributors sold Iclusig held limited inventory that was designated for patients, thereby limiting the risk of return. For European customers, who are provided with a limited right of return, the criteria for revenue recognition is met at the time of shipment and revenue is recognized at that time, provided all other revenue recognition criteria are met.

In connection with the temporary suspension of Iclusig described above, the Company terminated its existing contracts with specialty pharmacies and specialty distributors in the United States. In addition, the Company accepted product returns for Iclusig in connection with the temporary suspension. These returns primarily related to Iclusig held by specialty pharmacies and specialty distributors for which revenue had not been recognized. Returns for which revenue had been previously recognized were not significant. At December 31, 2013, the Company owed approximately $4.2 million to former customers in the United States which had paid for product purchases and committed to return those purchases in connection with the temporary suspension of Iclusig. This amount is included within other current liabilities on the consolidated balance sheet as of December 31, 2013.

The Company has written contracts or standard terms of sale with each of its customers and delivery occurs when the customer receives Iclusig. The Company evaluates the creditworthiness of its customers to determine whether collection is reasonably assured. In order to conclude that the price is fixed or determinable, the Company must be able to (i) calculate its gross product revenues from the sales to its customers and (ii) reasonably estimate its net product revenues. The Company calculates gross product revenues based on the wholesale acquisition cost that the Company charges its customers for Iclusig. The Company estimates its net product revenues by deducting from its gross product revenues (i) trade allowances, such as invoice discounts for prompt payment and customer fees, (ii) estimated government and private payor rebates, chargebacks and discounts, such as Medicare and Medicaid reimbursements in the United States, and (iii) estimated costs of incentives offered to certain indirect customers including patients. These deductions from gross revenue to determine net revenue are also referred to as gross to net deductions.

Trade Allowances: The Company provides invoice discounts on Iclusig sales to certain of its customers for prompt payment and pays fees for certain distribution services, such as fees for certain data that its customers provide to the Company. The Company deducts the full amount of these discounts and fees from its gross product revenues at the time such discounts and fees are earned by such customers.

Rebates, Chargebacks and Discounts: In the United States, the Company contracts with Medicare, Medicaid, other government agencies and various private organizations (collectively, payors) to make Iclusig, when commercially available, eligible for purchase by, or for partial or full reimbursement from, such payors. The Company estimates the rebates, chargebacks and discounts it will provide to payors and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's estimates of rebates, chargebacks and discounts are based on (1) the contractual terms of agreements in place with payors, (2) the government-mandated discounts applicable to government-funded programs, and (3) the estimated payor mix. Government rebates that are invoiced directly to the Company are recorded in other accrued expenses on the consolidated balance sheet. For qualified programs that can purchase the Company's products at a lower contractual government or commercial price, the customers charge back to the Company the

difference between their acquisition cost and the lower contractual government or commercial price, which the Company records as an allowance against accounts receivable on the consolidated balance sheet. In Europe, the Company is subject to mandatory rebates and discounts in markets where government-sponsored healthcare systems are the primary payers for healthcare. These rebates and discounts are recorded in other accrued expenses on the consolidated balance sheet.

Other Incentives: Other incentives that the Company offers to indirect customers include co-pay assistance rebates provided by the Company to commercially insured patients who have coverage for Iclusig and who reside in states that permit co-pay assistance programs. The Company's co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Iclusig's purchase price to a specified dollar amount. In each period, the Company records the amount of co-pay assistance provided to eligible patients based on the terms of the program.

The following table summarizes activity in each of the above product revenue allowances and reserve categories for 2013:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Other Incentives/ Returns	Total
Balance, January 1, 2013	$ —	$ —	$ —	$ —
Provision	1,158	2,721	180	4,059
Payments or credits	(1,140)	(2,206)	(103)	(3,449)
Balance, December 31, 2013	$ 18	$ 515	$ 77	$ 610

The reserves above, included in the Company's consolidated balance sheets are summarized as follows:

In thousands	December 31, 2013
Reductions of accounts receivable	$ 64
Other accrued expenses	546
Total	$ 610

Patients in Europe are also being treated with Iclusig in the framework of clinical trials and related studies and in named patient programs. In 2012, the French regulatory authority granted an *Autorisation Temporaire d'Utilisation* (ATU), or Temporary Authorization for Use, for Iclusig for the treatment of patients with CML and Ph+ ALL under a nominative program on a patient-by-patient basis. The Company began shipping Iclusig under this program during the year ended December 31, 2012. Until all revenue recognition criteria are met (including a fixed or determinable price), all amounts received under this program (approximately $8.8 million as of December 31, 2013) have not been recorded as revenue. This program concluded on September 30, 2013 and all outstanding amounts have been received. Upon completion of this program, the Company became eligible to ship Iclusig directly to customers in France as of October 1, 2013. These shipments have not met the criteria for revenue recognition as the price for these shipments is not yet fixed or determinable. These shipments totaled $4.1 million for the period from October 1, 2013 to December 31, 2013, of which $1.8 million was received as of December 31, 2013. The Company will record these shipments, as well as shipments under the ATU program, as revenue once the price is fixed or determinable.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of accounts receivable from customers and cash held at financial institutions. The Company believes that such customers and financial institutions are of high credit quality. As of December 31, 2013, a portion of the Company's cash and cash equivalent accounts were concentrated at a single financial institution, which potentially exposes the Company to credit risks. The Company does not believe that there is significant risk of non-performance by the financial institution and the Company's cash on deposit at this financial institution is fully liquid.

For the year-ended December 31, 2013, three individual customers accounted for 24 percent, 15 percent and 13 percent of net product revenue, respectively. As of December 31, 2013, two individual customers accounted for 15 percent and 13 percent of accounts receivable, respectively. No other customer accounted for more than 10 percent of net product revenue or accounts receivable.

Revenues in 2012 and 2011 primarily related to one license agreement discussed in Note 2.

Advertising Costs

In connection with the commercial launch of Iclusig during 2013, the Company began incurring advertising costs. Advertising costs are expensed as incurred. For the year ended December 31, 2013, advertising costs totaled $1.0 million.

Income Taxes

The Company accounts for income taxes using an asset and liability approach to financial accounting and reporting for income taxes. Deferred income tax assets and liabilities are computed annually for differences between the financial statement basis and the income tax basis of assets and liabilities that will result in taxable or deductible amounts in the future. Such deferred income tax computations are based on enacted tax laws and rates applicable to the years in which the differences are expected to affect taxable income. A valuation allowance is established when it is necessary to reduce deferred income tax assets to the amount that is considered to be more-likely-than-not realizable.

The Company does not recognize a tax benefit unless it is more likely than not that the tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit that is recorded for these positions is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. Any interest and penalties on uncertain tax positions are included within the tax provision.

Stock-Based Compensation

The Company awards stock options and other equity-based instruments to its employees, directors and consultants and provides employees the right to purchase common stock (collectively “share-based payments”), pursuant to stockholder approved plans. Compensation cost related to such awards is measured based on the fair value of the instrument on the grant date and is recognized on a straight-line basis over the requisite service period, which generally equals the vesting period.

Executive Compensation Plan

The Company has an unfunded deferred executive compensation plan that defers the payment of annual bonus awards to officers to future periods as specified in each award. The value of the awards is indexed to the value of specified mutual funds. The Company accrues a liability based on the value of the awards ratably over the vesting period. The recorded balances of such awards are increased or decreased based on the actual total return and quoted market prices of the specified mutual funds.

Segment Reporting and Geographic Information

The Company organizes itself into one operating segment reporting to the Chief Executive Officer.

In 2013, product revenue from customers outside the United States totaled 9%. All other product, license and collaboration and service revenues in 2013, 2012, and 2011 were generated within the United States. Long lived assets outside the United States were insignificant for all periods presented.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

On January 14, 2014, the Company jointly announced with Medinol Ltd., the initiation of two registration trials of Medinol's stent system that incorporates ridaforolimus. The commencement of enrollment in the clinical trials, along with the submission of an investigational device exemption with the FDA, will trigger milestone payments to the Company of $3.8 million, expected in 2014.

Recent Accounting Pronouncements

In July 2013, the FASB issued ASU 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*. ASU 2013-11 requires, unless certain conditions exists, an unrecognized tax benefit or a portion of an unrecognized tax benefit to be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, similar to a tax loss or a tax credit carryforward. The Company will apply this standard beginning January 1, 2014. The adoption of the standard is not expected to have a material impact on the Company's consolidated financial statements.

2. Collaboration and License Agreements with Merck & Co., Inc.

In July 2007, the Company entered into a collaboration agreement with Merck & Co., Inc., or Merck, for the joint global development, manufacture and commercialization of ridaforolimus, the Company's investigational oral mTOR inhibitor, for use in cancer (the "Collaboration Agreement"). In May 2010, the Company entered into an amended and restated agreement with Merck for ridaforolimus (the "License Agreement"), which replaced the Collaboration Agreement. These agreements are described below.

The Collaboration Agreement (July 2007 to May 2010)

Under the terms of the Collaboration Agreement, as in effect until May 4, 2010, Merck and the Company were conducting a broad-based development program for the use of ridaforolimus in multiple types of cancer. Each party funded 50 percent of global development costs incurred. Under the terms of the Collaboration Agreement, Merck paid the Company an initial up-front payment of $75 million in July 2007 and milestone payments of $53.5 million through May 4, 2010, based on the achievement of specified clinical and regulatory events.

The License Agreement (May 2010 to present)

Under the terms of the License Agreement, the Company granted Merck an exclusive license to develop, manufacture and commercialize ridaforolimus in oncology, and Merck assumed full responsibility for all activities related to the development, manufacture and commercialization of ridaforolimus and agreed to fund 100 percent of all ridaforolimus costs incurred after January 1, 2010. The License Agreement provided that Merck would develop ridaforolimus in multiple oncology indications. If ridaforolimus received regulatory approval, Merck would be responsible for selling ridaforolimus worldwide, and would pay the Company tiered double-digit royalties on global net sales.

Under the License Agreement, in 2010 Merck paid the Company an initial up-front fee of $50 million and approximately $12.8 million for its share of costs incurred in the period from January 1, 2010 to May 4, 2010 related to development, manufacture and commercial activities for ridaforolimus in accordance with the cost-sharing provisions of the Collaboration Agreement as in effect during that period. In addition, in 2011, Merck paid the Company a $25 million milestone payment for the acceptance of the marketing authorization application in Europe for the sarcoma indication, which was subsequently withdrawn by Merck in November 2012.

For the years ended December 31, 2013, 2012 and 2011, the Company recorded service revenue of approximately $27,000, $44,000 and $111,000, respectively. The cost of such services is reflected in operating expenses in the year in which they were incurred. License revenue that is not related to the Merck arrangement is not material in any of the years presented.

On February 20, 2014, the Company received notice from Merck that it is terminating the license agreement. Per the terms of the license agreement, this termination will become effective nine months from the date of the notice at which time all rights to ridaforolimus in oncology licensed to Merck will be returned to the Company.

3. Marketable Securities

The Company has classified its marketable securities as available-for-sale and, accordingly, carries such securities at fair value.

At December 31, 2013, the Company had no marketable securities.

At December 31, 2012, all of the Company's marketable securities consisted of United States government or agency securities, all of which matured within 12 months. At December 31, 2012, the aggregate fair value and amortized cost of the Company's marketable securities were $45,035,000 and $45,015,000, respectively. Gross unrealized gains were $20,000 at December 31, 2012 and are included in accumulated other comprehensive income (loss) in the consolidated balance sheets.

4. Inventory

All of the Company's inventories relate to the manufacturing of Iclusig. The following table sets forth the Company's inventories as of December 31, 2013 and 2012:

In thousands	2013	2012
Raw materials	$ —	$ —
Work in process	3,170	—
Finished goods	234	6
Total	$ 3,404	$ 6
Current portion	$ 419	$ 6
Non-current portion included in Other assets, net	$2,985	$ —

Upon approval of Iclusig by the FDA on December 14, 2012, the Company began capitalizing inventory costs for Iclusig manufactured in preparation for the product launch in the United States. In periods prior to December 14, 2012, the Company expensed costs associated with Iclusig, including raw materials, work-in-process and finished goods, as development expenses. The Company has not capitalized inventory costs related to its other drug development programs. Non-current inventory consists of work-in-process inventory that was manufactured in order to provide adequate supply of Iclusig in the United States and Europe and to support continued clinical development.

Due to the temporary suspension of Iclusig in the United States and the decrease in expected demand for Iclusig under the revised USPI, the Company assessed the need for an inventory write-down for excess inventory for its inventory on hand at December 31, 2013. This review included all components of inventory, including raw materials, work-in-process and finished goods inventory. Inventory balances on hand were compared to the expected uses of inventory in the future, taking into account the estimated future global demand for Iclusig in the foreseeable future, as well as the estimated shelf-life of the

Company's inventory components. From this analysis, the Company determined that approximately $7.1 million of its inventory was excess at December 31, 2013 and recorded a charge to cost of product revenue to write down inventory in the fourth quarter of 2013. In addition, during 2013 the Company also wrote down finished goods that will expire and not be sold. Total charges for 2013 for excess inventory, as well as finished goods inventory that will expire before it is sold, was approximately $7.6 million.

In connection with this review, the Company also charged $1.3 million of vendor advances to cost of product revenue as the advances relate to future inventory production that will result in excess inventory.

5. Property and Equipment, Net

Property and equipment, net, was comprised of the following at December 31, 2013 and 2012:

In thousands	2013	2012
Leasehold improvements	$ 25,714	$ 24,020
Construction in progress	99,908	—
Equipment and furniture	23,466	19,876
	149,088	43,896
Less accumulated depreciation and amortization	(40,311)	(36,215)
	$108,777	$ 7,681

As of December 31, 2013, the Company has recorded construction in progress and a facility lease obligation of $99.4 million related to a lease for a new facility under construction in Cambridge, Massachusetts. See Note 10 for further information.

Depreciation and amortization expense for the years ended December 31, 2013, 2012 and 2011 was $4.1 million, $2.8 million and $2.8 million, respectively.

6. Intangible and Other Assets, Net

Intangible and other assets, net, were comprised of the following at December 31, 2013 and 2012:

In thousands	2013	2012
Capitalized patent and license costs	$5,975	$5,975
Less accumulated amortization	(5,007)	(4,982)
	968	993
Inventory, non-current	2,985	—
Other assets	1,861	2,131
	$ 5,814	$ 3,124

Amortization expense for intangible assets was $25,000, $218,000 and $1.7 million in 2013, 2012 and 2011, respectively. The weighted average amortization period for intangible assets was 17.0 years, 17.0 years and 14.9 years in 2013, 2012 and 2011, respectively. The estimated future amortization expense is $28,000 per year for 2014, 2015, 2016, 2017, and 2018 and $828,000 thereafter.

For the years ended December 31, 2012 and 2011, the Company recorded charges to operating expenses of $5.2 million and $312,000, respectively, to reflect impairment of the carrying value of certain capitalized patents and licenses or purchased technology. In 2012 **,** the Company recorded a charge of $4.8 million to reflect impairment of the carrying value of intangible assets associated with ridaforolimus, following the decision in June 2012 by the FDA not to approve the NDA filed by Merck for the treatment of patients with soft tissue or bone sarcomas. The impairment of the carrying value of intangible assets was based on management's assessment of the uncertainty related to the timing and amount of future cash flows anticipated from these assets. No impairment charges were recorded in 2013.

7. Other Current Liabilities

Other current liabilities consisted of the following at December 31, 2013 and 2012:

In thousands	2013	2012
Amounts received in advance of revenue recognition	$ 10,434	$ —
Amounts due to former customers	4,172	—
Other	530	698
	$15,136	$698

Amounts received in advance of revenue recognition consists of payments received from customers in France. Amounts due to former customers consists of amounts due to former customers for product returns.

8. Long-term Debt and Capital Lease Obligations

Long-term debt and capital lease obligations were comprised of the following at December 31, 2013 and 2012:

In thousands	2013	2012
Bank term loan	$9,100	$ 11,200
Capital lease obligations	—	15
	9,100	11,215
Less current portion	(4,200)	(2,115)
	$ 4,900	$ 9,100

The term loan provides for quarterly payments of principal and interest with final scheduled maturity on December 31, 2015. The loan bears interest at LIBOR plus 1.25 to 2.25 percent, depending on the percentage of the Company's liquid assets on deposit with or invested through the bank, or at the prime rate. The effective interest on the loan was 1.42 percent at December 31, 2013. The loan is secured by a lien on all assets of the Company excluding intellectual property, which the Company has agreed not to pledge to any other party. The loan requires the Company to maintain a minimum of $15.0 million in unrestricted cash, cash equivalents and investments. The loan also contains certain covenants that restrict additional indebtedness, additional liens and sales of assets, and dividends, distributions or repurchases of common stock.

The future scheduled principal payments due under the term loan were as follows at December 31, 2013:

In thousands	
Year ended December 31:	
2014	$ 4,200
2015	4,900
	9,100
Less current portion	(4,200)
Long-term portion	$ 4,900

9. Executive Compensation Plan

Under the Company's deferred executive compensation plan, the Company accrues a liability for the value of the awards ratably over the vesting period. The grant date values of awards made in 2012 and 2011 were $1.1 million and $1.6 million, respectively. There were no awards in 2013. The net expense for this plan was $963,000, $2.8 million and $1.7 million in 2013, 2012 and 2011, respectively. The estimated future expense for unvested awards based on the value at December 31, 2013 is $74,000 for 2014.

10. Leases, Licensed Technology and Other Commitments

Facility Leases

The Company conducts the majority of its operations in a 100,000 square foot office and laboratory facility under a non-cancelable operating lease that extends to July 2019 with two consecutive five-year renewal options. The Company maintains an outstanding letter of credit of $1.4 million in accordance with the terms of the amended lease. In May 2012, the Company entered into a three-year operating lease agreement for an additional 26,000 square feet of office space. Future non-cancelable minimum annual rental payments through July 2020 under these leases are $6.7 million in 2014, $6.2 million in 2015, $5.5 million in 2016, $5.6 million in 2017, $5.7 million in 2018 and $3.3 million thereafter.

Binney Street, Cambridge, Massachusetts

In January 2013, the Company entered into a lease agreement for approximately 244,000 square feet of laboratory and office space in two adjacent, connected buildings which are under construction in Cambridge, Massachusetts. Construction is expected to be completed in early 2015. Under the terms of the original lease, the Company leased all of the rentable space in one of the two buildings and a portion of the available space in the second building. In September 2013, the Company entered into a lease amendment to lease all of the remaining space, approximately 142,000 square feet, in the second building, for an aggregate of 386,000 square feet in both buildings. The terms of the lease amendment were consistent with the terms of the original lease.

In connection with this lease, the landlord is providing a tenant improvement allowance for the costs associated with the design, engineering, and construction of tenant improvements for the leased facility. The tenant improvements will be in accordance with the Company's plans and include fit-out of the buildings to construct appropriate laboratory and office space, subject to approval by the landlord. To the extent the stipulated tenant allowance provided by the landlord is exceeded, the Company is obligated to fund all costs incurred in excess of the tenant allowance. The scope of the planned tenant improvements do not qualify as "normal tenant improvements" under the lease accounting guidance. Accordingly, for accounting purposes, the Company is the deemed owner of the buildings during the construction period.

As construction progresses, the Company records the project construction costs incurred as an asset, along with a corresponding facility lease obligation, on the consolidated balance sheet for the total amount of project costs incurred whether funded by the Company or the landlord. Upon completion of the buildings, the Company will determine if the asset and corresponding financing obligation should continue to be carried on its consolidated balance sheet under the accounting guidance. Based on the current terms of the lease, the Company expects to continue to be the deemed owner of the buildings upon completion of the construction period.

The initial term of the lease is for 15 years from substantial completion of the buildings with options to renew for three terms of five years each at market-based rates. The base rent is subject to increases over the term of the lease. Based on the original and amended leased space, the non-cancelable minimum annual lease payments for the annual periods beginning upon commencement of the lease are $5.3 million, $8.4 million, $26.6 million, $30.4 million and $30.9 million in the first five years of the lease and $347.1 million in total thereafter, plus the Company's share of the facility operating expenses and other costs that are reimbursable to the landlord under the lease.

In January 2013, the Company established a letter of credit as security for the lease of $5.8 million upon signing of the lease, which is supported by restricted cash. In connection with the lease amendment, the Company increased the letter of credit to $9.2 million in October 2013.

Lausanne, Switzerland

In January 2013, the Company entered into a lease agreement for approximately 22,000 square feet of office space in a building then under construction in Lausanne, Switzerland, which the Company occupied in 2014. The term of the lease is for ten years, with options for extension of the term and an early termination at the Company's option after five years. Non-cancelable minimum annual lease payments are expected to be approximately $1.1 million in 2014, 2015, 2016 and 2017, $1.2 million in 2018 and $5.9 million in total thereafter.

Total rent expense for 2013, 2012 and 2011 was $6.1 million, $5.9 million and $2.0 million, respectively. Total future non-cancelable minimum annual rental payments for the leases described above as well as other Company leases, for the next five years and thereafter is $7.8 million, $12.6 million, $15.0 million, $33.3 million, $37.2 million and $387.3 million, respectively.

Licensed Technology

The Company has entered into agreements with several universities under the terms of which the Company has received exclusive licenses to technology and intellectual property. The agreements, which are generally cancelable by the Company, provide for the payment of license fees and/or minimum payments, which are generally creditable against future royalties. Fees paid by the Company amounted to $145,000 in each of 2013, 2012 and 2011, and are expected to amount to $235,000 in each of 2014 and 2015, $55,000 in 2016, $50,000 in each of 2017 and 2018, and $35,000 in 2019. In addition, the agreements provide for payments upon the achievement of certain milestones in product development. The agreements also require the Company to fund certain costs associated with the filing and prosecution of patent applications.

Other Commitments

The Company has entered into employment agreements with twenty officers of the Company. The agreements for these officers have remaining terms as of December 31, 2013 through the end of 2014, providing for aggregate base salaries of $6.7 million for 2014.

11. Stockholders' Equity and Warrants

Preferred Stock

The Company has authorized 10,000,000 shares of preferred stock which the Board of Directors is authorized to designate and issue in different series. In connection with the Section 382 Rights Plan discussed below, the Company designated 500,000 shares of preferred stock as Series A Junior Participating Preferred Stock (the "Series A Junior Preferred Stock"). The Series A Junior Preferred Stock, when and if issued, has certain rights and privileges including rights to dividends, voting rights and preferential rights in the event of a liquidation of the Company. Each share of Series A Junior Preferred Stock participates in dividends and voting rights on a 1,000 to 1 basis with each share of common stock.

Common Stock and Warrants

On June 20, 2013, following stockholder approval, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, to increase the number of authorized shares of the Company's common stock from 240,000,000 to 450,000,000 shares.

On February 25, 2009, the Company sold 14,378,698 shares of its common stock in a registered direct offering to institutional investors, at a purchase price of $1.69 per share, resulting in net proceeds after fees and expenses of $22.8 million. The investors also received warrants to purchase an additional 10,784,024 shares of the Company's common stock exercisable at a price of $2.15 per share in cash or pursuant to the net exercise provisions of the warrants. The warrants became exercisable on August 25, 2009 and were scheduled to expire on February 25, 2012 if not exercised by that date. During the year ended December 31, 2010, 1,220,414 warrants were exercised for proceeds to the Company of approximately $2.6 million. During the year ended December 31, 2011, a total of 3,757,767 warrants were exercised for proceeds to the Company of approximately $8.1 million. In 2012, the remaining 5,805,843 warrants were exercised for proceeds to the Company of approximately $12.5 million. Prior to exercise, the warrant liability was recorded at fair value, with the adjustment to carrying value recognized in earnings. Upon exercise, the sum of the fair value of the exercised warrants and the proceeds received were credited to additional paid-in-capital and totaled $87.0 million in 2012. Upon the exercise of these remaining warrants, the balance of the warrant liability was credited to stockholders' equity and the liability was eliminated.

On December 20, 2011, the Company sold 24,725,000 shares of its common stock in an underwritten public offering at a purchase price of $10.42 per share. Net proceeds of this offering, after underwriting discounts and commissions and expenses, were approximately $243.1 million.

On January 29, 2013, the Company sold 16,489,893 shares of its common stock in an underwritten public offering at a purchase price of $19.60 per share. Net proceeds of this offering, after underwriting discounts and commissions and expenses, were approximately $310.0 million.

On December 14, 2011, the Company filed a shelf registration statement with the SEC for the issuance of an unspecified amount of common stock, preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, from time to time at prices and on terms to be determined at the time of any such offering. This registration statement was effective upon filing and will remain in effect for up to three years from filing.

Section 382 Rights Plan

On November 1, 2013, the Company announced that the Company's Board of Directors adopted a shareholder rights plan in the form of a Section 382 Rights Plan designed to preserve the Company's tax assets. As a part of the plan, on October 31, 2013, the Company's Board of Directors declared a dividend of one Series A Junior Preferred Stock fractional share purchase right for each share of the Company's common stock outstanding as of November 11, 2013. Effective on November 1, 2013, if any group or person acquires 4.99% or more of the Company's outstanding shares of common stock, or if a group or person that already owns 4.99% or more of the Company's common stock acquires additional shares representing 0.5% or more of the Company's common stock, then, subject to certain exceptions, there would be a triggering event under the plan. The rights would then separate from the Company's common stock and would be adjusted to become exercisable to purchase 1/1000 share of the Company's Series A Junior Preferred Stock having a market value equal to twice the exercise price of $20.00, resulting in significant dilution in the ownership interest of the acquiring person or group. The Company's Board of Directors has the discretion to exempt any acquisition of the Company's common stock from the provisions of the plan and has the ability to terminate the plan prior to a triggering event.

12. Fair Value of Financial Instruments

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3—Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

As of December 31, 2013, the Company did not hold any assets recorded at fair value. The following table presents information about the Company's marketable securities as of December 31, 2012 and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	December 31, 2012			
In thousands	Total	Level 1	Level 2	Level 3
Marketable securities	$45,035	$ —	$45,035	$ —

At December 31, 2012, the Company's marketable securities were carried at fair value. The marketable securities consisted of U.S. government or government backed securities with remaining maturities of less than one year. Marketable securities are classified as Level 2 in the fair value hierarchy as their prices are based on observable inputs but not for identical securities. Therefore, their fair value is based on observable inputs other than quoted prices included within Level 1.

For 2012 and 2011, the fair value of warrants was determined using the Black-Scholes option valuation model. The increase in the fair value of the warrants was recognized in other income (expense) in the consolidated statements of operations. The changes in the fair value of the warrant liability for the years ended December 31, 2012 and 2011 were as follows:

In thousands	2012	2011
Balance, beginning of the year:	$ 58,639	$ 28,815
Issuance of warrants	—	—
Revaluation of warrants	15,924	46,715
Exercise of warrants	(74,563)	(16,891)
Balance, end of year	$ —	$ 58,639

At December 31, 2013 and 2012, the carrying amounts of cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The carrying amount of the Company's bank term loan approximates fair value due to its variable interest rate and other terms. All

such measurements are Level 2 measurements in the fair value hierarchy. The Company's obligation under its executive compensation plan is based in part on the current fair market value of specified mutual funds, which is therefore stated at its estimated fair value. The carrying amount of the Company's leased buildings under construction in Cambridge, Massachusetts and the related long term facility lease obligation reflect replacement cost, which approximates fair value. This measurement is a Level 3 fair value measurement.

13. Stock Compensation

ARIAD Stock Option and Stock Plans

The Company's 2001 and 2006 stock option and stock plans (the "Plans") provide for the awarding of nonqualified and incentive stock options, stock grants, restricted stock units, performance share units and other equity-based awards to officers, directors, employees and consultants of the Company. Stock options become exercisable as specified in the related option certificate, typically over a three or four-year period, and expire ten years from the date of grant. Stock grants, restricted stock units and performance share units provide the recipient with ownership of common stock subject to terms of vesting, any rights the Company may have to repurchase the shares granted or other restrictions. The 2001 Plan has no shares remaining available for grant, although existing stock options granted under this Plan remain outstanding. As of December 31, 2013, there were 8,079,200 shares available for awards under the 2006 Plan. The Company generally issues new shares upon the exercise or vesting of stock plan awards.

Employee Stock Purchase Plan

In 1997, the Company adopted the 1997 Employee Stock Purchase Plan ("ESPP") and reserved 500,000 shares of common stock for issuance under this plan. In June 2008, the ESPP was amended to reserve an additional 500,000 shares of common stock for issuance, and in June 2009, the plan was further amended to reserve an additional 750,000 shares of common stock for issuance. Under this plan, substantially all of the Company's employees may, through payroll withholdings, purchase shares of the Company's common stock at a price of 85 percent of the lesser of the fair market value at the beginning or end of each three-month withholding period. In 2013, 2012 and 2011, 101,300, 66,531 and 87,331 shares of common stock were issued under the plan, respectively. Compensation cost is equal to the fair value of the discount on the date of grant and is recognized as compensation in the period of purchase.

Stock-Based Compensation

The Company's statements of operations included total compensation cost from awards under the Plans and purchases under the ESPP for the years ended December 31, as follows:

In thousands	2013	2012	2011
Compensation cost from:			
Stock options	$ 16,364	$10,626	$ 2,893
Stock and stock units	18,458	9,467	4,601
Purchases of common stock at a discount	599	248	181
	$ 35,421	$ 20,341	$7,675
Compensation cost included in:			
Research and development expense	$15,150	$ 9,846	$ 3,782
Selling, general and administrative expense	20,271	10,495	3,893
	$ 35,421	$ 20,341	$7,675

Stock Options

Stock options are granted with an exercise price equal to the closing market price of the Company's common stock on the date of grant. Stock options generally vest ratably over three or four years and have contractual terms of ten years. Stock options are valued using the Black-Scholes option valuation model and compensation cost is recognized based on such fair value over the period of vesting on a straight-line basis.

The following table summarizes information about stock options as of and for the years ended December 31 as follows:

In thousands, except per share amounts	2013	2012	2011
Weighted average fair value of options granted, per share	$ 8.38	$ 13.04	$ 5.80
Total cash received from exercises of stock options	4,847	9,677	4,648
Total intrinsic value of stock options exercised	13,829	27,572	5,169

The weighted average fair value of options granted in the years ended December 31, 2013, 2012 and 2011, reflect the following weighted-average assumptions:

	2013	2012	2011
Expected life of options granted *(in years)*	6.9	7.1	7.5
Expected volatility	76%	76%	75%
Risk-free rate	1.74%	1.32%	2.53%
Expected dividends	0%	0%	0%

The expected life assumption is based on an analysis of historical behavior of participants related to options awarded over time. The expected volatility assumption is based on an average of the historical volatility and the implied volatility of the Company's common stock, derived from an analysis of historical traded and quoted options on the Company's common stock. The risk-free rate is based on the forward U.S. Treasury yield curve. The expected dividends reflect the Company's current and expected future policy for dividends on its common stock.

Stock option activity under the Company's stock plans for the year ended December 31, 2013 was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding, January 1, 2013	8,228,334	$ 10.20
Granted	4,732,275	$ 13.10
Forfeited	(1,597,853)	$17.92
Exercised	(983,088)	$ 4.93
Options outstanding, December 31, 2013	10,379,668	$ 10.83

The following table summarizes information about stock options outstanding as of December 31, 2013:

	Options Outstanding	Options Exercisable	Options Vested and Expected To Vest
Number of options	10,379,668	4,489,008	10,188,693
Weighted average exercise price per share	$ 10.83	$ 7.86	$ 10.73
Aggregate intrinsic value *(in 000's)*	$ 11,240	$ 6,886	$ 11,217
Weighted average remaining contractual term *(years)*	6.98	4.18	6.94

Options expected to vest consist of options scheduled to vest in the future less expected forfeitures.

At December 31, 2013, total unrecognized compensation cost related to non-vested stock options outstanding amounted to $39.0 million. That cost is expected to be recognized over a weighted-average period of 2.6 years.

Stock and Stock Unit Grants

Stock and stock unit grants carry restrictions as to resale for periods of time or vesting provisions over time are based on the achievement of performance measures as specified in the grant. Stock and stock unit grants are valued at the closing market price of the Company's common stock on the date of grant and compensation expense is recognized over the requisite service period, vesting period or period during which restrictions remain on the common stock or stock units granted.

Stock and stock unit activity under the Company's stock plans for the year ended December 31, 2013 was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2013	1,903,445	$ 9.55
Granted / awarded	1,798,448	$ 15.24
Forfeited	(209,986)	$ 16.05
Vested or restrictions lapsed	(1,444,307)	$ 9.12
Outstanding, December 31, 2013	2,047,600	$ 14.18

The total fair value of stock and stock unit awards that vested in 2013, 2012 and 2011 was $25.5 million, $27.8 million and $8.0 million, respectively. The total unrecognized compensation expense for restricted shares or units that have been granted or are probable to be awarded was $18.6 million at December 31, 2013 and will be recognized over 1.9 years on a weighted average basis.

Included in stock and stock units outstanding in the above table are (i) 173,500 performance share units, awarded in April 2011, that vested in December 2013, one year after the FDA approval of Iclusig in December 2012, and (ii) performance share units awarded in March 2012 of which 274,400 vested upon the achievement of the performance condition, marketing authorization of Iclusig by the European Commission in July 2013, and 258,400 that will vest annually, in equal increments, over the next two years on the anniversary date of the achievement of the performance condition.

Stock and stock units outstanding above also include 333,000 performance share units awarded in 2013. The number of shares that may vest, if any, related to the 2013 performance share unit awards is dependent on the achievement, and timing of the achievement, of the performance criteria defined for the award. The compensation cost for such performance-based stock awards will be based on the awards that ultimately vest and the grant date fair value of those awards. The Company begins to recognize compensation expense related to performance share units when achievement of the performance condition is probable. In 2013, the Company concluded that it was probable that the performance condition related to the 2013 performance share unit awards would be met. The performance condition is based upon continued success in specific research and development initiatives. The total compensation expense for these performance share units may be up to 60% higher if the performance condition for this award is met prior to December 31, 2014.

14. Net Loss Per Share

Basic net loss per share amounts have been computed based on the weighted-average number of common shares outstanding. Diluted net loss per share amounts is computed based on the weighted-average number of common shares outstanding plus the dilutive effect, if any, of potential common shares. The computation of potential common shares has been performed using the treasury stock method.

The calculation of net loss and the number of shares used to compute basic and diluted earnings per share for the years ended December 31, 2013, 2012 and 2011 are as follows:

In thousands, except per share amounts	2013	2012	2011
Net loss	$(274,158)	$(220,872)	$(123,603)
Weighted average shares outstanding – basic and diluted	183,575	164,964	132,375
Net loss per share – basic and diluted	$ (1.49)	$ (1.34)	$ (0.93)

For the years ended December 31, 2013, 2012 and 2011, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

In thousands	2013	2012	2011
Stock options	10,380	8,228	7,381
Restricted stock and restricted stock units	2,048	1,903	2,785
Warrants	—	—	5,806
	12,428	10,131	15,972

15. Accumulated Other Comprehensive Income (Loss)

The changes in accumulated other comprehensive income (loss) for the year-ended December 31, 2013 were as follows:

In thousands	Net Unrealized Gains (reclassification adjustment) on Marketable Securities	Cumulative Translation Adjustment	Defined Benefit Pension Obligation	Total
Balance, January 1, 2013	$ 20	$ —	$ —	$ 20
Reclassification adjustment	(20)	—	—	(20)
Other comprehensive loss	—	(40)	(1,495)	(1,535)
Balance, December 31, 2013	$ —	$ (40)	$(1,495)	$(1,535)

16. Income Taxes

The Company is subject to U.S. federal and various state corporate income taxes as well as taxes in foreign jurisdictions where subsidiaries have been established. Loss before provision for income taxes and the provision for income taxes consist of the following for the years ended December 31, 2013, 2012 and 2011:

In thousands	2013	2012	2011
Loss before provision for income taxes			
Domestic	$(192,998)	$(182,974)	$(123,603)
Foreign	(80,721)	(37,898)	—
Total	$ (273,719)	$ (220,872)	$(123,603)
Provision for income taxes			
Current:			
Federal	$ —	$ —	$ —
State	216	—	—
Foreign	223	—	—
Total	$ 439	$ —	$ —

The Company did not incur a deferred income tax provision or benefit in 2013, 2012 or 2011.

A reconciliation of the federal statutory corporate income tax rate to the effective income tax rate for the years ended December 31, 2013, 2012 and 2011 is as follows:

	2013	2012	2011
Statutory federal income tax rate	(35)%	(35)%	(35)%
State income tax rate, net of federal benefit	(2)	(4)	(4)
Revaluation of warrant liability	—	3	13
Other permanent differences	—	(1)	—
Foreign rate differential	9	6	—
Change in valuation allowance	28	31	26
Effective tax rate	— %	— %	— %

The components of deferred income taxes were as follows at December 31:

In thousands	2013	2012
Deferred tax liabilities:		
Intangibles	$ 388	$ 398
Unrealized currency gain	10,892	7,330
Total deferred tax liabilities	11,280	7,728
Deferred tax assets:		
Net operating loss carryforwards	166,951	96,997
Federal and state tax credit carryovers	28,645	19,654
Depreciation	3,607	4,785
Stock-based compensation	7,780	5,491
Other	7,977	3,703
Total deferred tax assets	214,960	130,630
Deferred tax assets, net	203,680	122,902
Valuation allowance	(203,680)	(122,902)
Total deferred taxes	$ —	$ —

At December 31, 2013, the Company had available estimated net operating loss carryforwards and research and development credit carryforwards for federal, foreign and state tax reporting purposes as follows:

	Amount (in thousands)	Expiring if not utilized
Net operating loss carryforwards:		
Federal	$498,728	2024 through 2033
State	$ 90,329	2033
Foreign	$ 122,031	2021
Research and development credit carryforwards:		
Federal	$ 25,882	2018 through 2033
State	$ 4,388	2005 through 2028

Included in the federal net operating loss carryforwards above is approximately $50.3 million related to stock-based compensation tax deductions in excess of book compensation expense which will be credited to additional paid-in-capital when such reductions reduce taxes payable. Although these net operating losses are included in the carryforwards above, they are not reflected in the table of deferred tax assets as the excess tax benefits are not yet realized.

During 2012, the Company transferred certain intellectual property rights related to Iclusig to its wholly-owned subsidiary in Switzerland. Although the transfer of intellectual property rights between consolidated entities did not result in any gain in the consolidated results of operations, the Company generated a taxable gain in the U.S. that is substantially offset by existing tax loss and credit carryforwards. Any taxes incurred related to the intercompany transactions are treated as a prepaid tax in the Company's consolidated balance sheet and amortized to income tax expense over the life of the intellectual property. The amount of tax amortized to the provision for income taxes for the year ended December 31, 2013 is approximately $150,000.

Since the Company has not yet achieved sustained profitable operations, management believes its deferred tax assets do not satisfy the more likely than not realization criteria and has recorded a valuation allowance for all deferred tax assets as of December 31, 2013 and 2012. The valuation allowance increased by $80.8 million in 2013, decreased by $70.5 million in 2012, and increased by $28.5 million in 2011.

The Company does not recognize a tax benefit unless it is more likely than not that the tax position will be sustained upon examination by tax authorities, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit recognized for these positions is measured at the largest amount of benefit that is greater than 50 percent likelihood of being realized upon ultimate settlement. Deferred tax assets that do not meet these recognition criteria are not recorded and the Company recognizes a liability for uncertain tax positions that may result in tax payments. The Company recognizes interest and penalties as a component of the provision for incomes taxes. In 2013, the Company recorded approximately $65,000 of interest expense as a component of the provision for income taxes.

In 2013, the Company's uncertain tax positions increased to approximately $24.7 million, related to certain uncertain tax benefits that arose in 2013 and 2012. Of this amount, the Company has reduced its deferred tax assets and associated valuation allowance by $19.2 million and recorded a long-term liability of $2.0 million. If such unrecognized tax benefits were realized and not subject to valuation allowances, the Company would recognize a tax benefit of $21.2 million. No uncertain tax positions are expected to be resolved within the next twelve months. A reconciliation of the reserve for uncertain tax benefits (including state tax matters without federal benefits) is as follows:

In thousands	2013	2012
Uncertain tax positions, beginning of the year:	$ 24,404	$ —
Gross increases – tax positions in current period	249	24,404
Uncertain tax positions, end of year	$24,653	$24,404

Due to the Company's historical net operating loss position, the Company's U.S. federal and Massachusetts tax returns remain open to examination for three years after the Company utilizes that year's net operating loss carryforward. The Company's earliest year which generated a net operating loss included in the Company's current net operating loss carryforward is 2004 for U.S. federal tax purposes. The Company's Massachusetts state tax returns from 2009 to 2012 remain open to examination. All tax years for foreign subsidiaries are also open to audit in their respective jurisdictions.

17. Restructuring Actions

In the fourth quarter of fiscal 2013, the Company incurred expenses of $4.8 million associated with employee workforce reductions of approximately 155 positions, designed to reduce the Company's operating expenses and extend its cash runway. The Company recorded $2.2 million of the employee separation costs in research and development expense and $2.6 million in selling, general and administrative expense. A rollforward of the restructuring liability for 2013 is as follows:

In thousands	2013
Balance, January 1, 2013	$ —
Charges	4,751
Amounts paid	(2,531)
Balance, December 31, 2013	$ 2,220

The $2.2 million restructuring liability at December 31, 2013 is expected to be paid through the third quarter of fiscal 2014. On the accompanying consolidated balance sheet at December 31, 2013, the restructuring liability balance of $2.2 million was classified as a component of accrued compensation and benefits.

18. Defined Benefit Pension Obligation

On March 1, 2013, the Company established a defined benefit pension plan for employees in its Switzerland subsidiary. The plan provides benefits to employees upon retirement, death or disability. The Company uses December 31 as the year-end measurement date for this plan.

Summarized information regarding changes in the plan obligations and plan assets, the funded status and the amounts recorded as of December 31, 2013 is as follows:

In thousands	
Changes in benefit obligation	
Benefit obligation at plan establishment	$ 5,621
Service cost	994
Interest cost	105
Plan participants' contributions	283
Actuarial gain	(192)
Benefits received	1,065
Benefit obligation as of December 31, 2013	7,876
Changes in plan assets	
Fair value of plan assets at plan establishment	3,853
Actual return on plan assets	77
Employer contributions	720
Plan participants' contributions	283
Benefits received	1,065
Fair value of plan assets as of December 31, 2013	5,998
Unfunded liability as of December 31, 2013	$ 1,878

This unfunded liability is recognized in other long-term liabilities in the accompanying consolidated balance sheet as of December 31, 2013.

The projected benefit obligation, the accumulated benefit obligation and the fair value of the plan assets as of December 31, 2013 were as follows:

In thousands	
Projected benefit obligation	$ 7,876
Accumulated benefit obligation	$ 7,947
Fair value of plan assets	$5,998

The net periodic benefit cost for the defined benefit pension plan for the year ended December 31, 2013 was as follows:

In thousands	
Service cost	$ 994
Interest cost	105
Expected return on plan assets	(85)
Amortization of prior service cost	134
Net periodic benefit cost	$1,148

Other changes in the plan assets and the benefit obligation that are recognized in accumulated other comprehensive income (loss) and other comprehensive loss for the year ended December 31, 2013 were as follows:

In thousands	
Establishment of plan	$(1,768)
Net gain	139
Amortization of prior service cost	134
Total	$(1,495)

The prior service cost for the defined benefit pension plan that will be amortized from accumulated other comprehensive income (loss) into net periodic benefit cost over the next fiscal year is $161,000.

The assumptions used to determine the benefit obligation at December 31, 2013 were as follows:

Discount rate	2.25%
Rate of compensation increase	1.50%

The assumptions used to determine net periodic benefit costs for 2013 were as follows:

Discount rate	2.00%
Expected long-term return on plan assets	2.00%
Rate of compensation increase	1.50%

The assets of the plan are held in a collective investment account. All plan investments are classified as level 2 within the fair value hierarchy.

The Company expects to contribute $942,000 to its defined benefit pension plan in 2014.

The following benefit payments, which reflect expected future service, as appropriate, are expected to be paid:

In thousands	
2014	$ 370
2015	423
2016	456
2017	486
2018	509
2019 - 2023	2,631
Total	$4,875

19. Litigation

On October 10, 2013, October 17, 2013, December 3, 2013 and December 6, 2013, purported shareholder class actions, styled *Jimmy Wang v. ARIAD Pharmaceuticals, Inc., et al.*, *James L. Burch v. ARIAD Pharmaceuticals, Inc., et al.*, *Greater Pennsylvania Carpenters' Pension Fund v. ARIAD Pharmaceuticals, Inc., et al*, and *Nabil Elmachtoub v. ARIAD Pharmaceuticals, Inc., et al*, respectively, were filed in the United States District Court for the District of Massachusetts (the "District Court"), naming the Company and certain of

its officers as defendants. The lawsuits allege that the Company made material misrepresentations and/or omissions of material fact regarding clinical and safety data for Iclusig in its public disclosures during the period from December 12, 2011 through October 8, 2013 or October 17, 2013, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. On January 9, 2014, the District Court consolidated the actions and appointed lead plaintiffs. On February 18, 2014, the lead plaintiffs filed an amended complaint as contemplated by the order of the District Court. The amended complaint extends the class period for the Securities Exchange Act claims through October 30, 2013. In addition, plaintiffs allege that certain of the Company's officers, present and former directors and certain underwriters made material misrepresentations and/or omissions of material fact regarding clinical and safety data for Iclusig in connection with the Company's January 24, 2013 follow-on public offering of common stock in violation of Sections 11 and 15 of the Securities Act of 1933, as amended. The plaintiffs seek unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees.

On November 6, 2013, a purported derivative lawsuit, styled *Yu Liang v. ARIAD Pharmaceuticals, Inc., et al.,* was filed in the United States District Court for the District of Massachusetts (the "District Court"), on behalf of the Company naming its directors and certain of its officers as defendants. On December 6, 2013, an additional purported derivative lawsuit, styled *Arkady Livitz v. Harvey J. Berger, et al*, was filed in the District Court. The lawsuits allege that the Company's directors and certain of its officers breached their fiduciary duties related to the clinical development and commercialization of Iclusig and by making misrepresentations regarding the safety and commercial marketability of Iclusig. The lawsuits also assert claims for unjust enrichment and corporate waste, and for misappropriation of information and insider trading by the officers named as defendants. On January 23, 2014, the District Court consolidated the actions. On February 3, 2014, plaintiffs designated the *Yu Liang* complaint as the operative complaint as contemplated by the order of the District Court. The plaintiffs seek unspecified monetary damages, changes in the Company's corporate governance policies and internal procedures, restitution and disgorgement from the individually named defendants, and an award of costs and expenses, including attorney fees.

Additional complaints may be filed against the Company and its directors and officers related to the Company's disclosures and announcements concerning the safety, marketing and commercial distribution and further clinical development of Iclusig in the United States.

The Company believes that these actions are without merit. At this time, no assessment can be made as to the likely outcome of these lawsuits or whether the outcome will be material to the Company.

From time to time, the Company may be subject to various claims and legal proceedings. If the potential loss from any claim, asserted or unasserted, or legal proceedings is considered probable and the amount is reasonably estimated, the Company will accrue a liability for the estimated loss.

ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A: CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in paragraph (e) of Rules 13a-15 and 15d-15 under the Securities Exchange Act of 1934) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, particularly during the period in which this Annual Report on Form 10-K was being prepared.

(b) *Changes in Internal Controls.* There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company's internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2013. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework* (*1992*). Based on our assessment we believe that, as of December 31, 2013, the Company's internal control over financial reporting is effective based on those criteria.

Deloitte & Touche LLP, the independent registered public accounting firm that audited the Company's consolidated financial statements, has issued an attestation report on the Company's internal control over financial reporting as of December 31, 2013, which is included below.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
ARIAD Pharmaceuticals, Inc.
Cambridge, Massachusetts

We have audited the internal control over financial reporting of ARIAD Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2013, based on criteria established in *Internal Control—Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company'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 by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. 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 the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the criteria established in *Internal Control—Integrated Framework* (*1992*) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2013 of the Company and our report dated March 3, 2014 expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 3, 2014

ITEM 9B: OTHER INFORMATION

On January 21, 2014, we entered into an exclusive Master Services Agreement and related statements of work with Biologics, Inc., a specialty pharmacy based in Cary, North Carolina, to provide for the distribution of Iclusig in the United States to patients, physicians, health care providers and payers, including management of all data reporting, patient access and support services and our copay program. The term of the agreement is for one year with two automatically renewing one year extensions unless terminated earlier by either party. The agreement may be terminated by either party on 30 days' notice, upon the bankruptcy or insolvency of either party, or upon a party's breach that is not cured within specified periods. A copy of the Master Services Agreement and related statements of work are filed with this Annual Report as Exhibit 10.12 and are incorporated herein by reference.

PART III

ITEM 10: DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Board of Directors,” “Executive Officers,” “Section 16(a) Beneficial Ownership Reporting Compliance” and “Corporate Code of Conduct and Ethics” in the Company’s Definitive Proxy Statement for the 2014 Annual Meeting of Stockholders.

ITEM 11: EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Executive Compensation”, “Compensation Committee Interlocks and Insider Participation”, “Compensation Discussion and Analysis”, “Compensation Committee Report”, “Board of Directors” and “Compensation Practices and Policies Relating to Risk Management” in the Company’s Definitive Proxy Statement for the 2014 Annual Meeting of Stockholders.

ITEM 12: SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s Definitive Proxy Statement for the 2014 Annual Meeting of Stockholders.

ITEM 13: CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Board of Directors” and “Certain Relationships and Related Transactions” in the Company’s Definitive Proxy Statement for the 2014 Annual Meeting of Stockholders.

ITEM 14: PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Ratification of Selection of Independent Registered Public Accounting Firm” in the Company’s Definitive Proxy Statement for the 2014 Annual Meeting of Stockholders.

PART IV

ITEM 15: EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) The following Consolidated Financial Statements, Notes thereto and Report of Independent Registered Public Accounting Firm have been presented in Item 8:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Comprehensive Loss

Consolidated Statements of Stockholders' Equity

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

(a)(2) Financial Statement Schedules:

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto.

(a)(3) The Exhibits listed in the Exhibit Index are filed herewith in the manner set forth therein.

(b) See (a) (3) above.

(c) See (a) (2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge and Commonwealth of Massachusetts on the 3rd day of March, 2014.

ARIAD PHARMACEUTICALS, INC.

By: **/s/ Harvey J. Berger, M.D.**
Name: **Harvey J. Berger, M.D.**
Title: **Chairman, Chief Executive Officer and President**

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/ Harvey J. Berger, M.D. **Harvey J. Berger, M.D.**	**Chairman of the Board of Directors, Chief Executive Officer and President (Principal Executive Officer)**	**March 3, 2014**
/s/ Edward M. Fitzgerald **Edward M. Fitzgerald**	**Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)**	**March 3, 2014**
_____ **Alexander J. Denner, Ph.D.**	**Director**	
/s/ Jay R. LaMarche **Jay R. LaMarche**	**Director**	**March 3, 2014**
/s/ Athanase Lavidas, Ph.D. **Athanase Lavidas, Ph.D.**	**Director**	**March 3, 2014**
/s/ Massimo Radaelli, Ph.D. **Massimo Radaelli, Ph.D.**	**Director**	**March 3, 2014**
/s/ Norbert G. Riedel, Ph.D. **Norbert G. Riedel, Ph.D.**	**Director**	**March 3, 2014**
/s/ Sarah J. Schlesinger, M.D. **Sarah J. Schlesinger, M.D.**	**Director**	**March 3, 2014**
/s/ Robert M. Whelan, Jr. **Robert M. Whelan, Jr.**	**Director**	**March 3, 2014**
/s/ Wayne Wilson **Wayne Wilson**	**Director**	**March 3, 2014**

ARIAD Pharmaceuticals, Inc.

Form 10-K for the Year Ended December 31, 2013

Exhibit List

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
3.1 .1	Certificate of Incorporation of ARIAD Pharmaceuticals, Inc., as amended		10-Q (Exhibit 3.1)	05/10/10	000-21696
.2	Certificate of Amendment of Certificate of Incorporation of ARIAD Pharmaceuticals, Inc., dated June 20, 2013		8-K (Exhibit 3.1)	06/24/13	000-21696
.3	Amended Certificate of Designation of Series A Preferred Stock of ARIAD Pharmaceuticals, Inc., dated November 1, 2013		8-K/A (Exhibit 3.1)	11/05/13	001-36172
3.2	Amended and Restated By-laws of ARIAD Pharmaceuticals, Inc.		8-K (Exhibit 3.1)	08/27/09	000-21696
4.1	Specimen common stock certificate of ARIAD Pharmaceuticals, Inc.	X			
4.2	Section 382 Rights Agreement, dated October 31, 2013, between ARIAD Pharmaceuticals, Inc. and Computershare Trust Company, N.A., as Rights Agent		8-K (Exhibit 4.1)	11/01/13	000-21696
Leases and Credit Agreements					
10.1 .1	Lease Agreement, dated January 8, 1992, between ARIAD Pharmaceuticals, Inc. and Forest City Cambridge, Inc.		10-Q (Exhibit 10.1)	04/30/93	000-21696
.2	Eighth Amendment to Lease dated October 30, 2006		10-K (Exhibit 10.57)	03/14/07	000-21696
.3	Ninth Amendment to Lease dated May 20, 2011, between ARIAD Corporation and UP 26 Landsdowne LLC		10-Q (Exhibit 10.1)	08/09/11	000-21696
.4	Assignment and Assumption dated December 31, 2011, by and between ARIAD Corporation and ARIAD Pharmaceuticals, Inc. (for lease at 26 Landsdowne Street)		10-K (Exhibit 10.1.4)	02/29/12	000-21696
10.2 .1	Lease Agreement, dated January 4, 2013 between ARIAD Pharmaceuticals, Inc. and ARE-MA REGION NO. 48, LLC (for lease at 75 Binney Street and 25 Binney Street)*		10-K (Exhibit 10.2)	03/01/13	000-21696
.2	First Amendment to Lease, dated September 16, 2013, between ARIAD Pharmaceuticals, Inc. and ARE-MA REGION NO. 48, LLC (for lease at 75 Binney Street and 25 Binney Street)*		10-Q (Exhibit 10.1)	11/12/13	001-36172
10.3 .1	Credit Agreement, dated as of March 12, 2003, by and among ARIAD Pharmaceuticals, Inc., ARIAD Corporation and ARIAD Gene Therapeutics, Inc. and Citizens Bank of Massachusetts		10-Q (Exhibit 10.1)	05/13/03	000-21696
.2	Amendment No. 1 to Credit Agreement, dated as of December 31, 2003		10-K (Exhibit 10.57)	03/02/04	000-21696
.3	Amendment No. 2 to Credit Agreement dated as of December 31, 2004		10-K (Exhibit 10.52)	02/18/05	000-21696

.4	Amendment No. 3 to Credit Agreement, dated as of March 26, 2008, by and among ARIAD Pharmaceuticals, Inc., ARIAD Corporation and ARIAD Gene Therapeutics, Inc. and RBS Citizens, National Association, successor by merger to Citizens Bank of Massachusetts		8-K (Exhibit 10.2.4)	03/27/08	000-21696
.5	Waiver and Amendment No. 4 to Credit Agreement dated as of June 19, 2009, by and among ARIAD Pharmaceuticals, Inc., ARIAD Corporation and RBS Citizens, National Association		10-Q (Exhibit 10.3)	08/10/09	000-21696
.6	Waiver and Amendment No. 5 to Credit Agreement dated as of December 14, 2009		10-K (Exhibit 10.2.6)	03/16/10	000-21696
.7	Amendment No. 6 to Credit Agreement, dated as of January 6, 2011		8-K (Exhibit 10.2.7)	01/12/11	000-21696
.8	Amendment No. 7 to Credit Agreement, dated as of December 28, 2011, by and among ARIAD Pharmaceuticals, Inc., ARIAD Corporation and RBS Citizens, National Association		10-K (Exhibit 10.2.8)	02/29/12	000-21696
10.4	Security Agreement - All Assets, dated as of March 12, 2003, by and between ARIAD Pharmaceuticals, Inc. and Citizens Bank of Massachusetts		10-Q (Exhibit 10.3)	05/13/03	000-21696
10.5	Security Agreement - All Assets, dated as of March 12, 2003, by and between ARIAD Corporation and Citizens Bank of Massachusetts		10-Q (Exhibit 10.4)	05/13/03	000-21696
10.6	Third Amended and Restated Term Note, dated March 26, 2008, issued by ARIAD Pharmaceuticals, Inc., ARIAD Corporation and ARIAD Gene Therapeutics, Inc. to RBS Citizens, National Association, successor by merger to Citizens Bank of Massachusetts		8-K (Exhibit 10.2.4)	03/27/08	000-21696
Agreements with Respect to Collaborations, Licenses, Research and Development					
10.7	Amended and Restated Agreement, dated as of December 12, 1997, between The Board of Trustees of The Leland Stanford Junior University and ARIAD Gene Therapeutics, Inc.*		10-K (Exhibit 10.14)	03/10/98	000-21696
10.8	License Agreement, effective January 26, 2005, by and between ARIAD Pharmaceuticals, Inc. and Medinol Ltd.*		10-Q (Exhibit 10.1)	05/10/05	000-21696
10.9	Supply Agreement, entered into as of January 26, 2005, by and between ARIAD Pharmaceuticals, Inc. and Medinol Ltd.*		10-Q (Exhibit 10.2)	05/10/05	000-21696
10.10	License Agreement, dated October 9, 2007, among ARIAD Pharmaceuticals, Inc., ARIAD Gene Therapeutics, Inc. and ICON Medical Corp.*		10-K (Exhibit 10.13)	03/16/10	000-21696
10.11	Amended and Restated Collaboration and Exclusive License Agreement, dated May 4, 2010, between ARIAD Pharmaceuticals, Inc. and Merck, Sharpe & Dohme Corp.*		10-Q (Exhibit 10.1)	08/09/10	000-21696
10.12	Master Services Agreement, effective as of January 21, 2014, between ARIAD Pharmaceuticals, Inc. and Biologics, Inc. **	X			
Agreements with Executive Officers and Directors					
10.13	Amended and Restated Executive Employment Agreement, dated April 30, 2010, between ARIAD Pharmaceuticals, Inc. and Harvey J. Berger, M.D.+		8-K (Exhibit 10.1)	05/03/10	000-21696
10.14	Amended and Restated Executive Employment Agreement, dated May 15, 2010, between ARIAD Pharmaceuticals, Inc. and David L. Berstein, Esq.+		10-Q (Exhibit 10.4)	08/09/10	000-21696
10.15	Amended and Restated Executive Employment Agreement, dated May 15, 2010, between ARIAD Pharmaceuticals, Inc. and Daniel M. Bollag, Ph.D.+		10-Q (Exhibit 10.5)	08/09/10	000-21696

10.16	.1	Amended and Restated Executive Employment Agreement, dated May 1, 2010, between ARIAD Pharmaceuticals, Inc. and Maria Cantor+		10-Q (Exhibit 10.1)	05/09/12	000-21696
	.2	First Amendment to Amended and Restated Executive Employment Agreement, dated January 25, 2012, between ARIAD Pharmaceuticals, Inc. and Maria Cantor+		10-Q (Exhibit 10.2)	05/09/12	000-21696
10.17		Amended and Restated Executive Employment Agreement, dated May 15, 2010, between ARIAD Pharmaceuticals, Inc. and Timothy P. Clackson, Ph.D.+		10-Q (Exhibit 10.6)	08/09/10	000-21696
10.18		Executive Employment Agreement, dated September 3, 2011, between ARIAD Pharmaceuticals, Inc. and Martin J. Duvall+		10-Q (Exhibit 10.1)	11/07/11	000-21696
10.19		Amended and Restated Executive Employment Agreement, dated May 15, 2010, between ARIAD Pharmaceuticals, Inc. and Edward M. Fitzgerald+		10-Q (Exhibit 10.8)	08/09/10	000-21696
10.20	.1	Amended and Restated Executive Employment Agreement, dated May 1, 2010, between ARIAD Pharmaceuticals, Inc. and Frank G. Haluska, M.D., Ph.D.+		10-Q (Exhibit 10.9)	08/09/10	000-21696
	.2	First Amendment to Amended and Restated Executive Employment Agreement, dated January 25, 2012 between ARIAD Pharmaceuticals, Inc. and Frank G. Haluska, M.D., Ph.D.+		10-Q (Exhibit 10.3)	05/09/12	000-21696
10.21		Nomination and Standstill Agreement, dated February 20, 2014, by and between ARIAD Pharmaceuticals, Inc., Dr. Alexander J. Denner, Sarissa Capital Management LP, Sarissa Capital Domestic Fund LP, Sarissa Capital Offshore Master Fund LP, Sarissa Capital Fund GP LP and Sarissa Capital Offshore Fund GP LLC+		8-K (Exhibit 99.1)	02/21/14	001-36172
10.22		Confidentiality Agreement, dated February 20, 2014, by and between ARIAD Pharmaceuticals, Inc., Dr. Alexander J. Denner, Sarissa Capital Management LP, Sarissa Capital Domestic Fund LP, Sarissa Capital Offshore Master Fund LP, Sarissa Capital Fund GP LP and Sarissa Capital Offshore Fund GP LLC+		8-K (Exhibit 99.2)	02/21/14	001-36172
10.23	.1	ARIAD Pharmaceuticals, Inc. 1997 Executive Compensation Plan+		10-K (Exhibit 10.41)	03/10/98	000-21696
	.2	Amendment to ARIAD Pharmaceuticals, Inc. 1997 Executive Compensation Plan+		10-Q (Exhibit 10.2)	11/09/05	000-21696
10.24		ARIAD Pharmaceuticals, Inc. 2005 Executive Compensation Plan (as amended and restated effective October 1, 2008)+		10-K (Exhibit 10.31)	03/16/09	000-21696
10.25		Director Compensation Arrangements+	X			
10.26		Form of Indemnity Agreement between ARIAD Pharmaceuticals, Inc. and its directors and officers+		10-K (Exhibit 10.33)	03/16/09	000-21696
Equity Compensation Plans						
10.27	.1	ARIAD Pharmaceuticals, Inc. 1991 Stock Option Plan for Employees and Consultants, as amended+		10-K (Exhibit 10.13)	03/31/95	000-21696
	.2	Amendment to the 1991 Stock Option Plan for Employees and Consultants+		10-Q (Exhibit 10.36)	08/12/97	000-21696
10.28		ARIAD Pharmaceuticals, Inc. 1991 Stock Option Plan for Directors+		10-Q (Exhibit 10.15)	04/30/93	000-21696
10.29	.1	ARIAD Pharmaceuticals, Inc. 1994 Stock Option Plan for Non-Employee Directors+		10-K (Exhibit 10.24)	03/31/95	000-21696

	.2	Amendment to the 1994 Stock Option Plan for Non-Employee Directors.+	10-Q (Exhibit 10.37)	08/12/97	000-21696
10.30		Amended and Restated ARIAD Pharmaceuticals, Inc. 1997 Employee Stock Purchase Plan+	Def 14A (Appendix A)	04/30/09	000-21696
10.31		ARIAD Pharmaceuticals, Inc. 2001 Stock Plan, as amended and restated+	10-Q (Exhibit 10.3)	11/09/05	000-21696
10.32	.1	ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan, as amended+	Def 14A (Appendix A)	04/30/12	000-21696
	.2	Form of Stock Option Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+	10-K (Exhibit 10.30.2)	02/29/12	000-21696
	.3	Form of Stock Grant Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+	10-K (Exhibit 10.30.3)	02/29/12	000-21696
	.4	Form of Restricted Stock Unit Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+	10-K (Exhibit 10.30.4)	02/29/12	000-21696
	.5	Form of Restricted Stock Grant Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+	10-K (Exhibit 10.30.5)	02/29/12	000-21696
	.6	Form of 2012 Performance Share Certificate under the ARIAD Pharmaceuticals, Inc. 2006 Long-Term Incentive Plan+	10-Q (Exhibit 10.5)	05/09/12	000-21696
21.1		Subsidiaries of ARIAD Pharmaceuticals, Inc.	X		
23.1		Consent of Deloitte & Touche LLP	X		
31.1		Certification of the Chief Executive Officer	X		
31.2		Certification of the Chief Financial Officer	X		
32.1		Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X		
101		The following materials from ARIAD Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements.	X		

(+) Management contract or compensatory plan or arrangement.
(*) Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.
(**) Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions.

Exhibit 4.1

016570| 003590|127C|RESTRICTED||4|057-423

COMMON STOCK

PAR VALUE $.001

COMMON STOCK

THIS CERTIFICATE IS TRANSFERABLE IN CANTON-MALVERN-JERSEY CITY, NJ AND COLLEGE STATION, TX

Certificate Number

ZQ 000000

Shares

000000****
000000**
****000000****
*****000000***
******000000**

ARIAD

ARIAD PHARMACEUTICALS, INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

THIS CERTIFIES THAT

MR. SAMPLE & MRS. SAMPLE & MR. SAMPLE & MRS. SAMPLE

CUSIP 04033A 10 0

SEE REVERSE FOR CERTAIN DEFINITIONS

is the owner of

ZERO HUNDRED THOUSAND ZERO HUNDRED AND ZERO

FULLY PAID AND NON-ASSESSABLE SHARES OF THE COMMON STOCK, $.001 PAR VALUE, OF

ARIAD Pharmaceuticals, Inc. transferable only on the books of the Corporation by the holder hereof in person or by duly authorized attorney upon surrender of this certificate properly endorsed. This certificate and the shares of Common Stock represented hereby are received and held subject to the laws of the State of Delaware and to the Certificate of Incorporation and the Bylaws of the Corporation, each as from time to time amended, and the owner of this certificate by accepting the same expressly assents thereto. This certificate is not valid unless countersigned by the Transfer Agent.

IN WITNESS WHEREOF, the Corporation has caused this certificate to be signed by the facsimile signatures of its duly authorized officers and a facsimile of its corporate seal to be hereunto affixed.

DATED <<Month Day, Year>>

Chairman and Chief Executive Officer

Senior Vice President and Chief Financial Officer

SEAL

1991

COUNTERSIGNED AND REGISTERED:
COMPUTERSHARE TRUST COMPANY, N.A.
TRANSFER AGENT AND REGISTRAR

By _____ AUTHORIZED SIGNATURE

SECURITY INSTRUCTIONS ON REVERSE

1234567

ARIAD

PO BOX 43004, Providence, RI 02940-3004

MR A SAMPLE
DESIGNATION (IF ANY)
ADD 1
ADD 2
ADD 3
ADD 4

CUSIP
Holder ID
Insurance Value
Number of Shares
DTC

XXXXXXXXX
XXXXXXXXXXX
1,000,000.00
123456
12345678 12345678901234

Certificate Numbers	Num	No. Owners	Total
12345678901234567890	1	1	1
12345678901234567890	2	2	2
12345678901234567890	3	3	3
12345678901234567890	4	4	4
12345678901234567890	5	5	5
12345678901234567890	6	6	6
Total Transaction			7

This certificate also evidences and entitles the holder hereof to certain Rights as set forth in a Rights Agreement dated as of October 31, 2013 (as it may be amended from time to time (the "Rights Agreement")), between ARIAD PHARMACEUTICALS, INC. (the "Company") and COMPUTERSHARE TRUST COMPANY, N.A., as Rights Agent (the "Rights Agent"), the terms of which (including restrictions on the transfer of such Rights) are hereby incorporated herein by reference and a copy of which is on file at the principal executive offices of the Company. Under certain circumstances, as set forth in the Rights Agreement, such Rights shall be evidenced by separate certificates and shall no longer be evidenced by this certificate. The Company shall mail to the holder of this certificate a copy of the Rights Agreement without charge after receipt of a written request therefor. RIGHTS THAT ARE OR WERE, AT ANY TIME ON OR AFTER THE DATE AN ACQUIRING PERSON BECOMES SUCH, BENEFICIALLY OWNED BY SUCH ACQUIRING PERSON OR ANY AFFILIATE OR ASSOCIATE OF SUCH ACQUIRING PERSON (AS SUCH TERMS ARE DEFINED IN THE RIGHTS AGREEMENT) AND BY ANY SUBSEQUENT HOLDER OF SUCH RIGHTS ARE NULL AND VOID AND NONTRANSFERABLE.

ABBREVIATIONS

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	- as tenants in common	UNIF GIFT MIN ACT-	. . . . . (Cust) . . . . . Custodian . . . . . (Minor)
TEN ENT	- as tenants by the entireties		under Uniform Gifts to Minors Act . . . . . (State)
JT TEN	- as joint tenants with right of survivorship and not as tenants in common	UNIF TRF MIN ACT	. . . . . (Cust) . . . . . Custodian (until age. . .). . . . . (Minor) under Uniform Transfers to Minors Act. . . . . (State)

Additional abbreviations may also be used though not in the above list.

ASSIGNMENT

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

For value received, _____ hereby sell, assign and transfer unto

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING POSTAL ZIP CODE, OF ASSIGNEE)

_____

_____

_____ Shares

of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney

to transfer the said stock on the books of the within-named Corporation with full power of substitution in the premises.

Dated: _____ 20____

Signature: _____

Signature: _____

Notice: The signature to this assignment must correspond with the name as written upon the face of the certificate, in every particular, without alteration or enlargement, or any change whatever.

Signature(s) Guaranteed: Medallion Guarantee Stamp

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15.

SECURITY INSTRUCTIONS

THIS IS WATERMARKED PAPER. DO NOT ACCEPT WITHOUT NOTING WATERMARK. HOLD TO LIGHT TO VERIFY WATERMARK.

The IRS requires that we report the cost basis of certain shares acquired after January 1, 2011. If your shares were covered by the legislation and you have sold or transferred the shares and requested a specific cost basis calculation method, we have processed as requested. If you did not specify a cost basis calculation method, we have defaulted to the first in, first out (FIFO) method. Please visit our website or consult your tax advisor if you need additional information about cost basis.

If you do not keep in contact with us or do not have any activity in your account for the time periods specified by state law, your property could become subject to state unclaimed property laws and transferred to the appropriate state.

1234567

Exhibit 10.12

CONFIDENTIAL

MASTER SERVICES AGREEMENT

This Master Services Agreement ("**Agreement**"), effective as of the last date written on the signature page below ("**Effective Date**"), is between ARIAD Pharmaceuticals, Inc., a Delaware corporation ("**ARIAD**") with a business address at 26 Landsdowne Street, Cambridge, Massachusetts, 02139, and Biologics, Inc., a North Carolina corporation ("**Vendor**"), with an office at 120 Weston Oaks Court, Cary, North Carolina, 27513. ARIAD and Vendor may also be referred to herein individually as a "**Party**," and collectively, as the "**Parties**."

The Parties agree as follows:

1. **Services**. Vendor shall provide to ARIAD the services (collectively, the "**Services**") specified in the Statement of Work attached hereto as Schedule 1 and any subsequent Statements of Work or scope of work documents approved in writing by ARIAD (each, a "**Statement of Work**"). Once executed, each Statement of Work shall be automatically governed by the terms hereof and incorporated by reference herein. The Services shall be performed in accordance with the terms and conditions contained herein and in accordance with the Statement of Work for each project. Unless a Statement of Work specifically states otherwise, in the event of any conflict between the terms of this Agreement and the terms of a Statement of Work, the terms of this Agreement shall govern. The Services for each project shall be performed by the Vendor personnel identified in each relevant Statement of Work, unless otherwise approved by ARIAD.

2. **Payment**.

2.1. ARIAD shall compensate Vendor for the satisfactory performance of the Services according to the terms set forth in each Statement of Work. Subject to ARIAD's prior written approval, ARIAD shall also reimburse Vendor for reasonable, necessary and documented expenses directly incurred in connection with the Services. ARIAD must approve in writing in advance any additional fee or expense.

2.2. Vendor must address all invoices for Services to ARIAD and send them to the attention of ARIAD's Accounts Payable Department at [***]. All invoices shall contain an itemized breakdown of all fees and expenses (and be accompanied by relevant supporting documentation), and shall be payable within 30 days after receipt; provided, however, that ARIAD may contest any invoice or portion thereof, to the extent that it reasonably believes that the charges reflected therein are inappropriate or lack a clear basis (paying all charges that are appropriate). Once any such issue or concern is resolved, ARIAD shall pay any remaining appropriate charges within thirty (30) calendar days of the date that such resolution occurs.

2.3. The Parties intend that all compensation paid hereunder will comply with the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and its implementing regulations (the "**Federal Anti-Kickback Statute**"). Vendor represents and warrants that: (i) the fees set forth in each Statement of Work represent fair market value for the performance of the Services; (ii) it performs similar services for other pharmaceutical and biotechnology companies pursuant to written services agreements; and (iii) the fees payable under each Statement of Work are consistent with the level of fees charged by Vendor for similar services. The Parties agree that the compensation set forth in each Statement of Work has not been determined in a manner that takes into account the volume or value of any referrals of business otherwise generated or that may be generated between the Parties for which payment may be made in whole or in part under any federal health care program. The Parties further acknowledge and agree that the compensation is not overtly or covertly, directly or indirectly, a rebate or discount on the purchase of ARIAD products.

2.4. Vendor represents and warrants that it shall not make any payments or other transfers of value, directly or indirectly, in connection with this Agreement to a healthcare provider, government official, hospital and/or any similar person or entity.

3. Confidentiality.

3.1. "**Confidential Information**" means all business and proprietary information relating to ARIAD, whether or not labeled or identified as "Confidential," including, without limitation, information or Materials (as defined in Section 8.1) given to Vendor by or on behalf of ARIAD, the terms of this Agreement and all Statements of Work, and any information Vendor observes or generates when performing Services under this Agreement.

3.1.1. Confidential Information shall not include information that (a) Vendor previously knew about or that it obtained outside of any prior contractual relationship with ARIAD, (b) is generally available to the public or publicly divulged through no fault of Vendor, or (c) is subsequently disclosed to Vendor by a third party who is not under any obligation to ARIAD.

3.2. Vendor acknowledges that, during the course of performing Services, its Personnel (as defined in Section 6.1) shall receive and gain access to Confidential Information relating to ARIAD's business, which is extremely competitive, and that Vendor's unauthorized disclosure of any such Confidential Information would result in serious harm to ARIAD.

3.3. Vendor shall maintain the confidentiality of Confidential Information during the term of this Agreement and for a period of ten (10) years following expiration or earlier termination. Vendor shall use the Confidential Information solely in connection with the Services and for no other purpose. Vendor agrees not to disclose the Confidential Information to any person or entity other than: (a) to employees, agents, subcontractors or consultants on an as-needed basis, provided such persons are bound under substantially similar confidentiality restrictions;

(b) to the extent required by court order, legal process, or Applicable Laws (as defined in Section 4 below), provided that Vendor (i) provides ARIAD prompt advance written notice thereof (to the extent permitted by Applicable Laws) to allow ARIAD to seek a protective order with respect to such disclosure, and (ii) thereafter disclose only the minimum information required to be disclose in order to comply; or (c) as expressly authorized in writing by ARIAD.

3.4. Vendor shall not duplicate any material containing Confidential Information, except in the direct performance of the Services. Vendor shall return all copies of materials containing Confidential Information upon Vendor's completion of the Services or upon any earlier termination of this Agreement.

3.5. All Confidential Information, and all patent, copyright, trade secret, trademark and other intellectual property rights therein, shall remain ARIAD's exclusive property. No license or conveyance of any such rights to Vendor is granted or implied under this Agreement.

3.6. Vendor acknowledges that it may receive material, non-public information about ARIAD or its affiliates and/or its or their business and that the United States securities laws prohibit trading in securities on the basis of such information.

3.7. For the avoidance of doubt, before Vendor discloses Confidential Information as defined in this Agreement, or any other data relating to the Products or this Agreement, to any of its Personnel as defined in Section 6 or to any third-party (and including without limitation pharmacy "switches," such as Relay Health and Experian, that transfer data between specialty pharmacies and payers), it shall ensure that any such Personnel or third-party as the case may be, agrees in writing that it shall not, either directly or indirectly (e.g., through a facilitator), disclose or permit to be disclosed such Confidential Information or data to any third party, including without limitation to any healthcare data vendors (e.g., IMS Health, Wolters Kluwer).

4. Compliance with Law. Vendor will comply with all Federal, state and local laws, regulations and orders that are applicable to Vendor's operations and provision of the Services including, but not limited to laws and regulations on direct-to-consumer advertising, data privacy including but not limited to the Health Insurance Portability and Accountability Act ("HIPAA"), data security, pharmaceutical advertising and promotional labeling, fraud and abuse laws and anti-kickback laws (collectively, "**Applicable Laws**"). Vendor will also comply with the terms of any instructions or protocols provided by ARIAD including any internal policies and/or scripts and templates provided by ARIAD regarding interactions with health care professionals or promotional/educational activities directed at ARIAD customers or their patients

5. Data Security and Privacy.

5.1. At times, ARIAD may provide Vendor with information that falls under the protection of certain data security and privacy laws. Vendor must implement and maintain appropriate and reasonable technical and organizational security measures to protect data that it creates, maintains or transmits and comply with all Applicable Laws and best practices in the healthcare information management industry.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

5.2. Vendor represents and warrants that it shall comply with all applicable laws related to "patient confidentiality and the protection of patient information, including, but not limited to, the regulations implementing the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), 45 C.F.R. Parts 160 and 164. Vendor shall not provide ARIAD with any data that may include patient names or identifiers. Any such data must be de-identified by Vendor in accordance with the HIPAA de-identification standard set forth at 45 C.F.R. 164.514(b), unless Vendor has on file a valid, HIPAA-compliant patient authorization.

6. Personnel.

6.1. "**Personnel**" means Vendor and any person or entity employed or engaged by Vendor, including, without limitation, its employees, contractors, consultants or agents who provide Services.

6.2. Vendor represents and certifies that all Personnel have never been and are not currently debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335(a), as amended, or any similar state law or regulation (collectively " **Debarred**"), excluded by the Office of Inspector General pursuant to 42 U.S.C. § 1320a-7, et seq. or any state agency from participation in any Federal or state health care program (collectively "**Excluded**") or otherwise disqualified or restricted by the FDA pursuant to 21 C.F.R. 312.70 or any other regulatory authority (collectively "**Disqualified**").

6.3. Vendor will not utilize any Debarred, Excluded or Disqualified Personnel to provide any Services hereunder.

6.4. Vendor will notify ARIAD immediately if any Personnel are threatened to become Debarred, Excluded or Disqualified.

7. Professional Standards and Subcontractors. Vendor represents and warrants that it has the facilities, personnel, experience and expertise sufficient in quality and quantity to perform the Services in a manner commensurate with professional standards generally applicable to its industry. ARIAD shall approve in advance and in writing any and all of Vendor's subcontractors used to perform the Services.

8. Ownership of Materials and Intellectual Property.

8.1. "**Materials**" mean any and all presentations, reports, information, inventions, concepts, data, or other works that (a) Vendor creates for ARIAD in connection with this Agreement, or (b) use Confidential Information.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

8.2. All Materials shall be the sole and exclusive property of ARIAD, and Vendor hereby assigns to ARIAD all of its right, title, interest and ownership in such Materials, and any intellectual property rights in such Materials, including, but not limited to, patents, patent applications, and copyrights ("**IP Rights**").

8.2.1. Vendor shall not, during or after the term of this Agreement, be entitled to or claim any right, title or interest herein or any commission, fee or other direct or indirect benefit from ARIAD, in respect of such Materials or IP Rights.

8.2.2. Vendor agrees to execute or cause its agents and employees to execute any documents necessary or desirable to secure or perfect ARIAD's legal rights and worldwide ownership in such Materials and IP Rights. Upon termination of this Agreement, or at any time prior thereto, Vendor shall, at ARIAD's request, transfer, assign and make available to ARIAD all Materials in Vendor's possession or control belonging to ARIAD.

8.2.3. Vendor shall treat the Materials and IP Rights as Confidential Information and shall not use them for the benefit of any party other than ARIAD or for any purpose other than in connection with the Services.

9. Inspection; Audit.

9.1. ARIAD and its agents or representatives shall be provided reasonable access to Vendor's facilities, during Vendor's regular hours of business, to perform quality assurance inspections at mutually agreeable times.

9.2. Vendor shall notify ARIAD as soon as reasonably practicable of all inspections or anticipated inspections of its facility conducted by any regulatory authority, including, without limitation, the FDA, that is directly related to the Services. Vendor shall allow ARIAD representatives to be present during any such inspections. Vendor shall promptly provide copies of any and all reports, citation, violations, warnings, and notices of deficiency received by Vendor in connection with such inspections.

9.3. During the term of the Agreement and for a period of two years thereafter, Vendor will keep complete and accurate records relating to the Services in sufficient detail to confirm Vendor's compliance with the terms of this Agreement. During such period, upon at least ten (10) days prior notice (which notice will specify the purpose of the audit and the time period to be audited), during normal business hours, ARIAD or its third party designee (the **"Auditor"**)), will be permitted to audit the relevant books and records of Vendor that are maintained in connection with the Services provided under this Agreement; provided however, that such audit right will be limited to no more than once per twelve (12) month period and no time period may be audited more than once, unless required by the FDA or any other government agency. Each audit will be at the sole expense of ARIAD provided; however, ARIAD will have no obligation to pay any costs incurred by Vendor, its employees or agents in cooperating with such audit.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

10. Records.

10.1. Vendor will maintain all Materials, data and documentation obtained or generated in the course of providing Services, including all computerized records and files (the "Records"), in a secure area protected by Vendor's commercially reasonable efforts from fire, theft and destruction.

10.2. Upon ARIAD's written instruction, all Records will either be (a) delivered to ARIAD in such form as is then currently in the possession of Vendor; (b) retained by Vendor for a period of 5 years from the Effective Date of the applicable Statement of Work, or as otherwise required by Applicable Laws; or (c) disposed of, pursuant to ARIAD's direction and written request, unless Vendor is required to store or maintain such Records under Applicable Laws. Vendor will not dispose of any such Records without first giving ARIAD 60 days' prior written notice of its intent to do so. Vendor may retain copies of any Records as are reasonably necessary for regulatory or insurance purposes, subject to Vendor's obligations of confidentiality.

11. **Representations and Warranties.** Vendor represents and warrants on behalf of itself, its affiliates and any person performing the Services (referred to collectively in this Section 11 as "Vendor") that:

11.1. The Services and work product shall be of professional quality and all information Vendor provides to ARIAD shall be accurate in accordance with commercially acceptable standards. Any Services provided by Vendor under ARIAD's technical direction that ARIAD claims are less than professional quality, or which renders any or all of Vendor's work product hereunder reasonably unreliable or unusable by ARIAD, shall be corrected by Vendor without charge to ARIAD provided that ARIAD provides written notice of alleged poor quality within 30 days after it first became aware of the issue.

11.2. Vendor's performance of the Services will not violate any proprietary rights of any third party, including, without limitation, confidential relationships and patent and copyright rights.

11.3. It has no obligations to or relationships with, and during the term of this Agreement will not create obligations to or relationships with, other parties, that would (a) create a conflict with performing the Services under this Agreement, or (b) prevent Vendor from performing the Services under this Agreement.

11.4. Vendor has and shall maintain all federal, state, and local licenses or registrations necessary to perform the Services (including, but not limited to the lawful handling, storage, dispensing and shipping of pharmaceutical products), and Vendor shall notify ARIAD immediately of any denial, revocation or suspension of, or any adverse action taken against, any such license or registration, or any material changes in the license or registration, that would obstruct Vendor's ability to perform the Services.

11.5. Vendor has the authority under Applicable Law, including but not limited to applicable board of pharmacy regulations, to perform the Services.

11.6. Vendor shall dispense ARIAD products strictly in accordance with ARIAD requirements and Applicable Law. With respect to ARIAD product subject to a Risk Evaluation and Mitigation Strategy ("REMS"), Vendor shall dispense such product strictly in accordance with such REMS or additional requirements.

11.7. Services for which any fees are to be paid under a Statement of Work are incremental to the services that Vendor typically performs for patients.

11.8. The clinical judgment of the patient's treating physician (or other healthcare provider) shall not be undermined or otherwise usurped in the performance of the Services. Vendor will not implement any intervention technique, counsel or encourage any patient or physician to use or prescribe ARIAD product over any other medically-appropriate product. Vendor shall not offer physicians or any other healthcare professionals any financial inducement to prescribe or switch patients to any ARIAD product.

11.9. Any Services which are to be performed by a nurse or pharmacist shall be performed by qualified, trained and competent nurses and pharmacists. Each such nurse or pharmacist shall (i) possess a current and valid license, certification, or legal authorization, as applicable, in his/her applicable profession in each state in which he/she will perform Services; (ii) have no prior practice-related infractions or disciplinary history from any governing organization (e.g., state boards of nursing); and (iii) be and remain in good standing in the applicable state. Notwithstanding the above, ARIAD may, in its sole discretion, preclude any individual nurse and/or pharmacist from performing Services. Any nurses performing Services shall be required to comply with paragraph 11.10 above.

11.10. In the course of performing Services, Vendor shall (i) not suggest that a ARIAD product is safer or more efficacious than the data in the product package insert demonstrates nor make comparative claims to other products that are not supported by the product package insert; and (ii) obtain ARIAD's prior written approval of the content of any such communication.

11.11. Vendor shall inform ARIAD promptly of any event or change in circumstances that may negatively affect Vendor's ability to perform any of its obligations under this Agreement in the manner contemplated by the Parties.

12. Indemnification; Limitation of Liability.

12.1. Vendor shall indemnify, defend and hold harmless ARIAD and its affiliates from and against any and all damages, liabilities, losses, costs and expenses (including, but not limited to, reasonable attorneys' fees) (collectively, "**Losses**") arising from or relating to any third-party claim, suit, action, investigation or proceeding (each, an "**Action**") as a result of a (a) material breach of this Agreement or any Statement of Work; (b) Vendor's negligence or willful malfeasance in performing the Services; or (c) infringement of any third party intellectual property.

12.2. ARIAD shall indemnify, defend and hold harmless Vendor from and against any and all Losses arising from or relating to any Action as a result of a (a) material breach of this Agreement or any Statement of Work; (b) ARIAD's negligence or willful malfeasance; or (c) infringement of any third party intellectual property.

12.3. Indemnification under Sections 12.1 and 12.2 will be provided only on the conditions that: (a) the indemnifying Party is given written notice within 15 calendar days after the indemnified Party receives notice of the subject Action (provided failure to give such notice within such period shall not bar a claim for indemnification except to the extent such failure has prejudiced the indemnifying Party); (b) the indemnifying Party has sole control of the defense and all related settlement negotiations, provided any settlement that would impose any monetary or injunctive obligation upon the indemnified Party shall be subject to such Party's prior written approval; and (c) the indemnified Party provides cooperation and information in furtherance of such defense, as reasonably required by the indemnifying Party.

12.4. Except for claims for (a) indemnification under Section 12.1 or 12.2, (b) personal injury due to negligence, (c) wrongful death, (d) willful misconduct or (e) fraud, in no event shall either Party be liable to the other for special, indirect, incidental, punitive, exemplary or consequential damages (including, but not limited to, loss of profits, loss of data or loss of use damages) even if such Party has been advised of the possibility of such damages or losses. Except for claims for (i) indemnification under Section 12.1 or 12.2, (ii) personal injury due to negligence, (iii) wrongful death, (iv) willful misconduct or (v) fraud, the entire liability of either Party to the other in connection with Services and any agreement between the Parties relating thereto (whether based on breach of contract, breach of warranty, negligence or any other legal theory) shall not exceed, in the aggregate, the total amount of fees paid or payable under this Agreement.

13. Term and Termination.

13.1. This Agreement shall commence on the Effective Date and shall continue in effect for one (1) year, unless terminated earlier in accordance with Section 13.

13.2. Vendor does not have the right to terminate this Agreement nor any Statement of Work without cause.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

13.3. This Agreement and any Statement of Work may be terminated:

13.3.1. By ARIAD for convenience upon 30 days written notice to Vendor;

13.3.2. By written agreement of the Parties; or

13.3.3. By written notice of either Party, if the other Party is in breach of its obligations, representations or warranties set forth in this Agreement, which breach is not cured within ten (10) days after receipt of written notice of such breach,

13.4. Notwithstanding the foregoing, either Party may terminate this Agreement immediately upon written notice if the other Party: (a) becomes insolvent; (b) becomes the subject of a petition in bankruptcy which is not withdrawn or dismissed within 60 days thereafter; (c) makes an assignment for the benefit of creditors; or (d) breaches any material obligation under this Agreement (including but not limited to payment obligations) and fails to cure such breach within 30 days after delivery of notice thereof by the non-breaching Party. ARIAD may terminate this Agreement, or any Statement of Work hereunder, for any reason upon 30 days' written notice.

13.5. Upon enactment of Federal, state or local legislation, rules or regulations, or the issuance of an administrative, judicial or legislative interpretation of existing laws, which, in the reasonable opinion of counsel to either Party, could render illegal or unenforceable the transactions contemplated by this Agreement or have a material adverse impact on such Party and/or any of its affiliates (economic or otherwise) if the Agreement remained in effect unmodified, the Parties shall negotiate in good faith to amend the Agreement to be consistent with the enactment or issuance; provided, however, that either Party may terminate the Agreement upon written notice if the Parties are unable to reach an agreement within thirty (30) days.

13.6. Upon termination of this Agreement or individual Statement of Work, Vendor shall: (a) be entitled only to the fees due and documented expenses incurred prior to notice of termination, which shall include reasonable and necessary non-cancelable expenses incurred prior to notice of termination; (b) return the prorated share of any fees ARIAD paid in advance under any Statement of Work; (c) transfer, assign, and make available to ARIAD all Materials, at ARIAD's request; (d) and give all reasonable cooperation toward transferring with approval of third parties its interest in all contracts and arrangements, if any, that Vendor properly entered into during the performance of this Agreement or individual Statement of Work, upon being duly released from the obligation thereof.

13.7. Provisions regarding the following matters shall survive the termination or expiration of this Agreement: Confidentiality, Data Security and Privacy, Ownership of Materials and Intellectual Property, Inspection, Records, Representations and Warranties, and Indemnification, Limitation of Liability, Term and Termination, Third-Party Obligations and Publicity, and General Provisions.

14. Insurance. Vendor represents that it maintains and will continue in force during the term of this Agreement, at its expense, commercial general liability insurance and errors and omissions insurance, each with a combined single limit of $1,000,000. Each Party shall be solely responsible for workmen's compensation claims brought by its respective employees, and will not hold the other liable for such claims. When this Agreement requires performance of Services on ARIAD's premises, Vendor shall maintain worker's compensation and employer's liability insurance covering its employees or agents engaged in such Services in amounts no less than required by Applicable Laws. Upon request, Vendor shall provide to ARIAD certificate(s) of insurance evidencing compliance with this Section.

15. Independent Contractors. The Parties to this Agreement are independent contractors, and nothing contained in this Agreement shall be construed to place the Parties in the relationship of employer and employee, partners, principal and agent or joint venturers. Neither Party shall have the power to bind or obligate the other Party, nor shall either Party hold itself out as having such authority.

16. Third-Party Obligations and Publicity. In connection with this Agreement, Vendor shall not make commitments or disbursements, incur obligations or disseminate any material of any kind using the name or any trademarks of ARIAD without ARIAD's prior written approval. Vendor agrees not to use ARIAD's name in any advertising or sales material without ARIAD's prior written consent.

17. General Provisions.

17.1. **Governing Law**. This Agreement shall be governed by the laws of the Commonwealth of Massachusetts, without reference to its conflicts of laws principles.

17.2. **Waivers.** The failure of either Party to take action as a result of a breach of this Agreement by the other Party shall constitute neither a waiver of the particular breach involved nor a waiver of either Party's right to enforce any provision of this Agreement through any remedy granted by Applicable Laws or this Agreement.

17.3. **Severability**. If any portion of this Agreement is found to be invalid or unenforceable by a court of competent jurisdiction, that finding shall not invalidate any other terms of this Agreement, and those terms shall remain in full force and effect.

17.4. **Integration and Amendments.** This Agreement, including each Statement of Work governed hereby, contains the entire understanding of the Parties with respect to the subject matter hereof, and supersedes all prior written or oral communications. This Agreement and each Statement of Work may not be modified or amended except by an instrument in writing signed by both Parties. No pre-printed terms of any subsequent purchase order or invoice will supersede the terms of this Agreement.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

17.5. **Assignment and Delegation.** Vendor may not assign this Agreement or any rights or obligations hereunder without the prior written consent of ARIAD. Any purported assignment in violation of this subsection shall be invalid.

17.6. **Successors and Assigns.** This Agreement binds and benefits the Parties and their respective successors and assigns.

17.7. **No Third-Party Beneficiaries**. Except as otherwise provided herein, this Agreement is intended to be solely for the benefit of the Parties hereto and is not intended to confer any benefits upon, or create any rights in favor of, any other person.

17.8. **Notices**. A notice or consent that occurs shall become effective when the intended recipient receives it. All notices, requests and other communications hereunder must be in writing and delivered personally, by facsimile transmission with answer back confirmation or by overnight courier, to the Parties at the following addresses or facsimile numbers:

If to ARIAD:	*If to Vendor:*
With a copy to:	*With a copy to:*
General Counsel ARIAD Pharmaceuticals, Inc. 26 Landsdowne Street Cambridge, MA 02139 Fax: (617) 225-2860	Biologics, Inc. Attn: Michele Coakley 120 Weston Oaks Court Cary, NC 27513 Fax: (919) 831-0440

17.9. **Non-Solicitation.** During the term of this Agreement, and for a period of 1 year thereafter, Vendor will not hire or retain as an employee, consultant, independent contractor or in any other capacity any employee or former employee of ARIAD who was involved in the project defined in the Statement of Work, nor any present or former consultant or independent contractor who was involved in the project defined in the Statement of Work on behalf of ARIAD. Similarly, during the term of this Agreement, and for a period of 1 year thereafter, ARIAD will not hire or retain as an employee, consultant, independent contractor or in any other capacity any employee or former employee of Vendor, nor any present or former consultant or independent contractor who was involved in the project defined in the Statement of Work on behalf of Vendor.

17.10. **Adverse Events/Product Complaints.** In the event Vendor is notified by any third party of an Adverse Event or Product Complaint concerning ARIAD's product Iclusig®, Vendor, utilizing instructions provided by ARIAD, shall immediately report Adverse Event and/or Product

Complaint information directly to ARIAD within twenty-four (24) hours of notification of such Adverse Event and/or Product Complaint or by the end of the next business day. Unless Vendor is required by law to report a complaint or Adverse Event, only ARIAD shall (i) notify the appropriate federal, state, and local authorities of any Vendor, Customer, or end-user, Adverse Events and/or Product Complaint (ii) evaluate any and all Adverse Events and/or Product Complaints from Vendor, Customers, or end-users, and (iii) respond regarding Adverse Events and/or Product Complaints, as ARIAD deems appropriate.

17.11. **Product Recall/Withdrawal**. ARIAD shall notify Vendor in the event of a Product recall or withdrawal and provide Vendor instructions on how to assist in implementing such recall or withdrawal. ARIAD, in its sole discretion, shall determine what, if any, assistance to request and shall make such a determination on a case-by-case basis. ARIAD shall compensate Vendor for the reasonable documented out-of-pocket expenses incurred in performing any assistance requested in writing by ARIAD.

17.12. **Force Majeure.** Neither Party will be liable for delay or failure of performance occasioned by causes beyond its control, including, but not limited to, acts of God or the public enemy, civil unrest, riots, acts of terrorism, declared or undeclared wars, fires, floods, unusually severe weather, earthquakes, acts of the Federal, state or local government (including any court decision), volcanoes, or pandemics ("Force Majeure Event"). If either Party is affected by a Force Majeure Event, the affected Party will give the other written notice, which will cause, without penalty to either Party, all obligations under this Agreement to be immediately suspended for a period of sixty (60) days. If the period of suspension caused by the Force Majeure Event exceeds that first sixty (60) day period, either Party may terminate the Agreement upon thirty (30) days written notice.

17.13. **Counterparts.** For the convenience of the parties, this Agreement may be (i) executed in counterparts, each of which shall be deemed to be an original, and both of which taken together shall constitute one agreement binding on both parties, and (ii) delivered electronically by email or facsimile transmission of executed signature pages. The parties agree that any signature delivered by email or facsimile transmission shall have the same force and effect as an original signature.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

To evidence the Parties' agreement to this Agreement, they have signed and delivered it as of the last date written below.

ARIAD Pharmaceuticals, Inc.

By: /s/ Marty J. Duvall
Name: Marty J. Duvall
Title: SVP, Commercial Operations
Date: 1/21/14

Biologics, Inc.

By: /s/ Daniel Duffy
Name: Daniel Duffy
Title: Chief Business Development Officer
Date: 1/14/14

SCHEDULE 1

CONFIDENTIAL – DO NOT COPY

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.12

CONFIDENTIAL

SCHEDULE 1

STATEMENT OF WORK #1
PROGRAM DESIGN, SET-UP & IMPLEMENTATION AND PROGRAM MANAGEMENT

This Statement of Work # 1("**SOW 1**") is entered into as of the last date written on the signature page below (" **Effective Date**") by and between ARIAD Pharmaceuticals, Inc. ("**ARIAD**"), with a business address at 26 Landsdowne Street, Cambridge, Massachusetts, 02139, and Biologics, Inc. (" **Vendor**"), with an office at 120 Weston Oaks Court, Cary, North Carolina, 27513, pursuant to the terms of the Master Services Agreement (the " **Master Services Agreement**") between ARIAD and Vendor dated January 14, 2014 which is incorporated hereunder in its entirety by reference. ARIAD and Vendor may also be referred to herein individually as a "**Party**," and collectively, as the "**Parties**."

PART I: PROJECT INFORMATION

A. Project Title

Iclusig® (ponatinib) Program Design, Set-Up, Implementation, and Program Management

B. General Description

ARIAD is in the business of marketing and selling pharmaceutical products and has developed a closed distribution model to support its product Iclusig® (ponatinib). ARIAD has selected Vendor as the exclusive specialty pharmacy provider of Product in the United States to patients, physicians, health care providers, and payers. As the exclusive provider of Product, Vendor will design, set-up, implement and manage a Product Program on behalf of ARIAD that will include the following components:

- sIND Patient Transition
- ARIAD PASS Customer Support Services
- Provider Relations & Outreach
- Patient Access Services
- ARIAD Copay Card Program
- Payor Access
- Specialty Pharmacy Services
- PAP, QuickStart & Assurance Program Eligibility & Distribution
- Data Aggregation & Reporting

This SOW sets forth the program design, set-up, implementation and program management services that Vendor shall perform for ARIAD (the "**Services**"). Vendor shall perform the Services described in this SOW in accordance with the highest professional standards and quality, and in a manner that shall not infringe, misappropriate, or violate the rights of any third party.

C. Tasks and Timeframe

Vendor shall perform the following Services in accordance with the terms and conditions of the Master Services Agreement and shall be compensated in accordance with the associated Service Fee identified below. Time is of the essence in the delivery of all services and deliverables.

Program Design, Set-Up & Implementation:

- Establish designated implementation and program teams
- Develop internal materials, SOPs and detailed workflows for program personnel
- Conduct training for all program team members (related to both Product and to the Program components)
- Establish data connectivity with Data Aggregator (third-party entity selected by ARIAD) for data imports and exports. Work with ARIAD and Data Aggregator to develop and implement program-specific reports
- Information System Customization
- Develop program communications, which shall be approved by ARIAD prior to use
- Designate specific toll free fax and telephone lines

Program Management: Monthly Administrative & On-Going Program Support Services

- Program management and oversight of program operations
- Monthly creation, review and delivery of ad-hoc program reports
- Quarterly business reviews and program insight
- Day-to-day administration and monitoring of program
- Management of quality review processes
- Maintenance of product environment and supporting technology infrastructure
- Network maintenance and program auditing
- Routine performance reporting and support for Ad Hoc performance report requests

D. Term

This SOW will be effective upon execution by a duly authorized representative of each Party (the "Effective Date"). This SOW shall expire on January 14, 2015, unless earlier terminated according to the terms of the Master Services Agreement or automatically renewed pursuant to this Section. This SOW shall automatically renew for two consecutive terms of one year each unless either Party provides the other Party with written notice of non-renewal at least thirty (30) days prior to the expiration date of this SOW.

PART II: COSTS AND PAYMENT SCHEDULE

In consideration of Vendor's performance of the Program Design, Set-Up & Implementation and Program Management services hereunder, ARIAD shall pay Vendor the Service Fees as set forth below. Vendor shall submit monthly invoices to ARIAD not later than thirty (30) calendar days after the end of each calendar month. Vendor's invoices must be accompanied by adequate supporting documentation for all amounts requested, as well as any other terms or information as reasonably requested by ARIAD. Invoices shall be due and payable within thirty (30) calendar days after ARIAD's receipt of such properly supported invoices; provided, however, that ARIAD may contest any invoice or portion thereof, to the extent that it reasonably believes that the charges reflected therein are inappropriate or lack a clear basis (paying all charges that are appropriate). Once any such issue or concern is resolved, ARIAD shall pay any remaining appropriate charges within thirty (30) calendar days of the date that such resolution occurs.

Program Design, Set-Up and Implementation	**$** [***] One-time, non-refundable fee Due to Vendor upon SOW signature by both parties
Program Management	**$** [***] per month

To evidence the Parties' agreement to this Agreement, they have signed and delivered it as of the last date written below.

ARIAD Pharmaceuticals, Inc.	**Biologics, Inc.**
By: /s/ Marty J. Duvall	By: /s/ Daniel Duffy
Name: Marty J. Duvall	Name: Daniel Duffy
Title: SVP, Commercial Operations	Title: Chief Business Development Officer
Date: 1/21/14	Date: 1/14/14

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Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.12

CONFIDENTIAL

SCHEDULE 2

STATEMENT OF WORK #2
SPECIALTY PHARMACY DATA REPORTING SERVICES

This Statement of Work #2 ("**SOW 2**") is entered into as of the last date written on the signature page below (" **Effective Date**") by and between ARIAD Pharmaceuticals, Inc. ("**ARIAD**"), with a business address at 26 Landsdowne Street, Cambridge, Massachusetts, 02139, and Biologics, Inc. (" **Vendor**"), with an office at 120 Weston Oaks Court, Cary, North Carolina, 27513, pursuant to the terms of the Master Services Agreement (the " **Master Services Agreement**") between ARIAD and Vendor dated January 14, 2014 which is incorporated hereunder in its entirety by reference. ARIAD and Vendor may also be referred to herein individually as a "**Party**," and collectively, as the "**Parties**."

PART I: PROJECT INFORMATION

A. Project Title

Iclusig® (ponatinib) ("**Product**") Specialty Pharmacy Data Reporting Services

B. General Description

ARIAD is in the business of marketing and selling pharmaceutical products and has developed a closed distribution model to support its product Iclusig® (ponatinib). ARIAD has selected Vendor as the exclusive specialty pharmacy provider of Product in the United States to patients, physicians, health care providers, and payers. This SOW sets forth the data reporting services Vendor shall perform for ARIAD relating to its distribution of Product. Vendor shall perform the Services in accordance with the highest professional standards and quality, and in a manner that shall not infringe, misappropriate, or violate the rights of any third party. Unless otherwise specified, if there is a dispute arising over a conflict or ambiguity between the terms and conditions of this Statement of Work and those in the Master Services Agreement, the terms and conditions of the Master Services Agreement shall control such dispute.

C. Definitions:

a. "Adverse Event" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have a causal relationship with this treatment. This includes the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action. For the purposes of this Statement of Work, any report of a patient death is considered an adverse event.

b. "Product Complaint" means: a report regarding a problem or potential problem with the quality, performance or safety of a medical product that has been distributed for commercial use. A complaint is generally initiated by a source external to the product manufacturer. A complaint includes information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product and its packaging/labeling, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the application.

c. "Affiliate" means, with respect to any entity, any other entity that directly or indirectly controls, is controlled by, or is under common control with, such first entity. For the purposes of this definition, "control," as applied to any entity, means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of that entity, whether through the ownership of voting securities, by contract, or otherwise.

d. "Master Services Agreement" means the Master Services Agreement between ARIAD and Vendor dated January 14, 2014

e. "Statement of Work" or "SOW" mean this Statement of Work 2 for specialty pharmacy data reporting services, pursuant to the Master Services Agreement and any exhibits attached hereto or incorporated by reference herein, and any Work Orders executed hereunder.

f. "Diverted Product" means (i) expired, defective, or out of specification Product that is diverted from planned destruction, (ii) Product within ARIAD's product quality specifications that is intended for one market and sold or transferred into another market in violation of applicable laws, regulations, ARIAD policies, or ARIAD contracts, (iii) Product theft from within the distribution or supply chain, (iv) Product acquired, repackaged, and sold by a third party in a standard or customary size or unit of measure that ARIAD currently offers for sale in the Territory, or (v) Product sold by ARIAD for use in non-domestic markets which is subsequently sold or imported for sale or use in the Territory.

g. "Inventory" means the sum of all Product quantities (i) on hand at Vendor's facility, and (ii) on order with ARIAD, including quantities in transit from ARIAD to Vendor's facility.

h. "National Drug Code (NDC)" means unique code assigned to the manufacturer, the drug product and the drug package

i. "Payer" means any health maintenance organization, preferred provider organization, indemnity insurance carrier, other health benefits plan or program, whether pre-paid, fee-for-service, employer self-funded or insured, or governmental agency which pays all or part of the cost of the prescription drug benefit for qualified members.

j. "Prior Authorization" means the process by which a Payer requires its prior approval for the coverage of a prescribed pharmaceutical product for a specified patient.

k. "Product(s)" means the pharmaceutical product(s) that is listed in the Master Services Agreement subject to the addition or deletion of specific Products by ARIAD in accordance with the Master Services Agreement.

l. "Data Reporting Services" means the services to be performed by Vendor for ARIAD hereunder, as further described in Section D, Exhibit A, and in any Work Order executed by the Parties hereunder.

m. "Data Reporting Fees" means the fees to be paid by ARIAD to Vendor the Services described in Part II hereunder.

n. "Territory" means the fifty (50) states of the United States, the District of Columbia, and Puerto Rico only.

o. "Unauthorized Deduction" means any deduction taken by Vendor against amounts due to ARIAD.

p. "WAC" means the wholesale acquisition cost for a Product communicated to Vendor by ARIAD and in effect on the date an order is received by ARIAD from Vendor; it is understood and agreed that WAC is ARIAD's list price to Vendor, and that it excludes data reporting fees, and any other discounts, allowances, and price concessions.

D. Data Reporting Services

Subject to and in accordance with the terms and conditions of the Master Services Agreement, Vendor shall perform the data reporting services described in Exhibit A (the "**Services**") during the term of this SOW. Vendor shall provide the Services in a timely and accurate manner in accordance with the schedules set forth in Exhibit A.

E. Product Purchase Terms and Conditions and Vendor Obligations

As the exclusive specialty pharmacy provider of Product, the following terms and conditions and Vendor obligations shall apply to Vendor's purchase and distribution of Product. The Parties acknowledge and agree that ARIAD shall not pay Vendor any service fees for satisfying the following terms, conditions and obligations.

i. Product Purchase: Vendor shall purchase 100% of its requirements of Product directly and exclusively from ARIAD and shall not purchase or accept Product from any entity or person other than ARIAD without prior written approval from ARIAD. Vendor shall not market, sell, distribute, dispense, transfer, or trade in any manner Product that has been obtained from any source other than ARIAD without prior written approval from ARIAD.

ii. Product Modifications: ARIAD reserves the right to add any new FDA-approved strength or package size of Product to this SOW at the same terms and conditions as the existing Product in this SOW, such addition being effective upon date indicated by ARIAD in its written notice to Vendor.

iii. Financial Responsibility: Vendor shall maintain its direct purchase account(s) with ARIAD in good credit standing, including without limitation meeting ARIAD's payment terms and conditions. ARIAD reserves the right to apply a credit limit to Vendor's direct purchase account(s) as deemed appropriate by ARIAD. Vendor shall maintain an adequate financial condition satisfactory to ARIAD and shall substantiate such condition with annual audited financial statements within 14 days upon request by ARIAD or as ARIAD otherwise requests in writing.

iv. Audit: As consistent with the "**Inspection; Audit**" and "**Records**" provisions of the Master Services Agreement, upon reasonable prior written notice, ARIAD shall have the right, at its own expense, any time during the term of SOW 2 to audit during normal business hours, either through its designee or on its own, Vendor's records, data and documentation regarding Product and to examine Vendor's inventory of Product at any Vendor Facilities. Vendor agrees to fully cooperate with ARIAD for the purpose of any audit conducted under this Section. Prior payment by ARIAD shall not preclude ARIAD from questioning the correctness, completeness, or accuracy of Vendor's data, and in the event that any inconsistencies or errors are discovered, Vendor shall rectify the errors immediately. In the event any such audit discloses an overpayment, Vendor shall promptly pay the amount thereof to ARIAD. This Section shall survive the expiration or earlier termination of the Master Services Agreement or of SOW 2.

v. Product Order Requirements: Vendor shall transmit orders for Product to ARIAD using an electronic data transmission or other process agreed to in writing by the Parties. Vendor shall transmit a maximum of up to four (4) orders per calendar week per approved pharmacy location owned or operated by Vendor ("**Approved Facility**"), unless ARIAD otherwise agrees in advance and in writing. Vendor agrees to pay for additional handling and shipping costs incurred by ARIAD on expedited Product orders. Vendor shall maintain in each and every Approved Facility an inventory on hand/on order not to exceed [***] ([***]) [***] on an NDC by NDC basis.

vi. Product Pricing: ARIAD shall invoice Vendor for its Product purchases at Wholesale Acquisition Cost, plus all applicable Federal and state taxes. ARIAD in its sole discretion will determine the effective date and time of any change in WAC. All orders for Product received by ARIAD prior to the effective date and time (5PM EST) of a change in WAC and subsequently shipped by ARIAD shall be invoiced by ARIAD at the old price. All orders for Product that ARIAD receives on or after the effective date and time (5PM EST) of a change in WAC and subsequently shipped by ARIAD shall be invoiced by ARIAD at the new price.

vii. Taxes: Vendor is responsible for payment of any tax, duty, custom, or other fee imposed by any federal, state, or local governmental authority on Product purchases. WAC is exclusive of any such tax, duty, custom, or fee and if ARIAD is collecting the same, it will be added to the invoice as a separate line item.

viii. Shipment & Delivery: Unless otherwise agreed by ARIAD and Vendor in writing, ARIAD will determine the time, route, and carrier of all Product shipments to Vendor. ARIAD will pay shipping costs associated with all Product shipments. Should Vendor request special routing which results in higher transportation costs, the difference in costs shall be paid by Vendor. Terms are F.O.B. Origin, with shipping and insurance to be prepaid by ARIAD. ARIAD agrees not to ship any product with less than 4 months of remaining shelf life at the time of delivery.

ix. Damages & Returns: With regard to any shipment referenced above that was (i) shipped to Vendor by ARIAD in error, (ii) damaged during transit and noted as such at time of delivery, and/or (iii) shorted in quantity of Product and noted as such at time of delivery, Vendor shall not revoke any acceptance of the shipment and shall notify the carrier and ARIAD immediately, but in any event no later than forty-eight (48) hours of receipt of the shipment. Vendor acknowledges and agrees risk of loss shall not pass back to ARIAD because of any shipping error, known damage, or known shortage, or for any other reason. Vendor shall provide any and all documentation requested by ARIAD in order to resolve the matter. Vendor shall return any such Product to ARIAD or its designee, in accordance with instructions provided by ARIAD. If any shipment referenced above, is damaged or contains a concealed damage or shortage, Vendor shall notify the carrier and ARIAD within three (3) calendar days and no later than five (5) calendar days after receipt of the shipment. Vendor shall provide any and all documentation requested by ARIAD in order to resolve the matter. Vendor shall return any such damaged Product to ARIAD or its designee, in accordance with instructions provided by ARIAD. ARIAD will provide its current Return Goods Policy to Vendor upon execution of contract.

x. Payment Terms: EFT 32. All payments must be made via EFT 32. ARIAD shall invoice Product orders on the date of shipment to Vendor. If the due date (day 32) falls on a Saturday, Sunday, or bank holiday, then the first business day after such Saturday, Sunday, or bank holiday shall be deemed the due date. If payment of undisputed amounts is not received by the due date identified in Section IX, as applicable, ARIAD reserves the right to charge Vendor simple interest on the overdue amount at the lower of (i) one and one-half percent (1 ½%) per month, or (ii) the maximum rate permitted by applicable law. Such simple interest shall accrue on a daily basis from the date on which payment became overdue up to the date on which ARIAD receives the full outstanding amount. Vendor must pay all invoices in full under the terms specified herein and no deductions are permitted except for ARIAD issued credit memo or for amounts reasonably disputed in good faith.

xi. Claims for Credit: Vendor shall notify ARIAD in writing of any claim seeking credit for delivery shortages, physical damage, pricing discrepancies, mis-shipments, or any other claim for credit within the time limits in Section VII above, as applicable. Vendor will cooperate with ARIAD in the processing of all claims, including without limitation providing reasonably available information and documents as requested by ARIAD, and returning damaged Product in accordance with ARIAD's return goods policy. Although ARIAD will investigate and resolve Vendor's claim within thirty (30) calendar days after receiving the claim and appropriate supporting documentation. Vendor shall not make any unauthorized deductions under this Statement of Work, including (i) shipment/delivery issues or (ii) any claim alleged by, or any debt owed by ARIAD to, an Affiliate of Vendor or any other third party.

xii. Handling & Storage of Product: Vendor shall maintain and provide to ARIAD, upon ARIAD's request, all documentation verifying that Vendor has met all legal and regulatory license and similar requirements in accordance with federal, state, and local laws, including all applicable

licenses or certifications associated with pharmaceutical product distribution in the Territory, such as Drug Enforcement Agency (DEA) numbers. Vendor shall maintain Product under proper storage conditions, in accordance with product labeling and ARIAD's instructions, during handling and dispensing. Vendor shall permit ARIAD to conduct a physical inspection of Vendor's Approved Facilities within ten (10) calendar days of a written request by ARIAD.

xiii. Adverse Events: In the event Vendor is notified by any third party of an Adverse Event or Product Complaint concerning a Product, Vendor shall immediately report Adverse Event and/or Product Complaint information directly to ARIAD within twenty-four (24) hours of notification of such Adverse Event and/or Product Complaint or by the end of the next business day utilizing instructions provided by ARIAD. Unless Vendor is required by law to report a complaint or Adverse Event, only ARIAD shall (i) notify the appropriate federal, state, and local authorities of any Vendor, Customer, or end-user, Adverse Events and/or Product Complaint (ii) evaluate any and all Adverse Events and/or Product Complaints from Vendor, Customers, or end-users, and (iii) respond regarding Adverse Events and/or Product Complaints, as ARIAD deems appropriate.

xiv. Product Recalls: ARIAD shall notify Vendor in the event of a Product recall or withdrawal and shall provide Vendor instructions on how to assist in implementing such recall or withdrawal. ARIAD, in its sole discretion, shall determine what, if any, assistance to request and shall make such a determination on a case-by-case basis. ARIAD shall compensate Vendor for the reasonable documented out-of-pocket expenses incurred by Vendor in performing any assistance requested by ARIAD in writing.

xv. Core Pharmacy Patient Services: As a specialty pharmacy, Vendor typically provides a wide array of services to patients and their caregivers. Upon receipt of each Product prescription referral, Vendor will perform the following activities, in accordance with the Master Services Agreement:

i. Vendor will perform its standard procedure for benefits investigation, prior authorization approval, insurance verification, co-pay collection, filling the prescription, contacting the patient and the provider, and shipping the completed prescription.

ii. Once Vendor is able to complete a Product prescription referral, it will follow its standard patient compliance and adherence services, and its standard process for refilling prescriptions each month for medically appropriate patients. Vendor will perform its standard adherence services only where refills are medically appropriate for the particular patient in accordance with the Product label and the patient's treating physician's instructions. Vendor shall not perform any patient adherence services for any patient who has discontinued use of Product due to adverse reactions or due to any clinical determination by the patient's prescribing physician.

iii. Vendor will distribute to the patient ARIAD-provided patient education materials with the first filled prescription (if available). Vendor will not alter or edit such materials, nor shall Vendor provide any other materials to patients without ARIAD's prior written approval.

xvi. Payer Networks: Vendor will use reasonable commercial efforts to secure product-specific Letter of Agreements (LOAs) with payers to gain in-network provider status with respect to dispensing Product.

E. Term and Termination

This SOW will be effective upon execution by a duly authorized representative of each Party (the "Effective Date"). This SOW shall expire on January 14, 2015, unless earlier terminated according to the terms of the Master Services Agreement or automatically renewed pursuant to this Section. This SOW shall automatically renew for two consecutive terms of one year each unless either Party provides the other Party with written notice of non-renewal at least thirty (30) days prior to the expiration date of this Agreement.

This SOW may be terminated by either Party, with or without cause, upon sixty (60) days' written notice to other Party

PART II: COSTS AND PAYMENT SCHEDULE

In consideration of Vendor's performance of the Data Reporting Services hereunder, ARIAD shall pay Vendor the Service Fees as set forth below. Vendor shall submit monthly invoices to ARIAD not later than thirty (30) calendar days after the end of each calendar month. Vendor's invoices must be accompanied by adequate supporting documentation for all amounts requested, as well as any other terms or information as reasonably requested by ARIAD. Invoices shall be due and payable within thirty (30) calendar days after ARIAD's receipt of such properly supported invoices; provided, however, that ARIAD may contest any invoice or portion thereof, to the extent that it reasonably believes that the charges reflected therein are inappropriate or lack a clear basis (paying all charges that are appropriate). Once any such issue or concern is resolved, ARIAD shall pay any remaining appropriate charges within thirty (30) calendar days of the date that such resolution occurs.

Data Reporting Services Fee	**$**[***] per each prescription dispensed

Data Reporting Services Fee: The Data Reporting Services Fee will be paid based on daily referral status/shipment report transmitted by the Vendor to the Daily Aggregator (as set forth below in Report # 1). The Data Reporting Services Fee will also be paid based on monthly 852 data transmitted by the Vendor to the Data Aggregator (as set forth below in Report #2). ARIAD reserves the right to quarterly written confirmation of Vendor's monthly 852 inventory file.

To evidence the Parties' agreement to this SOW, they have signed and delivered it as of the last date written below.

ARIAD Pharmaceuticals, Inc.

By: /s/ Marty J. Duvall
Name: Marty J. Duvall
Title: SVP, Commercial Operations
Date: 1/14/14

Biologics, Inc.

By: /s/ Daniel Duffy
Name: Daniel Duffy
Title: Chief Business Development Officer
Date: 1/14/14

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Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT A

Data Reporting Services

Report#1—Daily Referral Status/Shipment Report

Frequency: Daily, 10am ET

Filename: [***]

Location: [***] ([***])

Format: Pipe-delimited, Header Included

Receipt and Discrepancy Notification: N/A

[Data Set to be added once finalized]

Report#2 – Monthly 852 Inventory File

Frequency: Monthly, 10am ET, 1st business day of the month

Filename: [***]

Location: [***] ([***])

Format: Pipe-delimited, Header Included

Receipt and Discrepancy Notification: N/A

Data Element	Definition
Date	Product Activity Data period. Month End Date for SPs. In YYYYMMDD format.
Vendor #	SPP's vendor # from the Manufacturer. 3 Digit code of the SPP. "BLG"
Facilities #	SPP's Facilities number
Facilities Identifier	Facilities DEA / HIN number
Product Identifier NDC	Product eleven (11) digit National Drug Code (NDC) number. 11 digit NDC #: 15 mg tablet—76189053560, 45 mg tablet—76189053430
Product Unit of Measure	Product selling unit of measure. Include "EA" to represent each tablet of Product.
Quantity on Hand	Total units on hand and available for shipment at the end of the Product Activity Data period.
Quantity On Order	Total units ordered by SPP that have not yet been received and made available for sale at the end of the Product Activity Data period.
Quantity Received	Total units received by SPP during the Product Activity Data period.

Quantity Dispensed	Total units dispensed and shipped to 100% of SPP's patients, regardless of source of Product, during the Product Activity Data period. Excludes transfers between SPP's Facilities

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.12

CONFIDENTIAL

SCHEDULE 3

STATEMENT OF WORK #3
ARIAD ICLUSIG® PATIENT ACCESS & SUPPORT SERVICES (PASS)

This Statement of Work #3 ("**SOW 3**") is entered into as of the last date written on the signature page below ("**Effective Date**") by and between ARIAD Pharmaceuticals, Inc. ("**ARIAD**"), with a business address at 26 Landsdowne Street, Cambridge, Massachusetts, 02139, and Biologics Patient Access Services, Inc. ("**Vendor**"), with an office at 120 Weston Oaks Court, Cary, North Carolina, 27513, pursuant to the terms of the Master Services Agreement (the "**Master Services Agreement**") between ARIAD and Vendor dated January 14, 2014 which is incorporated hereunder in its entirety by reference.

PART I: PROJECT INFORMATION

A. Project Title

Iclusig® (ponatinib) ("**Product**") Patient Access & Support Services (PASS)

B. General Description

This SOW #3 sets forth the customer support, patient reimbursement support and product access support services, and data reporting related to such services, that Vendor shall perform for ARIAD with respect to Product (the "**Services**"). The parties acknowledge and agree that Vendor shall perform the Services solely with respect to patients who have valid prescriptions for Product. Vendor shall perform the Services described in this SOW #3 in accordance with the highest professional standards and quality, and in a manner that shall not infringe, misappropriate, or violate the rights of any third party.

C. Tasks and Timeframe

Vendor shall perform the following Services in accordance with the terms and conditions of the Master Services Agreement and ARIAD's PASS Program Business Rules, and Vendor shall be compensated in accordance with the associated Service Fee identified below.

Time is of the essence in the delivery of all services and deliverables. Vendor represents and warrants that none of the Services described in the SOW #3 for which fees are to be paid are standard services that Vendor ordinarily performs for patients absent payment from any manufacturer.

Patient Access & Support Services:

- Serve as Customer Service liaison available to respond to inquiries and general reimbursement support and product access questions from both healthcare providers and patients.
- Accept referrals from healthcare providers as point of initiation for coverage support, reimbursement support and/or co-pay assistance services via a dedicated fax and telephone line.
- Assist healthcare providers in understanding the prescription coverage landscape for Product, responding to all inquiries the same business day received (if received before 4:00 pm ET).
- Benefits Verification/Coverage Support:
    - Provide healthcare providers and/or patients with publically available information regarding coverage requirements for Product, such as the requirements for coverage under a particular insurance plan.
    - Upon confirmation from a healthcare provider that he/she has made the decision, based on his/her clinical judgment, that Product is appropriate for a particular patient, Vendor shall verify with the applicable payor the patient's available coverage (including coverage limitations, deductibles, co-pays, and prior authorization or pre-certification requirements) and provide healthcare provider with such patient-specific coverage and reimbursement information.
    - Provide healthcare providers with general information about any applicable pre-certification or prior authorization processes.
    - Vendor acknowledges and understands that it shall not assist healthcare providers or their staff in preparing or submitting precertification requests, prior authorization requests, or appeals of coverage denials.
- Based on eligibility guidelines and criteria established and provided by ARIAD, facilitate enrollment into the following ARIAD-sponsored patient assistance programs:
    - Iclusig Patient Assistance Program (PAP) (free drug program)
    - Iclusig QuickStart Program
    - Iclusig Assurance Program
- Dispense all free goods for the ARIAD-sponsored patient assistance programs listed above to eligible patients as determined by Vendor. Product will be obtained and held on consignment for ARIAD.
- Triage when appropriate all clinical questions from patients and healthcare providers to ARIAD Medical Affairs
- PASS Data and Performance Reporting (as set forth in Exhibit A)

When communicating with patients, healthcare providers or payors in the course of performing the Services described in this SOW #3, Vendor must disclose that it is providing the Services on behalf of ARIAD.

D. Term

This SOW #3 will be effective upon execution by a duly authorized representative of each Party (the "Effective Date"). This SOW #3 shall expire on January 22, 2015, unless earlier terminated according to the terms of the Master Services Agreement or automatically renewed pursuant to this Section. This SOW #3 shall automatically renew for two consecutive terms of one year each unless either Party provides the other Party with written notice of non-renewal at least thirty (30) days prior to the expiration date of this SOW #3.

PART II: COSTS AND PAYMENT SCHEDULE

In consideration of Vendor's performance of the Patient Access & Support Services and Data Reporting hereunder, ARIAD shall pay Vendor the Fees as set forth below. Vendor shall submit monthly invoices to ARIAD not later than thirty (30) calendar days after the end of each calendar month. Vendor's invoices must be accompanied by adequate supporting documentation for all amounts requested, as well as any other terms or information as reasonably requested by ARIAD. Invoices shall be due and payable within thirty (30) calendar days after ARIAD's receipt of such properly supported invoices; provided, however, that ARIAD may contest any invoice or portion thereof, to the extent that it reasonably believes that the charges reflected therein are inappropriate or lack a clear basis (paying all charges that are appropriate). Once any such issue or concern is resolved, ARIAD shall pay any remaining appropriate charges within thirty (30) calendar days of the date that such resolution occurs.

ARIAD PASS Customer Support Services	$ [***]per FTE per month*
ARIAD Daily PASS Reporting	$ [***]per month
Free Goods Product Distribution (includes Iclusig PAP, Iclusig QuickStart Program & Iclusig Assurance Program)	$ [***] per dispense

* As of the date written on the signature page below, Vendor shall dedicate [***] ([***]) FTEs to ARIAD Patient Access & Support Services (PASS). However, Vendor shall only invoice ARIAD for [***] ([***]) FTEs. On March 1, 2014, Vendor and ARIAD shall reassess ARIAD PASS call volume, productivity, and FTE requirements.

To evidence the Parties' agreement to this SOW #3, they have signed and delivered it as of the last date written below.

ARIAD Pharmaceuticals, Inc.

By: /s/ Marty J. Duvall
Name: Marty J. Duvall
Title: SVP, Commercial Operations
Date: 1/23/14

Biologics Patient Access Services, Inc.

By: /s/ Daniel Duffy
Name: Daniel Duffy
Title: Chief Business Development Officer
Date: 1/22/14

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Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

EXHIBIT A

Data Reporting

Report#1—Daily Programs File

Frequency: Daily, 10am ET
Filename: [***]
Location: [***] ([***])
Format: Pipe-delimited, Header Included
Receipt and Discrepancy Notification: N/A

[Data Set to be added once finalized]

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Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.12

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SCHEDULE 4

STATEMENT OF WORK #4
ARIAD ICLUSIG® COPAY CARD PROGRAM

This Statement of Work #4 ("**SOW #**4") is entered into as of the last date written on the signature page below ("**Effective Date**") by and between ARIAD Pharmaceuticals, Inc. ("**ARIAD**"), with a business address at 26 Landsdowne Street, Cambridge, Massachusetts, 02139, and Biologics, Inc. (" **Vendor**"), with an office at 120 Weston Oaks Court, Cary, North Carolina, 27513, pursuant to the terms of the Master Services Agreement (the "**Master Services Agreement**") between ARIAD and Vendor dated January 14, 2014 which is incorporated hereunder in its entirety by reference.

PART I: PROJECT INFORMATION

A. Project Title

ARIAD Iclusig® (ponatinib) Copay Card Program

B. General Description

ARIAD has designed and plans to implement a commercial copay card program for Iclusig ® ("Product") for the following purposes:

- To minimize the out-of-pocket (OOP) cost burden for eligible patients with commercial insurance covering Product to help facilitate access to Product therapy.
- To allow eligible patients with commercial insurance to pay no more than $10 per month, with an annual cap of $24,000; max amount is $8,000/month (no income eligibility requirements/state restriction)

This SOW #4 sets forth the services Vendor shall perform for ARIAD related to the administration of the ARIAD Iclusig ® (ponatinib) Copay Card Program (the **"Services"**). Vendor shall perform the Services described in this SOW #4 in accordance with the highest professional standards and quality, and in a manner that shall not infringe, misappropriate, or violate the rights of any third party.

C. Tasks and Timeframe

Vendor shall perform the following Services related to the implementation of the ARIAD Iclusig ® (ponatinib) Copay Card Program in accordance with the terms and conditions of the Master Services Agreement and ARIAD's program business rules. Vendor shall be compensated for the Services in accordance with the associated Service Fee identified below. Time is of the essence in the delivery of all services and deliverables.

- Vendor's pharmacy representatives will offer the Iclusig Copay Card Program to all eligible commercial patients with a monthly copay greater than $10, in full compliance with ARIAD's eligibility requirements.
- Vendor will verify patient eligibility to use the Iclusig Copay Card by verifying patient's insurance coverage.
- Vendor will develop a secondary payor account (ARIAD Copay Support) within the pharmacy Management Information System (MIS). This account will be used to adjudicate and record secondary claims that will reflect the amount of funds being applied to an eligible patient's commercial required copayment.
- At the end of each month, Vendor shall submit to ARIAD an invoice with supporting documentation (in full compliance with HIPAA) describing the co-pay assistance Vendor provided to eligible patients during such month. (including all ARIAD Copay Support Program outstanding funds for all active patients).
- ARIAD shall reimburse Vendor the full amount of co-pay assistance that Vendor provided to eligible patients within thirty (30) days of receipt and verification of Vendor's invoice and supporting documentation. Under no circumstances shall ARIAD reimburse Vendor for any co-pay assistance that Vendor provided to ineligible patients.
- The parties acknowledge and agree that Vendor shall perform the Services solely with respect to eligible patients who have valid prescriptions for Product.
- Vendor shall not engage in negotiation with insurers, health plans or other third parties regarding the Iclusig Copay Card Program.
- Vendor shall processes each claim in accordance with its usual reimbursement formula, without increasing the retail price or reimbursement formula for Product and without charging the patient any premium or other amount for handling the Iclusig Copay Card.
- Vendor shall not advertise the Iclusig Copay Card Program.

It is understood and agreed that the Iclusig Copay Card Program is for the sole benefit of eligible patients. Vendor may not capture or retain any of the value of the copay card savings.

D. Term

This SOW #4 will be effective upon execution by a duly authorized representative of each Party (the "Effective Date"). This SOW #4 shall expire on January 22, 2015, unless earlier terminated according to the terms of the Master Services Agreement or shall automatically renewed pursuant to this Section. This SOW #4 shall automatically renew for two consecutive terms of one year each unless either Party provides the other Party with written notice of non-renewal at least thirty (30) days prior to the expiration date of this SOW #4.

PART II: COSTS AND PAYMENT SCHEDULE

In consideration of Vendor's performance of the Copay Card Program Services hereunder, ARIAD shall pay Vendor the Fees as set forth below. Vendor shall submit monthly invoices to ARIAD not later than thirty (30) calendar days after the end of each calendar month. Vendor's invoices must be accompanied by adequate supporting documentation for all amounts requested, as well as any other terms or information as reasonably requested by ARIAD. Invoices shall be due and payable within thirty (30) calendar days after ARIAD's receipt of such properly supported invoices; provided, however, that ARIAD may contest any invoice or portion thereof, to the extent that it reasonably believes that the charges reflected therein are inappropriate or lack a clear basis (paying all charges that are appropriate). Once any such issue or concern is resolved, ARIAD shall pay any remaining appropriate charges within thirty (30) calendar days of the date that such resolution occurs.

Iclusig® Copay Card Program Administration Fee	$ [***] per month

To evidence the Parties' agreement to this Agreement, they have signed and delivered it as of the last date written below.

ARIAD Pharmaceuticals, Inc.

By: /s/ Marty J. Duvall
Name: Marty J. Duvall
Title: SVP, Commercial Operations
Date: 2/1/14

Biologics Patient Access Services, Inc.

By: /s/ Daniel Duffy
Name: Daniel Duffy
Title: Chief Business Development Officer
Date: 1/24/14

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Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.25

ARIAD Pharmaceuticals, Inc.
Director Compensation Arrangements

Effective January 1, 2014 and until further modified by the Board of Directors of ARIAD Pharmaceuticals, Inc. (the "Corporation"), the Corporation's non-employee directors will receive the compensation set forth below. Non-employee directors do not receive any other compensation for service on the Board of Directors or its committees, other than reimbursement of reasonable expenses. Directors who are also employees of the Corporation do not receive any additional compensation for their service on the Board of Directors. All equity awards are granted under the Corporation's 2006 Long Term Incentive Plan, as amended.

Upon initial appointment or election to the Board of Directors, the director will receive a one-time grant of 75,000 stock options, which will vest over three years in equal amounts on first, second and third anniversaries of the date of grant. The options will have a term of ten years. The exercise price for such options will be the closing price of the Corporation's common stock as quoted on the NASDAQ Global Select Market on the date of grant.

Each year, the directors will receive annual cash compensation of $70,000, paid in equal quarterly amounts on or about the last day of each calendar quarter. In lieu of cash, a director may elect to receive the equivalent value in restricted shares of the Corporation's common stock on January 31, subject to a lapsing repurchase right as to 25% of the shares on March 31, June 30, September 30 and December 31 of the year of the award. The number of shares will be determined based on the volume weighted average price (VWAP) of the Corporation's common stock for the month of December of the prior year. Such election to be paid in shares in lieu of cash must be made by January 15 of each calendar year. Upon initial appointment or election to the Board of Directors, the annual cash compensation for that year will be prorated beginning on the first day of the fiscal quarter in which he or she was initially appointed or elected and the individual may elect to be paid in shares in lieu of cash if such election is made within 10 days of election or appointment. If director dies, resigns or is removed during any quarter, he or she shall be entitled to a cash payment (or shares in lieu thereof) on a pro-rated basis through his or her last day of service.

Each year on January 31, the directors will receive annual equity grants consisting of 25,000 stock options and 12,500 restricted stock units which will vest as to 25% of the shares on March 31, June 30, September 30 and December 31 of the year of the award. The options will have a term of ten years. The exercise price for such options will be the closing price of the Corporation's common stock as quoted on the NASDAQ Global Select Market on the date of grant.

The Board of Directors has adopted stock ownership guidelines, to be phased in over five years, for the non-employee directors and the Corporation's Chief Executive Officer. The guideline for the non-employee directors is ownership of the Corporation's common stock with a value of at least three times the annual cash compensation and the guideline for the Chief Executive Officer is ownership of the Corporation's common stock with a value of at least six times his base salary.

Exhibit 21.1

SUBSIDIARIES OF ARIAD PHARMACEUTICALS, INC.

Subsidiary	Jurisdiction of Organization	% Owned
ARIAD Pharma S.A.	Greece	100%
ARIAD Pharma Ltd.	United Kingdom	100%
ARIAD Securities Corporation	Massachusetts, United States	100%
ARIAD Pharmaceuticals (Cayman) Inc.	Cayman Islands	100%
ARIAD Pharmaceuticals (Cayman) L.P.	Cayman Islands	99.9999%*
ARIAD Pharmaceuticals (Japan) GK	Japan	100%
ARIAD Pharmaceuticals (Luxembourg) Sàrl	Luxembourg	100%**
ARIAD Pharmaceuticals (Europe) Sàrl	Switzerland	100%***
ARIAD Pharmaceuticals (France) Sàrl	France	100%***
ARIAD Pharmaceuticals (Germany) GmbH	Germany	100%***
ARIAD Pharma (UK) Ltd	United Kingdom	100%***
ARIAD Pharmaceuticals (Italia) SRL	Italy	100%***
ARIAD Pharmaceuticals (Spain) SL	Spain	100%***
ARIAD Pharmaceuticals (Australia) Pty Ltd	Australia	100%***
ARIAD Pharmaceuticals (Benelux) B.V.	Netherlands	100%***
ARIAD Pharmaceuticals (Austria) GmbH	Austria	100%***
ARIAD Pharmaceuticals (Nordic) AB	Sweden	100%***
ARIAD Pharmaceuticals (Canada) ULC	Canada	100%***

* The remaining 0.0001% of ARIAD Pharmaceuticals (Cayman) LP is owned by ARIAD Pharmaceuticals, Inc.
** ARIAD Pharmaceuticals (Luxembourg) Sàrl is owned 100% by ARIAD Pharmaceuticals (Cayman) LP.
*** These subsidiaries are owned 100% by ARIAD Pharmaceuticals (Luxembourg) Sàrl.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 33-90854, 333-36597, 333-63706, 333-90480, 333-135473, 333-151683, 333-161515 and 333-182454 on Form S-8 and Registration Statement No. 333-178489 on Form S-3 of our reports dated March 3, 2014, relating to the consolidated financial statements of ARIAD Pharmaceuticals, Inc. and the effectiveness of ARIAD Pharmaceuticals, Inc.'s internal control over financial reporting, appearing in this Annual Report on Form 10-K of ARIAD Pharmaceuticals, Inc. for the year ended December 31, 2013.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 3, 2014

EXHIBIT 31.1

CERTIFICATIONS

I, Harvey J. Berger, M.D., certify that:

1. I have reviewed this annual report on Form 10-K of ARIAD Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 3, 2014

/s/ Harvey J. Berger, M.D.

Harvey J. Berger, M.D.
Chairman of the Board of Directors,
Chief Executive Officer and President

EXHIBIT 31.2

CERTIFICATIONS

I, Edward M. Fitzgerald, certify that:

1. I have reviewed this annual report on Form 10-K of ARIAD Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 3, 2014

/s/ Edward M. Fitzgerald

Edward M. Fitzgerald
Executive Vice President,
Chief Financial Officer and Treasurer

EXHIBIT 32.1

CERTIFICATION
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of ARIAD Pharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2013 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 3, 2014

/s/ Harvey J. Berger, M.D.
Harvey J. Berger, M.D.
Chairman of the Board of Directors,
Chief Executive Officer and President

Dated: March 3, 2014

/s/ Edward M. Fitzgerald
Edward M. Fitzgerald
Executive Vice President,
Chief Financial Officer and Treasurer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.