EXELIXIS, INC.
Form 10-K
March 02, 2015
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended: January 2, 2015, 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: 0-30235
EXELIXIS, INC.
(Exact name of registrant as specified in its charter)

Delaware	04-3257395
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

210 East Grand Ave.
South San Francisco, CA 94080
(650) 837-7000
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)
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 per Share	The Nasdaq Stock Market LLC

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 ý No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ¨ No ý
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 ý 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 ý 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. ý
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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer ý 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 Act). Yes ¨ No ý

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter: $665,606,336 (Based on the closing sales price of the registrant's common stock on that date. Excludes an aggregate of 3,271,257 shares of the registrant's common stock held by persons who were directors and/or executive officers of the registrant at June 27, 2014 on the basis that such persons may be deemed to have been affiliates of the registrant at such date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.)

As of February 26, 2015, there were 195,895,769 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than May 4, 2015, in connection with the registrant's 2015 Annual Meeting of Stockholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

EXELIXIS, INC.
ANNUAL REPORT ON FORM 10-K
INDEX

Table of Contents

PART I

Some of the statements under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business” and elsewhere in this Annual Report on Form 10-K are forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company’s or our industry’s results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “focus,” “assume,” “goal,” “objective,” “will,” “may,” “would,” “could,” “estimate,” “predict,” “project,” “target,” “potential,” “continu the negative of such terms or other similar expressions identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in “Item 1A. Risk Factors” as well as those discussed elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Exelixis has adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2010, a 52-week year, ended on December 31, 2010, fiscal year 2011, a 52-week year, ended on December 30, 2011, fiscal year 2012, a 52-week year, ended on December 28, 2012, fiscal year 2013, a 52-week year, ended on December 27, 2013, fiscal year 2014, a 53-week year, ended on January 2, 2015 and fiscal year 2015, a 52-week year, will end on January 1, 2016. For convenience, references in this report as of and for the fiscal years ended December 31, 2010, December 30, 2011, December 28, 2012, December 27, 2013 and January 2, 2015, are indicated on a calendar year basis, ended December 31, 2010, 2011, 2012, 2013 and 2014, respectively.

ITEM 1. BUSINESS

Overview

Exelixis, Inc. (“Exelixis,” “we,” “our” or “us”) is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. We were incorporated in Delaware in November 1994 as Exelixis Pharmaceuticals, Inc. and we changed our name to Exelixis, Inc. in February 2000. Our two most advanced assets are cabozantinib, our wholly-owned inhibitor of multiple receptor tyrosine kinases, and cobimetinib (GDC-0973/XL518), a potent, highly selective inhibitor of MEK, a serine/threonine kinase, which we out-licensed to Genentech (a member of the Roche Group), or Genentech.

Our development and commercialization efforts are focused primarily on cabozantinib. We are evaluating cabozantinib in a broad development program comprising over forty-five clinical trials, across multiple indications, including two ongoing phase 3 pivotal trials focusing on metastatic renal cell carcinoma, or mRCC, and advanced hepatocellular carcinoma, or HCC.

Cabozantinib was approved by the United States Food and Drug Administration, or FDA, on November 29, 2012, for the treatment of progressive, metastatic medullary thyroid cancer, or MTC, in the United States under the brand name COMETRIQ(R). COMETRIQ became commercially available in the United States in January 2013. In March 2014, the European Commission granted cabozantinib conditional marketing authorization for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, also under the brand name COMETRIQ. However, as discussed below, we have terminated the clinical development of cabozantinib in metastatic castration-resistant prostate cancer, or mCRPC, as a result of the clinical trials of cabozantinib for this indication not meeting their primary endpoints.

Our second most advanced oncology asset, cobimetinib, is being evaluated by Genentech in a broad development program, including coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation. On September 29, 2014, positive results from this trial were reported at the European Society for Medical Oncology, or ESMO, 2014 Congress. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined progression-free survival, or PFS. Roche has completed the Marketing Authorization Application, or MAA, for cobimetinib in combination with vemurafenib in the European Union. In the

United States, Genentech submitted its New Drug Application, or NDA, in December 2014 and the FDA has granted the NDA priority review, with a projected action date of August 11, 2015.

Table of Contents

Our Strategy

We believe that the available clinical data demonstrate that cabozantinib has the potential to be a broadly active anti-cancer agent that can make a meaningful difference in the lives of patients. Our objective is to build cabozantinib into a significant oncology franchise. The initial regulatory approvals of COMETRIQ for MTC in the United States and European Union provide a niche market opportunity that allows us to gain commercialization experience while providing a solid foundation for potential expansion into larger cancer indications.

Our near-term internal development efforts for cabozantinib are focused on cancers for which we believe cabozantinib has the greatest significant therapeutic and commercial potential. We utilize our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or NCI-CTEP, and investigator sponsored trials, or ISTs, to generate additional data, allowing us to prioritize future late stage trials in a cost-effective fashion. We believe that this staged approach to building value represents the most rational and effective use of our resources.

Beyond our efforts regarding cabozantinib, under the terms of our various collaboration agreements, we are working with our corporate partners to realize the potential value of the compounds and programs we have out-licensed to them. The most notable of these is our cobimetinib collaboration with Genentech. In the aggregate, these partnered compounds could potentially be of significant value to us if their development programs progress successfully. For additional information regarding our work with our corporate partners, please see the section entitled Cobimetinib Collaboration and Other Collaborations.

COMETRIQ(R) (cabozantinib)

Cabozantinib inhibits the activity of multiple tyrosine kinases, including RET, MET, and VEGFR2. These receptor tyrosine kinases are involved in both normal cellular function and in pathologic processes such as oncogenesis, metastasis, tumor angiogenesis, and maintenance of the tumor microenvironment. On November 29, 2012, the FDA approved a capsule formulation of cabozantinib, COMETRIQ, for the treatment of progressive, metastatic MTC in the United States, and we launched COMETRIQ commercially in January 2013.

The recommended dose of COMETRIQ in progressive, metastatic MTC is 140 mg orally, once daily (one 80 mg capsule and three 20 mg capsules) administered without food. This dose may be withheld in response to certain adverse reactions, and upon resolution of adverse reactions may be reduced stepwise to 100 or 60 mg once daily to adjust the dose to each individual patient's tolerability. Permanent discontinuation is recommended for certain adverse reactions.

The COMETRIQ label has boxed warnings concerning risk of gastrointestinal perforations and fistulas, and severe hemorrhage. Other warnings and precautions include thrombotic events, wound complications, hypertension, osteonecrosis of the jaw, palmar-plantar erythrodysesthesia, proteinuria, reversible posterior leukoencephalopathy syndrome, caution regarding the potential for drug interactions with strong CYP3A4 inducers or inhibitors, the recommendation against use in patients with moderate or severe hepatic impairment, and the potential for embryo-fetal toxicity.

EXAM Pivotal Trial

COMETRIQ's safety and efficacy were assessed in an international, multi-center, randomized double-blinded controlled trial of 330 patients with progressive, metastatic MTC, known as EXAM (Efficacy of XL184 (Cabozantinib) in Advanced Medullary Thyroid Cancer). Patients were required to have evidence of actively progressive disease within 14 months prior to study entry. This assessment was performed by an Independent Radiology Review Committee, or IRRC, in 89% of patients and by the treating physicians in 11% of patients. Patients were randomized (2:1) to receive COMETRIQ 140 mg (n = 219) or placebo (n = 111) orally, once daily until disease progression determined by the treating physician or until intolerable toxicity. Randomization was stratified by age (≤ 65 years vs. > 65 years) and prior use of a tyrosine kinase inhibitor, or TKI. No cross-over was allowed at the time of progression. The primary endpoint was to compare progression-free survival, or PFS, in patients receiving COMETRIQ versus patients receiving placebo. Secondary endpoints included objective response rate and overall survival. The main efficacy outcome measures of PFS, objective response and response duration were based on IRRC-confirmed events using modified Response Evaluation Criteria in Solid Tumors (RECIST), which is a widely used set of rules that define when cancer patients improve ("respond"), stay the same ("stabilize") or worsen ("progress")

during treatments.

EXAM served as the basis for the regulatory approval of COMETRIQ in the U.S. and EU. A statistically significant prolongation in PFS was demonstrated among COMETRIQ-treated patients compared to those receiving placebo [HR 0.28 (95% CI: 0.19, 0.40); p<0.0001], with median PFS of 11.2 months in the COMETRIQ arm and 4.0 months in the placebo arm. Partial responses were observed only among patients in the COMETRIQ arm (27% vs. 0%; p<0.0001). The median duration of

Table of Contents

objective response was 14.7 months (95% CI: 11.1, 19.3) for patients treated with COMETRIQ. In November 2014, we announced completion of the overall survival analysis (OS), a secondary endpoint of the study. Consistent with an earlier interim analysis, there was no statistically significant difference in overall survival between the treatment arms. The median OS was 26.6 months for the COMETRQ arm and 21.1 months for the placebo arm (HR = 0.85; 95% CI 0.64, 1.12; p = 0.2409). The subgroup analysis by RET M918T mutation status, a known negative prognostic factor in MTC, revealed a large improvement in OS of 25.4 months for COMETRIQ-treated patients positive for the RET M918T mutation; the median OS was 44.3 months for the COMETRIQ arm and 18.9 months for the placebo arm (HR = 0.60; 95% CI 0.38, 0.95; p = 0.026, not adjusted for multiple subgroup testing). We will submit the final results for publication at an upcoming scientific forum and to regulatory authorities to satisfy post-marketing commitments.

Post-marketing Commitments

In connection with the approval of COMETRIQ for the treatment of progressive, metastatic MTC, we are subject to the following post-marketing requirements:

- A clinical study comparing a lower dose of COMETRIQ with the labeled dose of 140 mg. This study will evaluate safety and PFS in progressive, metastatic MTC patients.
- Submission of the overall survival analysis from the EXAM study (see above).
- Two clinical pharmacology studies assessing the pharmacokinetics of COMETRIQ, one to address the effect of administering COMETRIQ in conjunction with agents that increase gastric pH such as proton pump inhibitors, and the other study to assess the pharmacokinetics of COMETRIQ in patients with hepatic impairment. Both studies have been completed.
- Four non-clinical studies to further assess the carcinogenicity, mutagenicity and teratogenicity of COMETRIQ. The mutagenicity and teratogenicity studies have been completed.

Commercialization

COMETRIQ became commercially available in the United States in January 2013 and is being marketed in the United States principally through a small internal commercial team with relevant expertise in the promotion, distribution and reimbursement of oncology drugs. Effective January 6, 2015, the wholesale acquisition cost of COMETRIQ is $11,945 for a 28-day supply. COMETRIQ has been flat priced, meaning each dosage strength is priced the same. We currently estimate that there are between 500 and 700 first and second line metastatic MTC patients diagnosed in the United States each year who will be eligible for COMETRIQ.

We have scaled our commercial organization so that it is commensurate with the size of the market opportunity for progressive, metastatic MTC. We have also designed our commercial organization to maintain flexibility, and to enable us to quickly scale up if additional indications are approved in the future or scale down if we are not successful in gaining approval of additional indications. We believe we have created an efficient commercial organization, taking advantage of outsourcing options where prudent to maximize the effectiveness of our commercial expenditures.

To help ensure that all eligible progressive, metastatic MTC patients have appropriate access to COMETRIQ, we have established a comprehensive reimbursement and support program called Exelixis Access Services. Through Exelixis Access Services, we: provide co-pay assistance to qualified, commercially insured patients to help minimize out-of-pocket costs; provide free drug to uninsured patients who meet certain clinical and financial criteria; and make contributions to an independent co-pay assistance charity to help patients who do not qualify for our co-pay assistance program. In addition, Exelixis Access Services is designed to provide comprehensive reimbursement support services, such as prior authorization support, benefits investigation, and if needed, appeals support.

COMETRIQ is distributed in the United States exclusively through Diplomat Specialty Pharmacy, an independent specialty pharmacy that allows for efficient delivery of the medication by mail directly to patients.

To further support appropriate utilization of COMETRIQ, our Medical Affairs department is responsible for responding to physician inquiries with appropriate scientific and medical education and information.

EMA Marketing Authorization Application for COMETRIQ

In February 2009, COMETRIQ received orphan drug designation in the European Union from the Committee for Orphan Medicinal Products for the treatment of MTC. The European Commission granted COMETRIQ conditional approval for the treatment of adult patients with progressive, unresectable, locally advanced, or metastatic MTC in March 2014.

4

Table of Contents

During 2013, we entered into an agreement with a term ending on December 31, 2015, with Swedish Orphan Biovitrum, or Sobi, to support the distribution and commercialization of COMETRIQ for the approved MTC indication primarily in the European Union, Switzerland, Norway, Russia and Turkey, and potentially other countries in the event that COMETRIQ is approved for commercial sale in such jurisdictions. In January 2015, the parties amended and restructured their agreement, which was due to expire on December 31, 2015, extending its term to December 31, 2019. The agreement remains limited to the approved MTC indication in the indicated territories, and we continue to maintain commercial rights for all other potential cabozantinib oncology indications on a global basis. Under the amended terms, however, our payments to Sobi transition from fixed fees paid by Exelixis to Sobi to support initial build out of the COMETRIQ European infrastructure to a sales margin-based approach. We have the ability to terminate the agreement at will at any time upon payment of certain pre-determined fees.

Named Patient Use Program

Through our agreement and amended agreement with Sobi, we have established the infrastructure to make COMETRIQ available upon request under a named patient use, or NPU, program in countries of the European Union and in other regions outside of the United States where it is not yet commercially approved. An NPU program provides access to drugs unapproved in that country, but approved elsewhere, for a single patient or a group of patients in a particular country.

Cabozantinib Development Program

Despite the failure of cabozantinib to meet the primary endpoints in our clinical trials of cabozantinib for the treatment of patients with third line mCRPC, we believe that cabozantinib's broad clinical activity profile is attractive and will allow commercial differentiation from other available commercial products, assuming regulatory approval. The cabozantinib clinical development program consists of a wide range of trials. We are the sponsor of some of those trials, including two pivotal studies, and the remainder are being conducted through our CRADA with NCI-CTEP and our IST program. The most advanced clinical programs for cabozantinib beyond progressive, metastatic MTC are focused on the treatment of mRCC and advanced HCC. We expect to expand the cabozantinib development program to other tumor indications based on encouraging interim data that have emerged from our randomized discontinuation trial, or RDT, as well as other clinical trials. Objective tumor responses have been observed in patients treated with cabozantinib in 15 individual tumor types investigated in phase 1 and 2 clinical trials to date, reflecting the broad potential clinical activity and commercial opportunity of this product candidate. In addition, we have observed resolution of metastatic bone lesions on bone scan in patients with mCRPC, metastatic breast cancer or melanoma in the RDT, in patients with RCC and patients with differentiated thyroid cancer in a phase 1 clinical trial, and in patients with bladder cancer in an NCI-CTEP-sponsored phase 2 clinical trial.

To support the future development of cabozantinib, our Medical Affairs department is responsible for responding to unsolicited physician inquiries with appropriate scientific and medical education and information, preparing scientific presentations and publications, and overseeing the process for ISTs. It is a priority for us to continue to evaluate cabozantinib across a broad range of tumor types, including non-small cell lung cancer, or NSCLC, ovarian cancer, melanoma, breast cancer, differentiated thyroid cancer and others, to support further prioritization of our clinical and commercial options. In addition, post-marketing requirements in connection with the approval of COMETRIQ in progressive, metastatic MTC dictate that we conduct additional studies related to dosing in progressive, metastatic MTC, pharmacokinetics, carcinogenicity, mutagenicity and teratogenicity of COMETRIQ as more fully described above under "--Post-marketing Commitments."

mRCC

METEOR (Metastatic RCC Phase 3 Study Evaluating Cabozantinib vs. Everolimus), a phase 3 pivotal trial comparing cabozantinib to everolimus in patients with mRCC who have experienced disease progression following treatment with at least one prior VEGFR TKI, was initiated in May 2013. The trial is designed to enroll 650 patients at approximately 200 sites. Patients are being stratified based on the number of prior VEGFR-TKI therapies received and commonly applied RCC risk criteria. Patients are being randomized 1:1 to receive 60 mg of cabozantinib daily or 10 mg of everolimus daily and no cross-over will be allowed between the study arms. The primary endpoint for METEOR is PFS, and the secondary endpoints are overall survival and objective response rate. The target enrollment of 650 patients was achieved in November 2014. We expect top-line safety and efficacy data from METEOR in the

second quarter of 2015.

HCC

CELESTIAL (Cabozantinib Phase 3 Controlled Study In Hepatocellular Carcinoma), a phase 3 pivotal trial comparing cabozantinib to placebo in patients with advanced HCC who have previously been treated with sorafenib was initiated in September 2013. The trial is designed to enroll 760 patients at approximately 200 sites. Patients are being randomized 2:1 to receive 60 mg of cabozantinib daily or placebo. The primary endpoint for CELESTIAL is overall survival, and the secondary endpoints include objective response rate and PFS. We expect top-line results from CELESTIAL in 2017.

Table of Contents

NSCLC

In November 2014, we announced positive top-line results from a randomized phase 2 trial of cabozantinib and erlotinib alone or in combination as second- or third-line therapy in patients with stage IV EGFR wild-type NSCLC. This trial (Study E1512) is sponsored through our CRADA with NCI-CTEP. Study E1512 was designed and is being conducted by the ECOG-ACRIN Cancer Research Group.

In the E1512 trial, 125 patients were randomized to one of the three arms: erlotinib, cabozantinib, or the combination. During a pre-planned interim ECOG-ACRIN Data Safety Monitoring Committee analysis for futility, it was determined that the trial met its primary endpoint of improving progression-free survival (PFS) with cabozantinib alone and also with the combination of cabozantinib plus erlotinib, as compared to erlotinib alone, and the results were highly statistically significant. Safety data were consistent with those observed in other trials of cabozantinib. At the time of analysis, the median follow-up was 5.9 months and overall survival data were immature. The results of the trial are the subject of ongoing analyses and will be submitted by the investigators for presentation at a future medical conference.

mCRPC

Beginning in 2011, we implemented a focused clinical strategy to investigate cabozantinib in a comprehensive development program for mCRPC. Two phase 3 pivotal trials, COMET-1 (Cabozantinib MET Inhibition CRPC Efficacy Trial-1) and COMET-2, were designed to explore cabozantinib as an oncology agent with a potentially beneficial impact on overall survival, pain, and narcotic usage. We initiated the COMET-1 trial with an overall survival endpoint in May 2012, and we initiated the COMET-2 trial with a pain palliation endpoint in December 2011.

On September 1, 2014, we announced top-line results from the final analysis of COMET-1, our trial of cabozantinib in men with mCRPC whose disease progressed after treatment with docetaxel as well as abiraterone and/or enzalutamide. The trial did not meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone. On December 1, 2014, we announced top-line results from the final analysis of COMET-2, our trial of cabozantinib in men with mCRPC who were suffering from moderate to severe pain despite optimized narcotic medication, and whose disease had progressed following treatment with docetaxel as well as abiraterone and/or enzalutamide. The trial did not meet its primary endpoint of alleviation of bone pain, as determined by comparing the percentage of patients in the two treatment arms who achieved a pain response at Week 6 that was confirmed at Week 12 without increase in narcotic medication. The safety profile of cabozantinib in the trial was consistent with that observed in previous studies in mCRPC.

Based on the outcomes of the COMET trials, we have terminated the clinical development of cabozantinib in mCRPC. Other studies in CRPC sponsored by us, including a randomized phase 2 study of cabozantinib in combination with abiraterone, have been halted.

Other Cancer Indications

We are evaluating the potential initiation of pivotal trials with cabozantinib in other tumor types, based on our belief that these increase the value of the cabozantinib franchise, accelerate potential revenues, and spread the development and commercialization risk for cabozantinib across multiple opportunities. We have launched two initiatives to expand the cabozantinib development program beyond our internal development efforts: our CRADA with NCI-CTEP and our IST program.

We entered into our CRADA with NCI-CTEP in November 2011. The proposed clinical trials approved to date under the CRADA include the following:

- Phase 2 or phase 1/2 clinical trials to help prioritize future pivotal trials of cabozantinib in disease settings where there is substantial unmet medical need and in which cabozantinib has previously demonstrated clinical activity, consisting of randomized phase 2 clinical trials in first line renal cell carcinoma, second or later line platinum pretreated persistent or recurrent ovarian cancer, ocular melanoma, prostate cancer and second line/third line EGFR-wt NSCLC.
- Additional phase 2 or phase 1/2 clinical trials to explore cabozantinib's potential utility in other tumor types, including endometrial cancer, bladder cancer, sarcomas, NSCLC (EGFR-activating mutation positive). differentiated thyroid cancer, triple-negative breast cancer, hormone-receptor-positive breast cancer, cutaneous melanoma (molecularly

selected patients), colorectal cancer and pancreatic neuroendocrine tumors/carcinoid. Positive results in these indications could lead to further study in randomized phase 2 or phase 3 clinical trials.

- Additional phase 1 clinical trials to further evaluate cabozantinib, consisting of a combination trial of cabozantinib and immunotherapy (nivolumab with or without ipilumumab) in genitourinary tumors, a trial to

Table of Contents

evaluate the safety and pharmacokinetics of cabozantinib in pediatric patients, and a trial of cabozantinib in patients with advanced solid tumors and human immunodeficiency virus.

Commencement of each of the proposed trials approved under the CRADA is subject to protocol development and satisfaction of certain other conditions. The proposed trials approved under the CRADA will be conducted under an investigational new drug application held by NCI-CTEP. We believe our CRADA reflects a major commitment by NCI-CTEP to support the broad exploration of cabozantinib's potential in a wide variety of cancers, each representing a substantial unmet medical need. NCI-CTEP provides funding for as many as 20 active clinical trials each year for a five-year period. We believe the agreement will enable us to broadly expand the cabozantinib development program in a cost-efficient manner.

Cabozantinib is being evaluated in a variety of ISTs under a program initiated in October 2010. Patients have enrolled in 24 trials 16 of which are currently accruing patients. An additional three studies are expected to initiate accrual soon.

XL888

XL888 is an Exelixis-discovered highly potent small molecule oral inhibitor of Heat Shock Protein 90 (HSP90), a molecular chaperone protein that affects the activity and stability of a range of key regulatory proteins, including kinases such as BRAF, MET and VEGFR2, which are implicated in cancer cell proliferation and survival. After completing phase 1 testing of the compound, we deprioritized XL888 and our other pipeline assets to focus our limited resources on our lead compound, cabozantinib. Investigators at the H. Lee Moffitt Cancer Center went on to conduct additional preclinical work showing activity of XL888 in vemurafenib-resistant melanoma models, the results of which provided the rationale for the initiation of an investigator-sponsored phase 1 trial conducted by investigators at the Moffitt Cancer Center.

In November 2014, we announced positive preliminary results from this phase 1 trial, which evaluated the safety and activity of XL888 in combination with vemurafenib in patients with unresectable stage III/IV BRAF V600 mutation-positive melanoma. The primary endpoint of the trial was to determine the safety and tolerability of the combination, including determination of a maximum tolerated dose, or MTD, or XL888. Secondary endpoints included objective response rate (RECIST-1 criteria), estimates of PFS and overall survival, and analysis of pharmacodynamic biomarkers. The trial had enrolled fifteen subjects, and at the time of data cut-off, objective tumor regression was observed in 11 of 12 response-evaluable patients (two complete responses and nine partial responses), for an objective response rate of 92%. Safety data for the combination identified tolerable dose levels of XL888 with full dose vemurafenib.

Based on these results, as well as findings from coBRIM, the phase 3 pivotal trial of cobimetinib, an Exelixis-discovered MEK inhibitor, and vemurafenib in previously untreated metastatic melanoma patients with a BRAF V600 mutation, investigators at the Moffitt Cancer Center plan to initiate a phase 1b IST of the triple combination of vemurafenib, cobimetinib and XL888 in a similar patient population.

Cobimetinib Collaboration

In December 2006, we entered into a worldwide co-development agreement with Genentech for the development and commercialization of cobimetinib. Cobimetinib is a potent, highly selective inhibitor of MEK, a serine/threonine kinase that is a component of the RAS/RAF/MEK/ERK pathway. This pathway mediates signaling downstream of growth factor receptors, and is prominently activated in a wide variety of human tumors. In preclinical studies, oral dosing of cobimetinib resulted in potent and sustained inhibition of MEK in RAS- or BRAF-mutant tumor models. Exelixis discovered cobimetinib internally and advanced the compound to investigational new drug, or IND, status. Genentech paid upfront and milestone payments of $25.0 million in December 2006 and $15.0 million in January 2007 upon signing of the co-development agreement and with the submission of the IND for cobimetinib. Under the terms of the agreement, we were responsible for developing cobimetinib through the determination of the MTD in a phase 1 clinical trial, and Genentech had the option to co-develop cobimetinib, which Genentech could exercise after receipt of certain phase 1 data from us. In March 2008, Genentech exercised its option, triggering a payment to us of $3.0 million, which we received in April 2008. After MTD was determined, we granted to Genentech an exclusive worldwide revenue-bearing license to cobimetinib in March 2009, at which point Genentech became responsible for completing the phase 1 clinical trial and subsequent clinical development. We received an additional $7.0 million

payment in March 2010.

In July 2014, we announced positive top-line results from coBRIM, the phase 3 pivotal trial conducted by Genentech evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation. Data were subsequently presented at ESMO in September 2014. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined PFS. The median PFS was 9.9 months for the combination of cobimetinib and vemurafenib versus 6.2 months for vemurafenib alone (hazard ratio [HR]=0.51, 95 percent CI 0.39-0.68; p<0.0001), demonstrating the combination reduced the risk of the disease worsening

Table of Contents

by half (49 percent). The median PFS as established by an independent review committee, or IRC, a secondary endpoint, was 11.3 months for the combination arm compared to 6.0 months for the control arm (HR=0.60, 95 percent CI 0.45-0.79; p=0.0003). Objective response rate, or ORR, another secondary endpoint, was 68% for the combination versus 45% for vemurafenib alone (p<0.0001). Overall survival data were not yet mature (HR=0.65, 95 percent CI 0.42-1.00; p=0.046), and at the interim analysis the p-value did not cross the pre-specified boundary for significance. The safety profile of the combination was consistent with that observed in a previous study.

On the basis of data from the coBRIM trial, Roche submitted a Marketing Authorization Application for cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation to the European Medicines Agency in September 2014. On December 15, 2014, Genentech completed the submission of its New Drug Application (NDA) with the FDA for cobimetinib. FDA has granted priority review to the NDA, with a PDUFA date of August 11, 2015. Priority Review is granted to a pharmaceutical product that, if approved, would meet an unmet medical need for a serious and life-threatening condition. Cobimetinib previously received Fast Track designation from the FDA for this indication.

In addition, the following clinical trials of cobimetinib in combination with other agents are ongoing, as disclosed on clinicaltrials.gov:

- A Study of MEHD7945A and Cobimetinib (GDC-0973) in Patients With Locally Advanced or Metastatic Cancers With Mutant KRAS (NCT01986166);
- A Phase 1b Study of MPDL3280A (an Engineered Anti-PDL1 Antibody) in Combination With Cobimetinib in Patients With Locally Advanced or Metastatic Solid Tumors (NCT01988896);
- Trial of Vemurafenib/Cobimetinib With or Without Bevacizumab in Patients With Stage IV BRAF V600 Mutant Melanoma (NCT01495988)
- A Phase 1b Study of MPDL3280A (an Engineered Anti-PDL1 Antibody) in Combination With Vemurafenib (Zelboraf®) or Vemurafenib Plus Cobimetinib in Patients With Previously Untreated BRAF V600-Mutation Positive Metastatic Melanoma (NCT01656642)
- A Study of Cobimetinib in Combination With Paclitaxel as First-line Treatment for Patients With Metastatic Triple-negative Breast Cancer (NCT02322814)
- A Study of Neo-adjuvant Use of Vemurafenib Plus Cobimetinib for BRAF Mutant Melanoma With Palpable Lymph Node Metastases (NCT02036086)
- A Phase II Study of Cobimetinib in Combination with Vemurafenib in Active Melanoma Brain Metastases (CoBRIM-B) (NCT02230306)
- Neoadjuvant Vemurafenib + Cobimetinib in Melanoma: NEO-VC (NCT02303951)

Under the terms of our co-development agreement with Genentech for cobimetinib, we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our share decreasing as sales increase, and we will share equally in the U.S. marketing and commercialization costs. The profit share has multiple tiers: we are entitled to 50% of profits from the first $200 million of U.S. actual sales, decreasing to 30% of profits from U.S. actual sales in excess of $400 million. We are entitled to low double-digit royalties on ex-U.S. net sales. In November 2013, we exercised an option under the co-development agreement to co-promote in the United States. As a result of exercising our option to co-promote, we may provide up to 25% of the total sales force for cobimetinib in the United States if commercialized, and will call on customers and otherwise engage in promotional activities using that sales force, consistent with the terms of the co-development agreement and a co-promotion agreement to be entered into by the parties.

Other Collaborations

We have established collaborations with other leading pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for various compounds and programs in our portfolio. Pursuant to these collaborations, we have fully out-licensed compounds or programs to a partner for further development and commercialization. We have no further development cost obligations under our collaborations and may be entitled to receive milestones and royalties, or in the case of cobimetinib, a share of profits (or losses) from commercialization.

With respect to our partnered compounds, other than cobimetinib, we are eligible to receive potential contingent payments totaling approximately $2.3 billion in the aggregate on a non-risk adjusted basis, of which 10% are related to clinical development milestones, 42% are related to regulatory milestones and 48% are related to commercial milestones, all to be achieved by the various licensees, which may not be paid, if at all, until certain conditions are met.

Table of Contents

Bristol-Myers Squibb

ROR Collaboration Agreement

In October 2010, we entered into a worldwide collaboration with Bristol-Myers Squibb pursuant to which each party granted to the other certain intellectual property licenses to enable the parties to discover, optimize and characterize ROR antagonists that may subsequently be developed and commercialized by Bristol-Myers Squibb. In November 2010, we received a nonrefundable upfront cash payment of $5.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the collaboration, we will be eligible to receive payments upon the achievement by Bristol-Myers Squibb of development and regulatory milestones of up to $252.5 million in the aggregate and commercialization milestones of up to $150.0 million in the aggregate, as well as royalties on commercial sales of any such products. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to a wholly-owned subsidiary.

Under the terms of the collaboration agreement, we were responsible for activities related to the discovery, optimization and characterization of the ROR antagonists during the collaborative research period. In July 2011, we earned a $2.5 million milestone payment for achieving certain lead optimization criteria. The collaborative research period began on October 8, 2010 and ended on July 8, 2013. Since the end of the collaborative research period, Bristol-Myers Squibb has and will continue to have sole responsibility for any further research, development, manufacture and commercialization of products developed under the collaboration and will bear all costs and expenses associated with those activities.

Bristol-Myers Squibb may, at any time, terminate the collaboration agreement upon certain prior notice to us on a product-by-product and country-by-country basis. In addition, either party may terminate the agreement for the other party's uncured material breach. In the event of termination by Bristol-Myers Squibb at will or by us for Bristol-Myers Squibb's uncured material breach, the license granted to Bristol-Myers Squibb would terminate, the right to such product would revert to us and we would receive a royalty-bearing license for late-stage reverted compounds and a royalty-free license for early-stage reverted compounds from Bristol-Myers Squibb to develop and commercialize such product in the related country. In the event of termination by Bristol-Myers Squibb for our uncured material breach, Bristol-Myers Squibb would retain the right to such product, subject to continued payment of milestones and royalties.

LXR Collaboration

In December 2005, we entered into a collaboration agreement with Bristol-Myers Squibb for the discovery, development and commercialization of novel therapies targeted against LXR, a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic disorders. This agreement became effective in January 2006, at which time we granted Bristol-Myers Squibb an exclusive worldwide license with respect to certain intellectual property primarily relating to compounds that modulate LXR, including BMS-852927 (XL041). During the research term, we jointly identified drug candidates with Bristol-Myers Squibb that were ready for IND-enabling studies. After the selection of a drug candidate for further clinical development by Bristol-Myers Squibb, Bristol-Myers Squibb agreed to be solely responsible for further preclinical development as well as clinical development, regulatory, manufacturing and sales/marketing activities for the selected drug candidate. We do not have rights to reacquire the drug candidates selected by Bristol-Myers Squibb. The research term expired in January 2010 and we transferred the technology to Bristol-Myers Squibb in 2011 to enable it to continue the LXR program. BMS has terminated development of XL041 and we have been advised that BMS is continuing additional preclinical research on the program. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to a wholly-owned subsidiary.

Under the collaboration agreement, Bristol-Myers Squibb paid us a nonrefundable upfront cash payment in the amount of $17.5 million and was obligated to provide research and development funding of $10.0 million per year for an initial research period of two years. In September 2007, the collaboration was extended at Bristol-Myers Squibb's request through January 12, 2009, and in November 2008, the collaboration was further extended at Bristol-Myers Squibb's request through January 12, 2010. Under the collaboration agreement, Bristol-Myers Squibb is required to pay us contingent amounts associated with development and regulatory milestones of up to $138.0 million per product for up to two products from the collaboration. In addition, we are also entitled to receive payments associated with

sales milestones of up to $225.0 million and royalties on sales of any products commercialized under the collaboration. In connection with the extension of the collaboration through January 2009 and subsequently through January 2010, Bristol-Myers Squibb paid us additional research funding of approximately $7.7 million and approximately $5.8 million, respectively. In December 2007, we received $5.0 million in connection with the achievement by Bristol-Myers Squibb of a development milestone with respect to BMS-852927 (XL041).

Sanofi

In May 2009, we entered into a global license agreement with Sanofi for SAR245408 (XL147) and SAR245409 (XL765), leading inhibitors of phosphoinositide-3 kinase, or PI3K, and a broad collaboration for the discovery of inhibitors of

Table of Contents

PI3K for the treatment of cancer. The license agreement and collaboration agreement became effective on July 7, 2009. In connection with the effectiveness of the license and collaboration, on July 20, 2009, we received upfront payments of $140.0 million ($120.0 million for the license and $20.0 million for the collaboration), less applicable withholding taxes of $7.0 million, for a net receipt of $133.0 million. We received a refund payment in December 2011 with respect to the withholding taxes previously withheld.

Under the license agreement, Sanofi received a worldwide exclusive license to SAR245408 (XL147) and SAR245409 (XL765), which are in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility, including funding, for all subsequent clinical, regulatory, commercial and manufacturing activities. As disclosed on ClinicalTrials.gov, SAR245408 (XL147) is currently being studied in a clinical trial evaluating pharmacokinetics of a tablet formulation in patients with solid tumors or lymphoma (NCT01943838). As disclosed on ClinicalTrials.gov, SAR245409 (XL765) is currently being studied in clinical trials in patients with lymphoma either as a single agent (NCT01403636) or in combination with bendamustine and/or rituximab (NCT01410513). In addition SAR245409 (XL765) is being studied in combination with a MEK inhibitor in patients with locally advanced or metastatic solid tumors (NCT01390818).

We will be eligible to receive contingent payments associated with development, regulatory and commercial milestones under the license agreement of $745.0 million in the aggregate, as well as royalties on sales of any products commercialized under the license.

Sanofi may, upon certain prior notice to us, terminate the license as to products containing SAR245408 (XL147) and SAR245409 (XL765). In the event of such termination election, Sanofi's license relating to such product would terminate and revert to us, and we would receive, subject to certain terms, conditions and potential payment obligations, licenses from Sanofi to research, develop and commercialize such products.

In December 2011, we entered into an agreement with Sanofi pursuant to which the parties terminated the discovery collaboration agreement and released each other from any potential liabilities arising under the collaboration agreement prior to effectiveness of the termination in December 2011. Each party retains ownership of the intellectual property that it generated under the collaboration agreement, and we granted Sanofi covenants not-to-enforce with respect to certain of our intellectual property rights. The termination agreement also provided that Sanofi would make a payment to us of $15.3 million, which we received in January 2012. If either party or its affiliate or licensee develops and commercializes a therapeutic product containing an isoform-selective PI3K inhibitor that arose from such party's work (or was derived from such work) under the collaboration agreement, then such party will be obligated to pay royalties to the other party based upon the net sales of such products. The termination agreement provides that Sanofi will make a one-time payment to us upon the first receipt by Sanofi or its affiliate or licensee of marketing approval for the first therapeutic product containing an isoform-selective PI3K inhibitor that arose from Sanofi's work (or was derived from such work) under the collaboration agreement.

Merck

In December 2011, we entered into an agreement with Merck pursuant to which we granted Merck an exclusive worldwide license to our PI3K-delta, or PI3K-d, program, including XL499 and other related compounds. Pursuant to the terms of the agreement, Merck has sole responsibility to research, develop, and commercialize compounds from our PI3K-d program. The agreement became effective in December 2011.

Merck paid us an upfront cash payment of $12.0 million in January 2012 in connection with the agreement. We will be eligible to receive payments associated with the successful achievement of potential development and regulatory milestones for multiple indications of up to $239.0 million. We will also be eligible to receive payments for combined sales performance milestones of up to $375.0 million and royalties on net-sales of products emerging from the agreement. Contingent payments associated with milestones achieved by Merck and royalties are payable on compounds emerging from our PI3K-d program or from certain compounds that arise from Merck's internal discovery efforts targeting PI3K-d during a certain period.

Merck may at any time, upon specified prior notice to us, terminate the license. In addition, either party may terminate the agreement for the other party's uncured material breach. In the event of termination by Merck at will or by us for Merck's uncured material breach, the license granted to Merck would terminate. In the event of a termination by us for Merck's uncured material breach, we would receive a royalty-free license from Merck to develop and commercialize certain joint products. In the event of termination by Merck for our uncured material breach, Merck would retain the

licenses from us, and we would receive reduced royalties from Merck on commercial sales of products.

Daiichi Sankyo

In March 2006, we entered into a collaboration agreement with Daiichi Sankyo for the discovery, development and commercialization of novel therapies targeted against the mineralocorticoid receptor, or MR, a nuclear hormone receptor

Table of Contents

implicated in a variety of cardiovascular and metabolic diseases. Under the terms of the agreement, we granted to Daiichi Sankyo an exclusive, worldwide license to certain intellectual property primarily relating to compounds that modulate MR, including CS-3150 (XL550). Daiichi Sankyo is responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds and we do not have rights to reacquire such compounds, except as described below.

Daiichi Sankyo paid us a nonrefundable upfront payment in the amount of $20.0 million and was obligated to provide research and development funding of $3.8 million over a 15-month research term. In June 2007, our collaboration agreement with Daiichi Sankyo was amended to extend the research term by six months over which Daiichi Sankyo was required to provide $1.5 million in research and development funding. In November 2007, the parties decided not to further extend the research term. For each product from the collaboration, we are also entitled to receive payments upon attainment of pre-specified development, regulatory and commercialization milestones. In December 2010, we received a milestone payment of $5.0 million in connection with an IND filing made by Daiichi Sankyo for CS-3150 (XL550) and, in August 2012, we received a milestone payment of $5.5 million in connection with the initiation of a phase 2 clinical trial for CS-3150 (XL550). Daiichi-Sankyo has recently initiated two large phase 2b trials of CS-3150 (XL550) in Japanese patients with hypertension and diabetic nephropathy, respectively. We are eligible to receive additional development, regulatory and commercialization milestone payments of up to $145.0 million. In addition, we are also entitled to receive royalties on any sales of certain products commercialized under the collaboration. Daiichi Sankyo may terminate the agreement upon 90 days' written notice in which case Daiichi Sankyo's payment obligations would cease, its license relating to compounds that modulate MR would terminate and revert to us and we would receive, subject to certain terms and conditions, licenses from Daiichi Sankyo to research, develop and commercialize compounds, that were discovered under the collaboration.

GlaxoSmithKline

In October 2002, we established a collaboration with GlaxoSmithKline to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. The collaboration involved three agreements: (1) a product development and commercialization agreement, (2) a stock purchase and stock issuance agreement, and (3) a loan and security agreement. During the term of the collaboration, we received $65.0 million in upfront and milestone payments, $85.0 million in research and development funding and loans in the principal amount of $85.0 million which have been repaid in full. In connection with the collaboration, GlaxoSmithKline purchased a total of three million shares of our common stock.

In October 2008, the development term under the collaboration concluded as scheduled. Under the terms of the collaboration, GlaxoSmithKline selected foretinib (XL880), an inhibitor of MET and VEGFR2, and had the right to choose one additional compound from a pool of compounds, which consisted of cabozantinib, XL281, XL228, XL820 and XL844 as of the end of the development term.

In July 2008, we achieved proof-of-concept for cabozantinib and submitted the corresponding data report to GlaxoSmithKline. In October 2008, GlaxoSmithKline notified us in writing that it decided not to select cabozantinib for further development and commercialization and that it waived its right to select XL281, XL228, XL820 and XL844 for further development and commercialization. As a result, we retained the rights to develop, commercialize, and/or license all of the compounds, subject to payment to GlaxoSmithKline of a 3% royalty on net sales of any product incorporating cabozantinib. We have discontinued development of XL820, XL228 and XL844.

In April 2014, we received a notice from GlaxoSmithKline of its intent to terminate the development of foretinib and to return it to us pursuant to the terms and conditions of the product development and commercialization agreement between the parties. The transition of the program was completed on December 23, 2014. In connection with the return of foretinib, the product development and commercialization agreement has terminated, although GlaxoSmithKline will continue to be entitled to a 3% royalty on net sales of any product incorporating cabozantinib, including COMETRIQ, and a 4% royalty on net sales of any product incorporating foretinib.

Manufacturing and Distribution

We contract with third parties to manufacture the raw materials, the active pharmaceutical ingredient, or API, and finished drug product for use in clinical studies. We also partner with third parties to manufacture, package and label COMETRIQ for commercial uses. We currently do not operate manufacturing facilities for clinical or commercial

production of COMETRIQ. We expect for the foreseeable future to continue to rely on third parties for the manufacture of the raw materials, API and finished drug product that are used in clinical studies and for commercial supplies of COMETRIQ. In this manner, we continue to build, oversee and maintain our supply chain.

Our multi-step supply chain for the manufacture and distribution of clinical and commercial supplies consists of several suppliers located in multiple countries. Raw materials are generally sourced from multiple third-party suppliers.

Table of Contents

Contract manufacturers in Europe and North America convert these raw materials into API for clinical and commercial purposes, respectively. We use multiple third parties to manufacture drug product for clinical purposes. We use a different third party to manufacture drug product, to package, and to label the finished product for commercial purposes. We use a single third party logistics provider to handle shipping and warehousing of our commercial supply of COMETRIQ in the United States and a single specialty pharmacy to dispense COMETRIQ to patients in fulfillment of prescriptions. We also rely on a third party, Sobi, to distribute and commercialize COMETRIQ for the treatment of metastatic MTC in the European Union where COMETRIQ is approved for commercial sale in such jurisdictions. In addition, Sobi is currently supporting access to COMETRIQ under an NPU program in the European Union and other regions outside of the United States.

For information regarding the risks we face in our manufacturing and distribution pipeline, including but not limited to those associated with our reliance on third parties, see Item 1A - Risk Factors - “If we are unable to maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to commercialize cabozantinib successfully”; “We lack the manufacturing capabilities and experience necessary to enable us to produce cabozantinib for clinical development or for commercial sale and rely on third parties to do so, which subjects us to various risks”; and “If third parties upon which we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib for the treatment of additional indications beyond the approved MTC indication.”

Government Regulation

For a discussion of the risks related to our compliance with government regulations, please see Item 1A - Risk Factors - “We are subject to certain healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition” and “Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell cabozantinib profitably.”

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products.

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

- preclinical laboratory and animal tests that must be conducted in accordance with Good Laboratory Practices;
- submission of an IND, which must become effective before clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug candidate for its intended use;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with Good Manufacturing Practices, or GMP, and Good Clinical Practices, or GCP; and
- FDA approval of a New Drug Application, or NDA, for commercial marketing, or of an NDA supplement, for approval of a new indication if the product is already approved for another indication.

The testing and approval process requires substantial time, effort and financial resources. Prior to commencing the first clinical trial with a product candidate, we must submit an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development. Further, an independent institutional review board for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial and provide its informed consent form before the trial commences at that center. Regulatory authorities or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1 – Studies are initially conducted in a limited patient population to test the product candidate for safety, dosage tolerance, absorption, metabolism, distribution and excretion in healthy humans or patients.
- Phase 2 – Studies are conducted with groups of patients afflicted with a specified disease in order to provide enough data to evaluate the preliminary efficacy, optimal dosages and expanded evidence of safety. Multiple

Table of Contents

phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive phase 3 clinical trials. In some cases, a sponsor may decide to run what is referred to as a "phase 2b" evaluation, which is a second, confirmatory phase 2 trial that could, if positive, serve as a pivotal trial in the approval of a product candidate.

- Phase 3 – When phase 2 evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, phase 3 trials are undertaken in large patient populations to further evaluate dosage, to provide replicate statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called phase 4 studies may be made a condition to be satisfied after a drug receives approval. Failure to satisfy such post-marketing commitments can result in FDA enforcement action, up and to including withdrawal of NDA approval. The results of phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA's adverse drug reaction reporting system. The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA, or as part of an NDA supplement. The submission of an NDA or NDA supplement requires payment of a substantial user fee to FDA. The FDA may convene an advisory committee to provide clinical insight on NDA review questions. The FDA may deny approval of an NDA or NDA supplement by way of a Complete Response letter if the applicable regulatory criteria are not satisfied, or it may require additional clinical data and/or an additional pivotal phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA or NDA supplement does not satisfy the criteria for approval. An NDA may be approved with significant restrictions on its labeling, marketing and distribution under a Risk Evaluation and Mitigation Strategy. Once issued, the FDA may withdraw product approval if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. 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.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Government regulation may delay or prevent marketing of product candidates or new diseases for a considerable period of time and impose costly procedures upon our activities. The FDA or any other regulatory agency may not grant approvals for new indications for our product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Targets and pathways identified in vitro may be determined to be less relevant in clinical studies and results in animal model studies may not be predictive of human clinical results. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages. Further, even after regulatory approval is obtained, 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.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may, in their independent medical judgment, prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does,

however, restrict manufacturers' communications on the subject of off-label use. Additionally, a significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for off-label uses and other sales practices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, false claims laws, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement.

The United States Orphan Drug Act promotes the development of products that demonstrate promise for the diagnosis and treatment of diseases or conditions that affect fewer than 200,000 people in the United States. Upon FDA receipt of Orphan

Table of Contents

Drug Designation, the sponsor is eligible for tax credits of up to 50% for qualified clinical trial expenses, the ability to apply for annual grant funding, waiver of Prescription Drug User Fee Act application fee, and upon approval, the potential for seven years of market exclusivity for the orphan-designated product for the orphan-designated indication.

Regulation Outside of the United States

In addition to regulations in the United States, we are subject to regulations of other countries governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure 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, we may apply for designation of a product as an Orphan Drug for the treatment of a specific indication in the European Union before the application for marketing authorization is made. Orphan Drugs in Europe 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.

Healthcare Regulation

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, also apply to our business. If we fail to comply with those laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws that may affect our ability to operate include, but are not limited to: the federal Anti Kickback Statute, which prohibits. among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; and federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payers that are false or fraudulent. Additionally, we are subject to state law equivalents of each of the above federal laws, which may be broader in scope and apply regardless of payer, and many of which differ from each other in significant ways and may not have the same effect, further complicate compliance efforts.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who are expected to prescribe our products and from whom we obtain patient health information, are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology and Clinical Health Act, or HIPPA. Although we are not directly subject to HIPPA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity, including healthcare providers, in a manner that is not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states

requiring security breach notification. These laws could create liability for us or increase our cost of doing business. International laws, such as the EU Data Privacy Directive (95/46/EC) and Swiss Federal Act on Data Protection, regulate the processing of personal data within Europe and between European countries and the United States. Failure to provide adequate privacy protections and maintain compliance with safe harbor mechanisms could jeopardize business transactions across borders and result in significant penalties.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or the PPACA, created a federal requirement under the federal Open Payments program, that requires certain manufacturers to track and report to the Centers for Medicare and Medicaid Services, or CMS, annually certain payments and other transfers of value provided to physicians and teaching hospitals made in the previous calendar year. In addition, there are

Table of Contents

also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

Reimbursement

Sales of COMETRIQ and any future products of ours will depend, in part, on the extent to which their costs will be covered by third-party payers, such as government health programs, commercial insurance and managed healthcare organizations. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Third-party payers may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a third-party payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Additionally, one third-party payer's decision to cover a particular drug product does not ensure that other payers will also provide coverage for the drug product, or will provide coverage at an adequate reimbursement rate.

These third-party payers 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, when available. 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 product revenue and results.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new 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 plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. 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. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our 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 payers 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 payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the PPACA, enacted in March 2010, has had a significant impact on the health care industry. The PPACA is intended to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the PPACA is expected to, among other things, 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 full impact of the PPACA on our operations, as many of PPACA's reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet occurred or have not been addressed fully. In June 2012, the U.S. Supreme Court upheld the constitutionality of the PPACA, except that the Court held unconstitutional the provision of PPACA authorizing the Secretary of the U.S. Department of Health and Human Services to withdraw all of a state's Medicaid funding if the state declines to participate in the PPACA's expansion of Medicaid eligibility. Yet, some states have indicated that

they intend to not implement certain sections of the PPACA, and some members of the U.S. Congress are still working to repeal the PPACA. As a result, the PPACA and/or certain of its provisions may be modified or eliminated by future legislation or litigation.

On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On

Table of Contents

January 2, 2013, the American Tax Payer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several providers.

In addition, in some non-U.S. jurisdictions, 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 the price structures of the United States and generally tend to be priced significantly lower.

For a discussion of risks we face related to the reimbursement process, please see Item 1A - Risk Factors - “If we are unable to obtain adequate coverage and reimbursement from third party payers for cabozantinib, our revenues and prospects for profitability will suffer.”

Competition

There are many companies focused on the development of small molecules and antibodies for cancer. Our competitors and potential competitors include major pharmaceutical and biotechnology companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Many of our competitors and potential competitors have significantly more financial, technical and other resources than we do, which may allow them to have a competitive advantage. See Item 1A - Risk Factors - “Our competitors may develop products and technologies that impair the value of cabozantinib and cobimetinib.”

Competition for Cabozantinib

We believe that our ability to successfully compete will depend on, among other things:

- efficacy, safety and reliability of COMETRIQ;
- timing and scope of regulatory approval;
- the speed at which we develop cabozantinib for the treatment of additional tumor types beyond progressive, metastatic MTC;
- our ability to complete preclinical testing and clinical development and obtain regulatory approvals for cabozantinib;
- our ability to manufacture and sell commercial quantities of COMETRIQ to the market;
- our ability to successfully commercialize COMETRIQ and secure coverage and adequate reimbursement in approved indications;
- product acceptance by physicians and other health care providers;
- skills of our employees and our ability to recruit and retain skilled employees;
- protection of our intellectual property; and
- the availability of substantial capital resources to fund development and commercialization activities.

We believe that the quality and breadth of activity observed with cabozantinib, the skill of our employees and our ability to recruit and retain skilled employees, our patent portfolio and our capabilities for research and drug development are competitive strengths. However, many large pharmaceutical and biotechnology companies have significantly larger intellectual property estates than we do, more substantial capital resources than we have, and greater capabilities and experience than we do in preclinical and clinical development, sales, marketing, manufacturing and regulatory affairs.

The markets for which we intend to pursue regulatory approval of cabozantinib are highly competitive. We are aware of products in research or development by our competitors that are intended to treat all of the tumor types we are targeting, and any of these products may compete with cabozantinib.

We believe that the principal competing anti-cancer therapy to COMETRIQ in progressive, metastatic MTC is AstraZeneca’s RET, VEGFR and EGFR inhibitor vandetanib, which has been approved by the FDA and the EMA for the treatment of symptomatic or progressive MTC in patients with unresectable, locally advanced, or metastatic

disease. In addition, we believe that COMETRIQ also faces competition as a treatment for progressive, metastatic MTC from off-label use of Bayer's and Onyx Pharmaceuticals' (a wholly-owned subsidiary of Amgen) multikinase inhibitor sorafenib, Pfizer's

Table of Contents

multikinase inhibitor sunitinib, Ariad Pharmaceutical's multikinase inhibitor ponatinib, and Eisai's multikinase inhibitor lenvatinib.

We believe that if cabozantinib is approved for the treatment of the indications for which we currently have ongoing phase 3 pivotal trials, its potential principal competition in such indications may include the following:

- RCC: Pfizer's axitinib, sunitinib and temsirolimus; Novartis' everolimus; Bayer's and Onyx Pharmaceuticals' sorafenib; GlaxoSmithKline's pazopanib; and Genentech's bevacizumab; and
- HCC: Bayer's and Onyx Pharmaceuticals' sorafenib; Bayer's regorafenib; and ArQule's tivantinib.

Examples of potential competition for cabozantinib in other cancer indications include: other VEGF pathway inhibitors, including Genentech's bevacizumab; other RET inhibitors including Eisai's lenvatinib and Ariad's ponatinib; and other MET inhibitors, including Amgen's AMG 208, Pfizer's crizotinib, ArQule's tivantinib, and Mirati's MGCD265; and immune checkpoint agents such as Bristol-Myers Squibb's ipilimumab and nivolimab and Merck's pembrolizumab.

Competition for Cobimetinib

We believe that if cobimetinib is approved for the treatment of advanced melanoma, its potential principal competition may include GlaxoSmithKline's trametinib and dabrafenib, Bristol-Myers Squibb's ipilimumab and nivolumab, Merck's pembrolizumab, Novartis' ecorafenib and Array's binimetinib.

Research and Development Expenses

Research and development expenses consist primarily of direct and indirect internal costs related to specific projects as well as fees paid to other entities that conduct certain research activities on our behalf, as well as laboratory supplies, consulting and facilities costs. Research and development expenses were $189.1 million for the year ended December 31, 2014, compared to $178.8 million for the year ended December 31, 2013, and $128.9 million for the year ended December 31, 2012.

Revenues

In 2014, we derived 99% of our revenues from Diplomat Specialty Pharmacy, which is located in the United States. We operate as a single business segment and have operations solely in the United States. Information regarding total revenues, net loss and total assets is set forth in our financial statements included in Item 8 of this Annual Report on Form 10-K.

Patents and Proprietary Rights

We actively seek patent protection in the United States, the European Union, and selected other foreign countries to cover our drug candidates and related technologies. Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. We have numerous patents and pending patent applications that relate to methods of screening drug targets, compounds that modulate drug targets, as well as methods of making and using such compounds. While many patent applications have been filed relating to the drug candidates that we have developed, the majority of these are not yet issued or allowed.

Cabozantinib is covered by an issued patent in the United States (U.S. Pat. No. 7,579,473) for the composition-of-matter of cabozantinib and pharmaceutical compositions thereof. Cabozantinib is also covered by an additional issued patent in the United States (covering certain methods of use) and also by an issued patent in Europe (covering cabozantinib's composition-of-matter and certain methods of use). These issued patents will expire in September 2024, subject to any available extensions. Foreign counterparts of the issued U.S. and European patents are pending in Australia, Japan and Canada, which, if issued, are anticipated to expire in 2024. We have patent applications pending in the United States, European Union, Australia, Japan and Canada covering certain synthetic methods related to making cabozantinib, which, if issued, are anticipated to expire in 2024. We have filed patent applications in the United States and other selected countries covering certain salts, polymorphs and formulations of cabozantinib that, if issued, are anticipated to expire in approximately 2030. We have filed several patent applications in the United States and other selected countries relating to combinations of cabozantinib with certain other anti-cancer agents that, if issued, are anticipated to expire in approximately 2030.

We have pending patent applications in the United States and European Union covering the composition-of-matter of our other drug candidates in clinical or preclinical development that, if issued, are anticipated to expire between 2023 and 2030.

Table of Contents

We have obtained licenses from various parties that give us rights to technologies that we deem to be necessary or desirable for our research and development. These licenses (both exclusive and non-exclusive) may require us to pay royalties as well as upfront and milestone payments.

For a discussion of risks we face related to our ability to protect and enforce our intellectual property rights and defend against third party claims of infringement, please see Item 1A - Risk Factors - Risks Related to Our Intellectual Property.

Employees

As of December 31, 2014, we had 98 full-time employees worldwide, 33 of whom held Ph.D. and/or M.D. degrees, most of whom were engaged in full-time research and development activities. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Available Information

We maintain a site on the worldwide web at www.exelixis.com; however, information found on our website is not incorporated by reference into this report. We make available free of charge on or through our website our Securities and Exchange Commission, or SEC, filings, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, copies of our filings with the SEC are available at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a site on the worldwide web that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

ITEM 1A. RISK FACTORS

The following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we deem immaterial also may impair our business operations. If any of the following risks or such other risks actually occurs, our business could be harmed.

Risks Related to Our Need for Additional Financing and Our Financial Results

If additional capital is not available to us, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts and we may breach our financial covenants.

We may need to access additional capital to:

- fund our operations and clinical trials;
- continue our research and development efforts;
- commercialize cabozantinib or any other future product candidates, if any such candidates receive regulatory approval for commercial sale; and
- fund the U.S. marketing and commercialization costs for cobimetinib we are obligated to share under our collaboration with Genentech or any similar costs we are obligated to fund under collaborations we may enter into in the future.

As of December 31, 2014, we had $242.8 million in cash and investments, which included $144.3 million available for operations, $12.2 million of short-term restricted investments available for public debt service obligations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $4.7 million of long-term restricted investments. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date to July 1, 2018 of $100.0 million principal amount of the Deerfield Notes, classified within current liabilities on our Consolidated Balance Sheet as of December 31, 2014, we anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues will enable us to maintain our operations through at least December 31, 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations beyond the next twelve months is highly dependent on the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related

net profits and losses, and royalties under our collaboration with Genentech. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets beyond the next twelve months, including but not limited to actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional

Table of Contents

curtailment of our development activities. However, our future capital requirements will be substantial, and we may need to access additional capital in the future. We may seek to access additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements; and, we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. The sale of equity or convertible debt securities in the future may be substantially dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and could contain other terms that are not favorable to our stockholders or us.

Our capital requirements will depend on many factors including but not limited to:

- the progress and scope of the development and commercialization activities with respect to cabozantinib;
- the commercial success of COMETRIQ and the revenues we generate;
- our obligation to share U.S. marketing and commercialization costs for cobimetinib under our collaboration with Genentech;
- the commercial success of cobimetinib and our share of related profits under our collaboration with Genentech;
- repayment of the $104.0 million principal amount outstanding of the Deerfield Notes, which mature on July 1, 2015 unless we exercise our extension option, for which we also will be required to make a mandatory prepayment in 2015 equal to 15% of certain revenues from collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum prepayment amount of $27.5 million and for which we may be subject to similar mandatory prepayment obligations in 2016, 2017 and 2018 if we exercise our extension option;
- our ability to repay the Deerfield Notes with our common stock, which we are only able to do under specified conditions;
- repayment of our $287.5 million aggregate principal amount of the 2019 Notes, which mature on August 15, 2019, unless earlier converted, redeemed or repurchased;
- whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to cabozantinib) that provide additional capital;
- our ability to control costs;
- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- the amount of our cash and cash equivalents, short- and long-term investments that serve as collateral for bank lines of credit;
- future clinical trial results;
- our need to expand our product and clinical development efforts;
- the cost and timing of regulatory approvals;
- the cost of clinical and research supplies for our clinical trials;
- the effect of competing technological and market developments; and
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in our loan and security agreement with Silicon Valley Bank. This agreement contains covenants or events of default requiring us to maintain specified collateral balances. The failure to comply with these covenants could result in an acceleration of the underlying debt obligations. If we are unable to remain in compliance with such covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

We have a history of net losses. We expect to continue to incur net losses, and we may not achieve or maintain profitability.

We have incurred annual net losses since inception through the year ended December 31, 2014, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the year ended

Table of Contents

December 31, 2014, we had a net loss of $268.5 million and as of December 31, 2014, we had an accumulated deficit of $1.8 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' (deficit) equity and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Our research and development expenditures and general and administrative expenses have exceeded our revenues for each year other than 2011, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve future profitability.

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013 and from the commercial launch through December 31, 2014, we have generated $40.1 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research.

The amount of our net losses will depend, in part, on the rate of growth, if any, in our sales of COMETRIQ, our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any, and receipt of royalties from cobimetinib sales outside the U.S., if any, partnering activities for cabozantinib, other license and contract revenues and the level of expenses, primarily with respect to development and commercialization activities for cabozantinib.

Our significant level of indebtedness could limit cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.

We incurred significant additional indebtedness and substantial debt service requirements as a result of our offering of the 2019 Notes in August 2012. As of December 31, 2014, our total consolidated indebtedness through maturity was $471.9 million (excluding trade payables). We may also incur additional indebtedness to meet future financing needs. If we incur additional indebtedness, it would increase our interest expense, leverage and operating and financial costs. Our indebtedness could have significant negative consequences for our business, results of operations and financial condition, including:

- making it more difficult for us to meet our payment and other obligations under the 2019 Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank or our other indebtedness;
- resulting in an event of default if we fail to comply with the financial and other restrictive covenants contained in our debt agreements, which event of default could result in all of our debt becoming immediately due and payable;
- increasing our vulnerability to adverse economic and industry conditions;
- subjecting us to the risk of increased sensitivity to interest rate increases on our indebtedness with variable interest rates, including borrowings under our loan and security agreement with Silicon Valley Bank;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes, including clinical trials, research and development, capital expenditures, working capital and other general corporate purposes;
- limiting our flexibility in planning for, or reacting to, changes in our business;
- preventing us from raising funds necessary to purchase the 2019 Notes in the event we are required to do so following a "Fundamental Change" as specified in the indenture governing the 2019 Notes, or to settle conversions of the 2019 Notes in cash;
- dilution experienced by our existing stockholders as a result of the conversion of the 2019 Notes or the Deerfield Notes into shares of common stock; and
- placing us at a possible competitive disadvantage with less leveraged competitors and competitors that may have better access to capital resources.

We cannot assure you that we will continue to maintain sufficient cash reserves or that our business will generate cash flow from operations at levels sufficient to permit us to pay principal, premium, if any, and interest on our indebtedness, or that our cash needs will not increase. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of the 2019

Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank, or any indebtedness which we have incurred or may incur in the future, we would be in default, which would permit the holders or the Trustee of the 2019 Notes or other indebtedness to accelerate the maturity of such notes or other indebtedness and could cause defaults under the 2019 Notes, the Deerfield Notes, our loan and security

Table of Contents

agreement with Silicon Valley Bank or our other indebtedness. Any default under the 2019 Notes, the Deerfield Notes, our loan and security agreement with Silicon Valley Bank, or any indebtedness that we have incurred or may incur in the future could have a material adverse effect on our business, results of operations and financial condition.

If a Fundamental Change, as defined in the indenture governing the 2019 Notes, occurs, holders of the 2019 Notes may require us to purchase for cash all or any portion of their 2019 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date. We may not have sufficient funds to purchase the notes upon a Fundamental Change. In addition, the terms of any borrowing agreements which we may enter into from time to time may require early repayment of borrowings under circumstances similar to those constituting a Fundamental Change. Furthermore, any repurchase of 2019 Notes by us may be considered an event of default under such borrowing agreements.

We may not realize the expected benefits of our cost-saving initiatives.

Reducing costs is a key element of our current business strategy. On September 2, 2014, as a consequence of the failure of COMET-1, one of our two phase 3 pivotal trials of cabozantinib in mCRPC, to meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization that when completed will result in a remaining workforce of approximately 80 full-time employees. The principal objective of the 2014 Restructuring was to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in mRCC and advanced HCC.

We expect to record an aggregate restructuring charge related to one-time termination benefits of approximately $6 million, of which approximately 95% was recorded in 2014 and the remainder is expected to be recorded in 2015. Although we do not yet have contractual commitments in place, we have made progress towards subleasing our facilities and therefore we expect to incur between $2 million and $6 million in facility-related charges as we exit certain facilities. We expect to incur additional charges as a result of the 2014 Restructuring, including property and equipment write-downs and other charges, and expect to record these expenses during fiscal year 2015 as they become determinable and as we exit certain facilities. Except for employee severance and other benefits and certain facility-related charges, we are currently unable to estimate the total amount or range of amounts expected to be incurred in connection with the 2014 Restructuring for each major type of cost or in the aggregate.

As a consequence of the workforce reductions as well as potential for sublease income and/or rent relief, we are actively marketing portions of our facilities for sublease. Estimates for sublease income and/or rent relief would require significant assumptions regarding the time required to contract with subtenants, the amount of idle space we would be able to sublease and potential future sublease rates. Until we were able to negotiate an exit to the lease or negotiate a sublease for the remaining term of the lease for our vacant buildings, we will need to continue to update our estimate of the lease exit costs in our financial statements.

If we experience excessive unanticipated inefficiencies or incremental costs in connection with restructuring activities, such as unanticipated inefficiencies caused by reducing headcount or failure to find acceptable subtenants, we may be unable to meaningfully realize cost savings and we may incur expenses in excess of what we anticipate. Either of these outcomes could prevent us from meeting our strategic objectives and could adversely impact our results of operations and financial condition.

We are exposed to risks related to foreign currency exchange rates.

Most of our foreign expenses incurred are associated with establishing and conducting clinical trials for cabozantinib. The amount of expenses incurred will be impacted by fluctuations in the currencies of those countries in which we conduct clinical trials. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. Consequently, changes in exchange rates may affect our financial position and results of operations.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives.
Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term and long-term investments consist primarily of readily marketable debt securities with remaining maturities of more than 90 days at the time of purchase. While as of the date of this report we are not aware of any

Table of Contents

downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since December 31, 2014, no assurance can be given that a deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or investments or our ability to meet our financing objectives.

We may not achieve expected benefits as a result of changes to our corporate structure.

During 2013, we engaged in intercompany transactions with a newly established wholly-owned foreign subsidiary pursuant to which such subsidiary acquired the existing and future intellectual property rights to exploit cabozantinib in jurisdictions outside of the United States, and we may establish additional wholly-owned foreign subsidiaries in the future. We established this structure in anticipation of an increase in the international nature of our business activities and to reduce our overall effective tax rate through changes in how we develop and use our intellectual property and the structure of our international procurement and sales, including by entering into transfer-pricing arrangements that establish transfer prices for our intercompany transactions. One of our objectives is to achieve a reduction in our overall effective tax rate in the future as a result. There can be no assurance that the taxing authorities of the jurisdictions in which we determine to operate or to which we will otherwise be deemed to have sufficient tax nexus will not challenge the tax benefits that we expect to realize as a result of the new structure. In addition, future changes to U.S. or non-U.S. tax laws, including proposed legislation to reform U.S. taxation of international business activities would negatively impact the anticipated tax benefits of the new structure. Any benefits to our tax rate will also depend on our ability and decision to operate our business in a manner consistent with the new structure of our corporate organization and applicable taxing provisions, including by eliminating the amount of cash distributed to us by our subsidiaries. If the intended tax treatment is not accepted by the applicable taxing authorities, changes in tax law negatively impact the structure or we do not operate our business consistent with the new structure and applicable tax provisions, we may fail to achieve the financial efficiencies that we anticipate as a result of the changes to our corporate structure, and our future operating results and financial condition may be negatively impacted.

Risks Related to Cabozantinib and Cobimetinib

We are dependent on the successful development and commercialization of cabozantinib.

The success of our business is dependent upon the successful development and commercialization of cabozantinib. As part of our strategy, we are dedicating substantially all of our proprietary resources to advance cabozantinib as aggressively as possible. On November 29, 2012, the FDA approved cabozantinib for the treatment of progressive, metastatic MTC in the United States under the brand name COMETRIQ(R), and we commercially launched COMETRIQ in late January 2013. In March 2014, the European Commission approved cabozantinib for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, also under the brand name COMETRIQ. The European Commission granted conditional marketing authorization following a positive opinion from CHMP, issued in December 2013. We view the approvals of COMETRIQ by the FDA and European Commission for MTC as transitional events towards our objective of developing cabozantinib into a significant oncology franchise. Our ability to realize this objective is contingent on, among other things, successful clinical development, regulatory approval and market acceptance of cabozantinib. The failure of COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in mCRPC, to meet their respective primary endpoints has impacted our ability to achieve our development and commercialization goals for cabozantinib. If we encounter additional difficulties in the development of cabozantinib in other indications beyond MTC due to any of the factors discussed in this “Risk Factors” section or otherwise, or we do not receive regulatory approval in such indications or are unable to successfully commercialize cabozantinib in such other indications if approved, we will not have the resources necessary to continue our business in its current form.

We are dependent on the successful development and commercialization of cobimetinib, and rely heavily on our partner, Genentech, for achieving that success.

We have entered into a worldwide co-development agreement with Genentech for the development and commercialization of cobimetinib, a compound discovered by Exelixis and licensed to Genentech in 2009 after determination of the maximum tolerated dose in a phase 1 clinical trial. Genentech is responsible for cobimetinib’s clinical development and, if cobimetinib is approved, for worldwide commercialization. Under the terms of our co-development agreement, we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our

share decreasing as sales increase, and we will share equally in the U.S. marketing and commercialization costs. Pursuant to our co-development agreement, we may provide up to 25% of the total sales force for cobimetinib in the United States, if cobimetinib is commercialized.

On September 29, 2014, positive results from coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation, were reported at the European Society for Medical Oncology, or ESMO, 2014 Congress. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined progression-free survival, or

Table of Contents

PFS. Roche has completed the Marketing Authorization Application, or MAA, for cobimetinib in combination with vemurafenib in the European Union. In the United States, Genentech submitted its New Drug Application, or NDA, in December 2014 and the FDA has granted the NDA priority review, with a projected action date of August 11, 2015. Under the terms of our co-development agreement, we rely heavily upon Genentech's leadership and expertise to commercialize and further develop cobimetinib. Moreover, we are obligated to contribute an equal share of financial resources as part of the U.S. commercialization process, but we do not control those costs. In addition, we are not able to control the amount and timing of resources that Genentech will devote to the development and commercialization of cobimetinib or to its marketing and distribution. Significant changes to Genentech's business strategy and priorities, over which we have no control, may adversely affect Genentech's willingness or ability to complete their obligations under our agreement, which would adversely affect our business and operations. Finally, regardless of the level of Genentech's efforts and investments in cobimetinib, cobimetinib may not be accepted by physicians, patients, health care payers, such as Medicare and Medicaid, and the medical community; and, additional clinical investigation into cobimetinib's potential in other indications may not provide positive data supporting product approval in such indications.

The commercial success of COMETRIQ for MTC and any other potential approvals of cabozantinib in additional indications in the future will depend upon the degree of market acceptance of cabozantinib among physicians, patients, health care payers, and the medical community.

Our ability to commercialize cabozantinib for the approved MTC indication and potentially other indications, if approved, will be highly dependent upon the extent to which cabozantinib gains market acceptance among physicians, patients, health care payers such as Medicare and Medicaid, and the medical community. If cabozantinib does not achieve an adequate level of acceptance, we may not generate significant future product revenues, and we may not become profitable. The degree of market acceptance of cabozantinib will depend upon a number of factors, including:

- the effectiveness, or perceived effectiveness, of cabozantinib in comparison to competing products;
- the existence of any significant side effects of cabozantinib, as well as their severity in comparison to those of any competing products;
- potential advantages or disadvantages in relation to alternative treatments;
- the timing of market entry relative to competitive treatments;
- indications for which cabozantinib is approved;
- the ability to offer cabozantinib for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of sales, marketing and distribution support; and
- sufficient third-party coverage and reimbursement.

If we are unable to maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to commercialize cabozantinib successfully.

We have established a small internal commercial organization that we believe is commensurate with the size of the market opportunity for the applicable approved MTC indication in the United States and European Union. We have also designed our commercial organization to maintain flexibility, and to enable us to quickly scale up if additional indications are approved in the future or scale down if we are not successful in gaining approval of additional indications. We believe we have created an efficient commercial organization, taking advantage of outsourcing options where prudent to maximize the effectiveness of our commercial expenditures. However, we may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to successfully market and sell cabozantinib. Maintaining sales, marketing, and distribution capabilities is expensive and time-consuming. Such expenses may be disproportional compared to the revenues we may be able to generate on sales of cabozantinib and have an adverse impact on our results of operations. If we are unable to maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenues and our business may be adversely affected.

We currently rely on a single third party logistics provider to handle shipping and warehousing of our commercial supply of COMETRIQ and a single specialty pharmacy to dispense COMETRIQ to patients in fulfillment of prescriptions in the United States. We also rely on a third party, Sobi, to distribute and commercialize COMETRIQ

for the treatment of the approved MTC indication primarily in the European Union and potentially other countries in the event that COMETRIQ is approved for commercial sale in those jurisdictions. Our current and anticipated future dependence upon the activities, and legal and regulatory compliance, of these or other third parties may adversely affect our future profit margins and our ability to supply COMETRIQ to the marketplace on a timely and competitive basis. For example, if our third party logistics provider's warehouse suffers a fire or damage from another type of disaster, the commercial supply of COMETRIQ could be destroyed,

Table of Contents

resulting in a disruption in our commercialization efforts. These or other third parties may not be able to provide services in the time we require to meet our commercial timelines and objectives or to meet regulatory requirements. We may not be able to maintain or renew our arrangements with third parties, or enter into new arrangements, on acceptable terms, or at all. Third parties could terminate or decline to renew our arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for logistics services or distribution of COMETRIQ on acceptable terms, our commercialization efforts may be delayed or otherwise adversely affected.

We are subject to certain healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

We are subject to certain healthcare laws and regulations and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Law, which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state and federal government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported priced may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and
- state and federal marketing expenditure tracking and reporting laws, which generally require certain types of expenditures in the United States to be tracked and reported (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities).

In addition, certain marketing practices, including off-label promotion, may also violate certain federal and state health regulatory fraud and abuse laws as well as false claims laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we, or our officers or employees, may be subject to penalties, including administrative civil and criminal penalties, damages, fines, withdrawal of regulatory approval, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to sell COMETRIQ or operate our business and also adversely affect our financial results.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition,

Table of Contents

most healthcare providers who are expected to prescribe our products and from whom we obtain patient health information are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business. International laws, such as the EU Data Privacy Directive (95/46/EC) and Swiss Federal Act on Data Protection, regulate the processing of personal data within Europe and between European countries and the United States. Failure to provide adequate privacy protections and maintain compliance with safe harbor mechanisms could jeopardize business transactions across borders and result in significant penalties.

If we are unable to obtain both adequate coverage and adequate reimbursement from third-party payers for cabozantinib, our revenues and prospects for profitability will suffer.

Our ability to successfully commercialize cabozantinib will be highly dependent on the extent to which coverage and reimbursement for it is, and will be, available from third-party payers, including governmental payers, such as Medicare and Medicaid, and private health insurers. Many patients will not be capable of paying for cabozantinib themselves and will rely on third-party payers to pay for, or subsidize, their medical needs. If third-party payers do not provide coverage or reimbursement for cabozantinib, our revenues and prospects for profitability will suffer. In addition, even if third-party payers provide some coverage or reimbursement for cabozantinib, the availability of such coverage or reimbursement for prescription drugs under private health insurance and managed care plans often varies based on the type of contract or plan purchased.

In addition, in some foreign countries, particularly the countries in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement and/or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of cabozantinib to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in the commercialization of cabozantinib. Third-party payers are challenging the prices charged for medical products and services, and many third-party payers limit reimbursement for newly-approved health care products. In particular, third-party payers may limit the indications for which they will reimburse patients who use cabozantinib. Cost-control initiatives could decrease the price we might establish for cabozantinib, which would result in lower product revenues to us.

Current healthcare laws and regulations and future legislative or regulatory reforms to the healthcare system may affect our ability to sell cabozantinib profitably.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell cabozantinib profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the PPACA, enacted in March 2010, substantial changes have been made to the way healthcare is financed by both governmental and private insurers, and those changes are significantly impacting the pharmaceutical industry. Provisions of the PPACA relevant to the pharmaceutical industry include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
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- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

Table of Contents

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report annually under the federal Open Payments program certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payment or "transfer of value" provided to physicians and teaching hospitals and any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

The PPACA may change in the future. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee on Deficit Reduction did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013 and will stay in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Further, under the recently enacted Drug Quality and Security Act, drug manufacturers will be subject to a number of requirements, including, product identification, tracing and verification, among others, that are designed to improve the detection and removal of counterfeit, stolen, contaminated or otherwise potentially harmful drugs from the U.S. drug supply chain. These requirements will be phased in over several years and compliance with this new law will likely increase the costs of the manufacture and distribution of drug products, which could have an adverse effect on our financial condition.

As a result of the overall trend towards cost-effectiveness criteria and managed healthcare in the United States, third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. They may use tiered reimbursement and may adversely affect demand for cabozantinib by placing it in an expensive tier. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse for newly approved drugs, which in turn will put pressure on the pricing of drugs. Further, we do not have experience in ensuring approval by applicable third-party payers outside of the United States for coverage and reimbursement of cabozantinib. We also anticipate pricing pressures in connection with the sale of cabozantinib due to the increasing influence of health maintenance organizations and additional legislative proposals.

Our competitors may develop products and technologies that impair the value of cabozantinib and cobimetinib. The pharmaceutical industry is highly fragmented and is characterized by rapid technological change. In particular, the area of kinase-targeted therapies is a rapidly evolving and competitive field. We face, and will continue to face, intense competition from biotechnology, biopharmaceutical and pharmaceutical companies, as well as academic research institutions, clinical reference laboratories and government agencies that are pursuing research activities similar to ours. Some of our competitors have entered into collaborations with leading companies within our target markets, including some of our existing collaborators. Some of our competitors are further along in the development of their products than we are. In addition, delays in the development of cobimetinib, and cabozantinib for the treatment of additional tumor types, could allow our competitors to bring products to market before us, which would impair the commercialization of cobimetinib or cabozantinib in such tumor types. Our future success will depend

upon our ability to maintain a competitive position with respect to technological advances. The markets for which we intend to pursue regulatory approval of cabozantinib and for which Roche and Genentech intend to pursue regulatory approval for cobimetinib are highly competitive. Further, our competitors may be more effective at using their technologies to develop commercial products. Many of the organizations competing with us have greater capital resources, larger research and development staff and facilities, more experience in obtaining regulatory approvals and more extensive product manufacturing and commercial capabilities than we do. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies and products, and those of our collaborators, obsolete and noncompetitive. There may also be drug candidates of which we are not aware at an earlier stage of development

Table of Contents

that may compete with cobimetinib and cabozantinib. In addition, cobimetinib and cabozantinib may compete with existing therapies that have long histories of use, such as chemotherapy and radiation treatments in cancer indications.

We lack the manufacturing capabilities and experience necessary to enable us to produce cabozantinib for clinical development or for commercial sale and rely on third parties to do so, which subjects us to various risks.

We do not have the manufacturing capabilities or experience necessary to enable us to produce materials for our clinical trials or for commercial sale of COMETRIQ and rely on third party contractors to do so. These third parties must comply with applicable regulatory requirements, including the FDA's current Good Manufacturing Practices, or cGMP and the European Commission's Guidelines on Good Distribution Practice. Our current and anticipated future dependence upon these third parties may adversely affect our future profit margins and our ability to develop and commercialize cabozantinib on a timely and competitive basis. These third parties may not be able to produce material on a timely basis or manufacture material at the quality or in the quantity required to meet our development and commercial timelines and applicable regulatory requirements. We may not be able to maintain or renew our existing third party manufacturing and supply arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third party manufacturers and suppliers could terminate or decline to renew our manufacturing and supply arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our clinical trials and commercialization efforts may be delayed or otherwise adversely affected.

Our third-party manufacturers may not be able to comply with the cGMP regulations, other applicable FDA regulatory requirements or similar regulations applicable outside of the United States. Additionally, if we are required to enter into new manufacturing or supply arrangements, we may not be able to obtain approval from the FDA of any alternate manufacturer or supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of cabozantinib. Failure of our third party manufacturers or suppliers or us to obtain approval from the FDA or to comply with applicable regulations could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of cabozantinib, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, any of which could have a significant adverse effect on our business. In addition, cabozantinib requires manufacturing to appropriate cGMP and quality standards. The failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could have also a significant adverse effect on our business.

Clinical testing of cabozantinib is a lengthy, costly, complex and uncertain process and may fail to demonstrate safety and efficacy.

Cabozantinib is being evaluated in a comprehensive development program for the treatment of RCC, HCC and a variety of other indications beyond the approved MTC indication. Clinical trials are inherently risky and may reveal that cabozantinib is ineffective or has unacceptable toxicity or other side effects that may significantly decrease the likelihood of regulatory approval in such indications. For example, COMET-1 and COMET-2, our two phase 3 pivotal trials of cabozantinib in mCRPC, failed to meet their respective primary endpoints of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone and to demonstrate improvement in pain response for patients treated by cabozantinib as compared to mitoxantrone/prednisone. Based on the outcome of the COMET trials, we have deprioritized the clinical development of cabozantinib in mCRPC.

The results of preliminary studies do not necessarily predict clinical or commercial success, and later-stage clinical trials may fail to confirm the results observed in earlier-stage trials or preliminary studies. Although we have established timelines for manufacturing and clinical development of cabozantinib based on existing knowledge of our compounds in development and industry metrics, we may not be able to meet those timelines.

We may experience numerous unforeseen events, during or as a result of clinical testing, that could delay or prevent commercialization of cabozantinib for the treatment of mRCC, advanced HCC, and other indications, including:

- cabozantinib may not prove to be efficacious or may cause, or potentially cause, harmful side effects;
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negative or inconclusive clinical trial results may require us to conduct further testing or to abandon projects that we had expected to be promising;

- our competitors may discover or commercialize other compounds or therapies that show significantly improved safety or efficacy compared to cabozantinib;
- patient registration or enrollment in our clinical testing may be lower than we anticipate, resulting in the delay or cancellation of clinical testing; and

Table of Contents

- regulators or institutional review boards may withhold authorization of cabozantinib, or delay, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their determination that participating patients are being exposed to unacceptable health risks.

If we were to have significant delays in or termination of our clinical testing of cabozantinib as a result of any of the events described above or otherwise, our expenses could increase and our ability to generate revenues could be impaired, either of which could adversely impact our financial results.

We have limited experience in conducting clinical trials and may not be able to rapidly or effectively continue the further development of cabozantinib or meet current or future requirements of the FDA or regulatory authorities in other jurisdictions, including those identified based on our discussions with the FDA or such other regulatory authorities. Our planned clinical trials may not begin on time, or at all, may not be completed on schedule, or at all, may not be sufficient for registration of cabozantinib or may not result in an approvable product.

Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of cabozantinib. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of factors relating to the clinical trial, including, among others:

- the number of patients who ultimately participate in the clinical trial;
- the duration of patient follow-up that is appropriate in view of the results or required by regulatory authorities;
- the number of clinical sites included in the trials; and
- the length of time required to enroll suitable patient subjects.

Any delay could limit our ability to generate revenues, cause us to incur additional expense and cause the market price of our common stock to decline significantly. Our partners under our collaboration agreements may experience similar risks with respect to the compounds we have out-licensed to them. If any of the events described above were to occur with such programs or compounds, the likelihood of receipt of milestones and royalties under such collaboration agreements could decrease.

If third parties upon which we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize cabozantinib for the treatment of additional indications beyond the approved MTC indication.

We do not have the ability to independently conduct clinical trials for cabozantinib, including our post-marketing commitments in connection with the approvals of COMETRIQ in MTC, and we rely on third parties we do not control such as the federal government (including NCI-CTEP, with whom we have our CRADA), third-party contract research organizations, or CROs, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or commercialize cabozantinib for additional indications beyond the approved MTC indication in the United States and European Union.

Cabozantinib is subject to a lengthy and uncertain regulatory process that may not result in the necessary regulatory approvals, which could adversely affect our ability to commercialize cabozantinib.

Cabozantinib, as well as the activities associated with its research, development and commercialization, are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for cabozantinib would prevent us from promoting its use. We have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals in the United States and other foreign jurisdictions is expensive, and often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. For example, before an NDA or NDA supplement can be submitted to the FDA, or MAA to the EMA or any application or submission to regulatory authorities in other jurisdictions, the product candidate must undergo extensive clinical trials, which can take many years and require substantial expenditures.

Any clinical trial may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. For example, the FDA could determine that the design of a clinical trial is inadequate to produce reliable results. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. The FDA has substantial discretion in the approval process and may refuse to approve any NDA or decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, varying

Table of Contents

interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of cabozantinib or any individual, additional indications.

In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of product development and regulatory agency review. Changes in regulatory approval policy, regulations or statutes or the process for regulatory review during the development or approval periods of cabozantinib may cause delays in the approval or rejection of an application.

Even if the FDA or a comparable authority in another jurisdiction approves cabozantinib, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, distribution, advertising, promotion, marketing and/or production of cabozantinib and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. For example, in connection with the FDA's approval of COMETRIQ for the treatment of progressive, metastatic MTC, we are subject to the various post-marketing requirements, including a requirement to conduct a clinical study comparing a lower dose of COMETRIQ to the approved dose of 140 mg daily COMETRIQ in progressive, metastatic MTC and to conduct other clinical pharmacology and preclinical studies. Failure to complete any post-marketing requirements in accordance with the timelines and conditions set forth by the FDA could significantly increase costs or delay, limit or eliminate the commercialization of cabozantinib. Further, these agencies may also impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Risks Related to Our Relationships with Third Parties

We are dependent upon our collaborations with major companies, which subjects us to a number of risks.

We have established collaborations with leading pharmaceutical and biotechnology companies, including Genentech, Bristol-Myers Squibb, Sanofi, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo, for the development and ultimate commercialization of certain compounds generated from our research and development efforts. We may pursue collaborations for selected unpartnered preclinical and clinical programs and compounds. Our dependence on our relationships with existing collaborators for the development and commercialization of compounds under the collaborations subjects us to, and our dependence on future collaborators for development and commercialization of additional compounds will subject us to, a number of risks, including:

- we may not be able to control the amount of U.S. marketing and commercialization costs for cobimetinib we are obligated to share under our collaboration with Genentech;
- we are not able to control the amount and timing of resources that our collaborators or potential future collaborators will devote to the development or commercialization of drug candidates or to their marketing and distribution;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our drug candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
- collaborators may experience financial difficulties;
- collaborators may not be successful in their efforts to obtain regulatory approvals in a timely manner, or at all;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may not comply with applicable healthcare regulatory laws;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors;
- we may be precluded from entering into additional collaboration arrangements with other parties in an area or field of exclusivity;
- future collaborators may require us to relinquish some important rights, such as marketing and distribution rights; and

- collaborations may be terminated or allowed to expire, which would delay, and may increase the cost of development of our drug candidates.

Table of Contents

If any of these risks materialize, we may not receive collaboration revenue or otherwise realize anticipated benefits from such collaborations, our product development efforts could be delayed and our business, operating results and financial condition could be adversely affected.

We may be unable to establish collaborations for selected preclinical and clinical compounds.

We may pursue new collaborations with leading pharmaceutical and biotechnology companies for the development and ultimate commercialization of selected preclinical and clinical programs and compounds, particularly those drug candidates for which we believe that the capabilities and resources of a partner can accelerate development and help to fully realize their therapeutic and commercial potential. We may not be able to negotiate additional collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional collaborations because of the numerous risks and uncertainties associated with establishing additional collaborations. If we are unable to negotiate additional collaborations, we may not be able to realize value from a particular drug candidate.

Risks Related to Our Intellectual Property

Data breaches and cyber-attacks could compromise our intellectual property or other sensitive information and cause significant damage to our business and reputation.

In the ordinary course of our business, we maintain sensitive data on our networks, including our intellectual property and proprietary or confidential business information relating to our business and that of our customers and business partners. The secure maintenance of this information is critical to our business and reputation. We believe that companies have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access. These threats can come from a variety of sources, all ranging in sophistication from an individual hacker to a state-sponsored attack. Cyber threats may be generic, or they may be custom-crafted against our information systems. Over the past year, cyber-attacks have become more prevalent and much harder to detect and defend against. Our network and storage applications may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. It is often difficult to anticipate or immediately detect such incidents and the damage caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information. A data security breach could also lead to public exposure of personal information of our clinical trial patients, customers and others. Cyber-attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations and divert attention of management and key information technology resources. These incidents could also subject us to liability, expose us to significant expense and cause significant harm to our reputation and business.

If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.

Our success will depend in part upon our ability to obtain patents and maintain adequate protection of the intellectual property related to our technologies and products. The patent positions of biopharmaceutical companies, including our patent position, are generally uncertain and involve complex legal and factual questions. We will be able to protect our intellectual property rights from unauthorized use by third parties only to the extent that our technologies are covered by valid and enforceable patents or are effectively maintained as trade secrets. We will continue to apply for patents covering our technologies and products as, where and when we deem appropriate. However, these applications may be challenged or may fail to result in issued patents. In addition, because patent applications can take many years to issue, third parties may have pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patents. In addition, our patents may be challenged or invalidated or may fail to provide us with any competitive advantages, if, for example, others were the first to invent or to file patent applications for closely related inventions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under

which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to "work" the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include our products or product candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patent

Table of Contents

and other intellectual property protection, which makes it difficult to stop infringement. We rely on trade secret protection for some of our confidential and proprietary information. We have taken security measures to protect our proprietary information and trade secrets, but these measures may not provide adequate protection. While we seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants, we cannot assure you that our proprietary information will not be disclosed, or that we can meaningfully protect our trade secrets. In addition, our competitors may independently develop substantially equivalent proprietary information or may otherwise gain access to our trade secrets.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money and adversely affect our ability to develop and commercialize products.

Our commercial success depends in part upon our ability to avoid infringing patents and proprietary rights of third parties and not to breach any licenses that we have entered into with regard to our technologies and the technologies of third parties. Other parties have filed, and in the future are likely to file, patent applications covering genes and gene fragments, techniques and methodologies relating to model systems and products and technologies that we have developed or intend to develop. If patents covering technologies required by our operations are issued to others, we may have to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, and may require us to pay substantial royalties, grant a cross-license to some of our patents to another patent holder or redesign the formulation of a product candidate so that we do not infringe third-party patents, which may be impossible to obtain or could require substantial time and expense.

Third parties may accuse us of employing their proprietary technology without authorization. In addition, third parties may obtain patents that relate to our technologies and claim that use of such technologies infringes on their patents. Regardless of their merit, such claims could require us to incur substantial costs, including the diversion of management and technical personnel, in defending ourselves against any such claims or enforcing our patents. In the event that a successful claim of infringement is brought against us, we may be required to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, or at all. Defense of any lawsuit or failure to obtain any of these licenses could adversely affect our ability to develop and commercialize products.

We may be subject to damages resulting from claims that we, our employees or independent contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and independent contractors were previously employed at universities or other biotechnology, biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, independent contractors or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or used or sought to use patent inventions belonging to their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and divert management’s attention. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key research personnel and/or their work product could hamper or prevent our ability to commercialize certain product candidates, which could severely harm our business.

Risks Related to Employees and Location

The loss of key personnel or the inability to retain and, where necessary, attract additional personnel could impair our ability to expand our operations.

We are highly dependent upon the principal members of our management, clinical and scientific staff, the loss of whose services might adversely impact the achievement of our objectives and the continuation of existing collaborations. Also, we may not have sufficient personnel to execute our business plan. Retaining and, where necessary, recruiting qualified clinical and scientific personnel will be critical to support activities related to advancing our clinical and preclinical development programs, and supporting our collaborative arrangements and our internal proprietary research and development efforts. The 2014 Restructuring could have an adverse impact on our ability to retain and recruit qualified personnel. Competition is intense for experienced clinical personnel, and we may be unable to retain or recruit clinical personnel with the expertise or experience necessary to allow us to pursue collaborations, develop our products and core technologies or expand our operations to the extent otherwise possible.

Further, all of our employees are employed “at will” and, therefore, may leave our employment at any time.

Our collaborations with outside scientists may be subject to restriction and change.

We work with scientific and clinical advisors and collaborators at academic and other institutions that assist us in our research and development efforts. These advisors and collaborators are not our employees and may have other commitments that limit their availability to us. Although these advisors and collaborators generally agree not to do competing work, if a

Table of Contents

conflict of interest between their work for us and their work for another entity arises, we may lose their services. In such a circumstance, we may lose work performed by them, and our development efforts with respect to the matters on which they were working may be significantly delayed or otherwise adversely affected. In addition, although our advisors and collaborators sign agreements not to disclose our confidential information, it is possible that valuable proprietary knowledge may become publicly known through them.

Our headquarters are located near known earthquake fault zones, and the occurrence of an earthquake or other disaster could damage our facilities and equipment, which could harm our operations.

Our headquarters are located in South San Francisco, California, and therefore our facilities are vulnerable to damage from earthquakes. We do not carry earthquake insurance. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, terrorism and similar events since any insurance we may maintain may not be adequate to cover our losses. If any disaster were to occur, our ability to operate our business at our facilities could be seriously, or potentially completely, impaired. In addition, the unique nature of our research activities could cause significant delays in our programs and make it difficult for us to recover from a disaster. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

Security breaches may disrupt our operations, subject us to liability and harm our operating results.

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

Risks Related to Environmental and Product Liability

We use hazardous chemicals and radioactive and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous materials, including chemicals and radioactive and biological materials. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may face liability for any injury or contamination that results from our use or the use by third parties of these materials, and such liability may exceed our insurance coverage and our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

In addition, our collaborators may use hazardous materials in connection with our collaborative efforts. In the event of a lawsuit or investigation, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials used by these parties. Further, we may be required to indemnify our collaborators against all damages and other liabilities arising out of our development activities or products produced in connection with these collaborations.

We face potential product liability exposure far in excess of our limited insurance coverage.

We may be held liable if any product we or our collaborators develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. Regardless of merit or eventual outcome, product liability claims could result in decreased demand for our product candidates, injury to our reputation, withdrawal of patients from our clinical trials, substantial monetary awards to third parties and the inability to commercialize any products that we may develop. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling or testing our products. We have obtained limited product liability insurance coverage for our clinical trials and commercial activities for cabozantinib in the amount of $15.0 million per occurrence and $15.0

million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for expenses or losses we may suffer. Moreover, if insurance coverage becomes more expensive, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, juries have awarded large judgments in class action lawsuits for claims based on drugs that had unanticipated side effects. In addition, the pharmaceutical, biopharmaceutical and biotechnology industries, in general, have been subject to significant medical malpractice litigation. A successful product liability claim or series of claims brought against us could harm our reputation and business and would decrease our cash reserves.

Table of Contents

Risks Related to Our Common Stock and the 2019 Notes

We expect that our quarterly results of operations will fluctuate, and this fluctuation could cause our stock price to decline, causing investor losses.

Our quarterly operating results have fluctuated in the past and are likely to fluctuate in the future. A number of factors, many of which we cannot control, could subject our operating results to volatility, including:

- the progress and scope of our development and commercialization activities;
- the commercial success of COMETRIQ and the revenues we generate;
- recognition of upfront licensing or other fees or revenues;
- payments of non-refundable upfront or licensing fees, or payment for cost-sharing expenses, to third parties;
- acceptance of our technologies and platforms;
- the success rate of our efforts leading to milestone payments and royalties;
- the introduction of new technologies or products by our competitors;
- the timing and willingness of collaborators to further develop or, if approved, commercialize our product candidates out-licensed to them;
- our ability to enter into new collaborative relationships;
- the termination or non-renewal of existing collaborations;
- the timing and amount of expenses incurred for clinical development and manufacturing of cabozantinib;
- adjustments to expenses accrued in prior periods based on management's estimates after the actual level of activity relating to such expenses becomes more certain;
- the impairment of acquired goodwill and other assets;
- the impact of our restructuring activities; and
- general and industry-specific economic conditions that may affect our collaborators' research and development expenditures.

A large portion of our expenses, including expenses for facilities, equipment and personnel, are relatively fixed in the short term. If we fail to achieve anticipated levels of revenues, whether due to the expiration or termination of existing contracts, our failure to obtain new contracts, our inability to meet milestones or for other reasons, we may not be able to correspondingly reduce our operating expenses, which could significantly harm our operating results for a particular fiscal period.

Due to the possibility of fluctuations in our revenues and expenses, we believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. As a result, in some future quarters, our operating results may not meet the expectations of securities analysts and investors, which could result in a decline in the price of our common stock.

Our stock price may be extremely volatile.

The trading price of our common stock has been highly volatile, and we believe the trading price of our common stock will remain highly volatile and may fluctuate substantially due to factors such as the following, many of which we cannot control:

- adverse results or delays in our or our collaborators' clinical trials;
- announcement of FDA approval or non-approval, or delays in the FDA review process, of cabozantinib or our collaborators' product candidates or those of our competitors or actions taken by regulatory agencies with respect to our, our collaborators' or our competitors' clinical trials;
- the commercial success of COMETRIQ and the revenues we generate;
- the timing of achievement of our clinical, regulatory, partnering and other milestones, such as the commencement of clinical development, the completion of a clinical trial, the filing for regulatory approval or the establishment of collaborative arrangements for cabozantinib or any of our other programs or compounds;
- actions taken by regulatory agencies with respect to cabozantinib or our clinical trials for cabozantinib;
- the announcement of new products by our competitors;
- quarterly variations in our or our competitors' results of operations;

Table of Contents

- developments in our relationships with our collaborators, including the termination or modification of our agreements;
- conflicts or litigation with our collaborators;
- litigation, including intellectual property infringement and product liability lawsuits, involving us;
- failure to achieve operating results projected by securities analysts;
- changes in earnings estimates or recommendations by securities analysts;
- financing transactions;
- developments in the biotechnology, biopharmaceutical or pharmaceutical industry;
- sales of large blocks of our common stock or sales of our common stock by our executive officers, directors and significant stockholders;
- departures of key personnel or board members;
- developments concerning current or future collaborations;
- FDA or international regulatory actions;
- third-party coverage and reimbursement policies;
- disposition of any of our subsidiaries, technologies or compounds; and
- general market, economic and political conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

These factors, as well as general economic, political and market conditions, may materially adversely affect the market price of our common stock. Excessive volatility may continue for an extended period of time following the date of this report.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs and divert management's attention and resources, which could have a material and adverse effect on our business.

Future sales of our common stock or conversion of our convertible notes, or the perception that such sales or conversions may occur, may depress our stock price.

A substantial number of shares of our common stock is reserved for issuance upon conversion of the 2019 Notes, upon the exercise of stock options, upon vesting of restricted stock unit awards, upon sales under our employee stock purchase program, upon exercise of certain warrants issued to Deerfield and upon conversion of the Deerfield Notes. The issuance and sale of substantial amounts of our common stock, including upon conversion of the 2019 Notes or the Deerfield Notes, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-related securities in the future at a time and price that we deem appropriate. Trading of the 2019 Notes is likely to influence and be influenced by the market for our common stock. For example, the price of our common stock could be affected by possible sales of common stock by investors who view the 2019 Notes as a more attractive means of equity participation in Exelixis and by hedging or arbitrage trading activity that we expect to occur involving our common stock.

The accounting method for convertible debt securities that may be settled in cash, such as the 2019 Notes, could have a material effect on our reported financial results.

Under Accounting Standards Codification, or ASC, Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. As a result of the application of ASC 470-20, we recognized $143.2 million as the initial debt discount with a corresponding increase to paid-in capital, the equity component, for the 2019 Notes. We will be required to record the amortization of this debt discount over the terms of the 2019 Notes, which may adversely affect our reported or future financial results and the market price of our common stock. In addition, if the 2019 Notes become convertible, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2019 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital. Finally, we use the if-converted method to compute earnings per share, which could be more dilutive than using the treasury stock method.

Certain provisions applicable to the 2019 Notes and the Deerfield Notes could delay or prevent an otherwise beneficial takeover or takeover attempt

Certain provisions applicable to the 2019 Notes and the indenture pursuant to which the 2019 Notes were issued, and the Deerfield Notes and the note purchase agreement governing the Deerfield Notes, could make it more difficult or more

Table of Contents

expensive for a third party to acquire us. For example, if an acquisition event constitutes a Fundamental Change under the indenture for the 2019 Notes or a Major Transaction under the note purchase agreement governing the Deerfield Notes, holders of the 2019 Notes or the Deerfield Notes, as applicable, will have the right to require us to purchase their notes in cash. In addition, if an acquisition event constitutes a Make-Whole Fundamental Change under the indenture for the 2019 Notes, we may be required to increase the conversion rate for holders who convert their 2019 Notes in connection with such Make-Whole Fundamental Change. In any of these cases, and in other cases, our obligations under the 2019 Notes and the indenture pursuant to which such notes were issued and the Deerfield Notes and the note purchase agreement governing the Deerfield Notes, as well as provisions of our organizational documents and other agreements, could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent or deter attempts by our stockholders to replace or remove our current management, which could cause the market price of our common stock to decline.

Provisions in our corporate charter and bylaws may discourage, delay or prevent an acquisition of us, a change in control, or attempts by our stockholders to replace or remove members of our current Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the inability of our stockholders to call special meetings of stockholders;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors;
- limitations on the removal of directors; and
- advance notice requirements for director nominations and stockholder proposals.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease a total of 367,773 square feet of office and laboratory facilities in South San Francisco, California. The leased premises comprise six buildings and are covered by four lease agreements, as follows:

- The first two leases cover three buildings for a total of 179,964 square feet and expire in 2017, with two five-year options to extend their respective terms prior to expiration. We have subleased a total of 79,275 square feet of portions of these buildings to four different subtenants. The terms of the subleases expire at the end of our lease term.
- The third lease covers two buildings for a total of 116,063 square feet and expires in 2018.
- The fourth lease covers a portion of one building containing 71,746 square feet and expires in 2015. We have subleased approximately 68,738 square feet of the building covered by the fourth lease to a single subtenant. The term of the sublease will expire at the end of our lease term.

We believe that our leased facilities have sufficient space to accommodate our current needs.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings. We may from time to time become a party to various legal proceedings arising in the ordinary course of business.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

35

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has traded on the NASDAQ Global Select Market (formerly the NASDAQ National Market) under the symbol "EXEL" since April 11, 2000. The following table sets forth, for the periods indicated, the high and low intraday sales prices for our common stock as reported by the NASDAQ Global Select Market:

	Common Stock Price	
	High	Low
Year ended December 27, 2013:		
Quarter ended March 29, 2013	$5.06	$4.32
Quarter ended June 28, 2013	$5.30	$4.33
Quarter ended September 27, 2013	$5.88	$4.58
Quarter ended December 27, 2013	$6.14	$4.66
Year ended January 2, 2015:		
Quarter ended March 28, 2014	$8.41	$3.37
Quarter ended June 27, 2014	$3.84	$3.02
Quarter ended September 26, 2014	$4.55	$1.51
Quarter ended January 2, 2015	$1.88	$1.26

On February 26, 2015, the last reported sale price on the NASDAQ Global Select Market for our common stock was $2.93 per share.

Holders

On February 26, 2015, there were approximately 488 holders of record of our common stock.

Dividends

Since inception, we have not paid dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and currently do not plan to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors. Our loan and security agreement with Silicon Valley Bank restricts our ability to pay dividends and make distributions. In addition, our note purchase agreement with Deerfield restricts our ability to make distributions.

Table of Contents

Performance Graph

This performance graph shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of ours under the Securities Act of 1933, as amended.

The following graph compares, for the five year period ended December 31, 2014, the cumulative total stockholder return for our common stock, the NASDAQ Stock Market (U.S. companies) Index, or the NASDAQ Market Index, and the NASDAQ Biotechnology Index. The graph assumes that $100 was invested on December 31, 2009 in each of our common stock, the NASDAQ Market Index and the NASDAQ Biotechnology Index and assumes reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

	December 31					
	2009	2010	2011	2012	2013	2014
Exelixis, Inc.	100	111	64	61	80	22
NASDAQ Market Index	100	117	115	130	183	208
NASDAQ Biotechnology Index	100	115	129	167	280	380

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial information has been derived from our audited consolidated financial statements. The financial information as of December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014, are derived from audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The financial information as of December 31, 2012, 2011 and 2010, and for each of the two years in the period ended December 31, 2011, are derived from audited consolidated financial statements not included in this Annual Report on Form 10-K. The following Selected Financial Data should be read in conjunction with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Item 8. Financial Statements and Supplementary Data” included elsewhere in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results of operations to be expected in the future.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues	$25,111	$31,338	$47,450	$289,636	$185,045
Operating expenses:					
Cost of goods sold	2,043	1,118	—	—	—
Research and development	189,101	178,763	128,878	156,836	210,678
Selling, general and administrative	50,829	50,958	31,837	33,129	33,020
Restructuring charge	7,596	1,231	9,171	10,136	32,744
Total operating expenses	249,569	232,070	169,886	200,101	276,442
(Loss) income from operations	(224,458)	(200,732)	(122,436)	89,535	(91,397)
Other income (expense), net	(44,266)	(44,124)	(25,102)	(12,543)	(1,005)
(Loss) income before taxes	(268,724)	(244,856)	(147,538)	76,992	(92,402)
Income tax (benefit) provision	(182)	(96)	107	1,295	(72)
Net (loss) income	$(268,542)	$(244,760)	$(147,645)	$75,697	$(92,330)
Net loss per share, basic	$(1.38)	$(1.33)	$(0.92)	$0.60	$(0.85)
Net loss per share, diluted	$(1.38)	$(1.33)	$(0.92)	$0.58	$(0.85)
Shares used in computing basic loss per share amounts	194,299	184,062	160,138	126,018	108,522
Shares used in computing diluted loss per share amounts	194,299	184,062	160,138	130,479	108,522

	December 31,				
	2014	2013	2012	2011	2010
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and investments	$242,760	$415,862	$633,961	$283,720	$256,377
Working (deficit) capital	$(4,619)	$178,756	$350,837	$136,500	$(16,455)
Total assets	$327,960	$503,287	$721,097	$393,262	$360,790
Long-term obligations	$270,929	$349,196	$342,959	$193,983	$186,702
Accumulated deficit	$(1,767,304)	$(1,498,762)	$(1,254,002)	$(1,106,357)	$(1,182,054)
Total stockholders’ (deficit) equity	$(114,829)	$66,238	$296,434	$90,632	$(228,325)

Table of Contents

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

Some of the statements under in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" are forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and involve known and unknown risks, uncertainties and other factors that may cause our company's or our industry's results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in, or contemplated by, the forward-looking statements. Words such as "believe," "anticipate," "expect," "intend," "plan," "focus," "assume," "goal," "objective," "will," "may" "would," "could," "estimate," "predict," "pro "continue," "encouraging" or the negative of such terms or other similar expressions identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Item 1A. Risk Factors" as well as those discussed elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

Exelixis is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Our two most advanced assets are cabozantinib, our wholly-owned inhibitor of multiple receptor tyrosine kinases, and cobimetinib (GDC-0973/XL518), a potent, highly selective inhibitor of MEK, a serine/threonine kinase, which we out-licensed to Genentech (a member of the Roche Group), or Genentech.

Our development and commercialization efforts are focused primarily on cabozantinib. We are evaluating cabozantinib in a broad development program comprising over forty-five clinical trials, across multiple indications, including two ongoing phase 3 pivotal trials focusing on mRCC, and advanced hepatocellular carcinoma, or HCC. Cabozantinib was approved by the United States Food and Drug Administration, or FDA, on November 29, 2012, for the treatment of progressive, metastatic medullary thyroid cancer, or MTC, in the United States under the brand name COMETRIQ(R). COMETRIQ became commercially available in the United States in January 2013. In March 2014, the European Commission granted cabozantinib conditional marketing authorization for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, also under the brand name COMETRIQ. However, as discussed below, we have terminated the clinical development of cabozantinib in metastatic castration-resistant prostate cancer, or mCRPC, as a result of the clinical trials of cabozantinib for this indication not meeting their primary endpoints.

Our second most advanced oncology asset, cobimetinib, is being evaluated by Genentech in a broad development program, including coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation. On September 29, 2014, positive results from this trial were reported at the European Society for Medical Oncology, or ESMO, 2014 Congress. The trial met its primary endpoint of demonstrating a statistically significant increase in investigator-determined progression-free survival, or PFS. Roche has completed the Marketing Authorization Application, or MAA, for cobimetinib in combination with vemurafenib in the European Union. In the United States, Genentech filed its New Drug Application, or NDA, in December 2014 and the FDA has granted the NDA priority review, with a projected action date of August 11, 2015.

Our Strategy

We believe that the available clinical data demonstrate that cabozantinib has the potential to be a broadly active anti-cancer agent that can make a meaningful difference in the lives of patients. Our objective is to build cabozantinib into a significant oncology franchise. The initial regulatory approvals of COMETRIQ for MTC in the United States and European Union provide a niche market opportunity that allows us to gain commercialization experience while providing a solid foundation for potential expansion into larger cancer indications.

Our near-term internal development efforts for cabozantinib are focused on cancers for which we believe cabozantinib has the greatest significant therapeutic and commercial potential. We utilize our Cooperative Research and Development Agreement, or CRADA, with the National Cancer Institute's Cancer Therapy Evaluation Program, or

NCI-CTEP, and investigator sponsored trials, or ISTs, to generate additional data, allowing us to prioritize future late stage trials in a cost-effective fashion. We believe that this staged approach to building value represents the most rational and effective use of our resources.

Table of Contents

Beyond our efforts regarding cabozantinib, under the terms of our various collaboration agreements, we are working with our corporate partners to realize the potential value of the compounds and programs we have out-licensed to them. The most notable of these is our cobimetinib collaboration with Genentech. In the aggregate, these partnered compounds could potentially be of significant value to us if their development programs progress successfully. For additional information regarding our work with our corporate partners, please see the section entitled Cobimetinib Collaboration and Other Collaborations in Item 1 - Business above.

Collaborations

We have established a collaboration with Genentech for cobimetinib and other collaborations with leading pharmaceutical companies, including Bristol-Myers Squibb Company, or Bristol-Myers Squibb, Sanofi, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited, or Daiichi Sankyo, for compounds and programs in our portfolio. Pursuant to these collaborations, we have fully out-licensed compounds or programs to a partner for further development and commercialization. We have no further development cost obligations under our collaborations and may be entitled to receive milestones and royalties, or in the case of cobimetinib, a share of profits (or losses) from commercialization.

With respect to our partnered compounds, other than cobimetinib, we are eligible to receive potential contingent payments totaling approximately $2.3 billion in the aggregate on a non-risk adjusted basis, of which 10% are related to clinical development milestones, 42% are related to regulatory milestones and 48% are related to commercial milestones, all to be achieved by the various licensees, which may not be paid, if at all, until certain conditions are met.

Certain Factors Important to Understanding Our Financial Condition and Results of Operations

Successful development of drugs is inherently difficult and uncertain. Our business requires significant investments in research and development over many years, and products often fail during the research and development process. Our long-term prospects depend upon our ability, and the ability of our partners, to successfully commercialize new therapeutics in highly competitive areas such as cancer treatment. Our financial performance is driven by many factors, including those described below, and is subject to the risks set forth in Item 1A - Risk Factors.

Limited Sources of Revenues and the Need to Raise Additional Capital

We have incurred annual net losses since inception through the year ended December 31, 2014, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the year ended December 31, 2014, we had a net loss of $268.5 million and as of December 31, 2014, we had an accumulated deficit of $1.8 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' (deficit) equity and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Our research and development expenditures and general and administrative expenses have exceeded our revenues for each year other than 2011, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve future profitability.

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013 and from the commercial launch through December 31, 2014, we have generated $40.1 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research.

The amount of our net losses will depend, in part, on the rate of growth, if any, in our sales of COMETRIQ, our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any, and receipt of royalties from cobimetinib sales outside the U.S., if any, partnering activities for cabozantinib, other license and contract revenues and the level of expenses, primarily with respect to development and commercialization activities for cabozantinib.

As of December 31, 2014, we had $242.8 million in cash and investments, which included $144.3 million available for operations, $12.2 million of short-term restricted investments available for public debt service obligations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank,

and $4.7 million of long-term restricted investments. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date to July 1, 2018 of $100.0 million principal amount of the Deerfield Notes, classified within current liabilities on our Consolidated Balance Sheet as of December 31, 2014, we anticipate that our current cash and cash equivalents, and short-term investments available for

Table of Contents

operations, and product revenues will enable us to maintain our operations through at least December 31, 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations beyond the next twelve months is highly dependent on the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related net profits and losses, and royalties under our collaboration with Genentech. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets beyond the next twelve months, including but not limited to actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional curtailment of our development activities. However, our future capital requirements will be substantial, and we may need to access additional capital in the future. We may seek to access additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements; and, we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

For a description of the factors upon which our capital requirements depend, please see "– Liquidity and Capital Resources – Capital Requirements."

Clinical Development and Commercialization of Cabozantinib

Our primary development and commercialization program is focused on cabozantinib, our wholly-owned inhibitor of multiple receptor tyrosine kinases, currently approved under the brand name COMETRIQ in the United States and the European Union for the treatment of metastatic MTC. However, cabozantinib may fail to show adequate safety or efficacy as an anti-cancer drug in clinical testing in other types of cancer. For example, our two phase 3 clinical trials (COMET-1 and COMET-2) of cabozantinib in men with mCRPC failed to meet their primary endpoints. Based on the outcomes of the COMET trials, we have terminated the clinical development of cabozantinib in mCRPC, and other studies in mCRPC sponsored by us, including a randomized phase 2 study of cabozantinib in combination with abiraterone, have been halted.

Furthermore, predicting the timing of the initiation or completion of clinical trials is difficult, and our trials may be delayed due to many factors, including factors outside of our control. The future development path of cabozantinib depends upon the results of each stage of clinical development. We continue to incur significant expenses for the development of cabozantinib as it advances in clinical development.

The commercial success of COMETRIQ will depend upon the degree of market acceptance of COMETRIQ among physicians, patients, health care payers, and the medical community. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Such expenses may be disproportional compared to the revenues we may be able to generate on sales of COMETRIQ and have an adverse impact on our results of operations. Further, if cabozantinib is approved for the treatment of an indication beyond the approved MTC indication, we expect to incur an increase in commercialization expenses in connection with any such approval.

Convertible Senior Subordinated Notes

In August 2012, we issued and sold $287.5 million aggregate principal amount of the 4.25% Convertible Senior Subordinated Notes due 2019, or the 2019 Notes, for net proceeds of $277.7 million. The 2019 Notes mature on August 15, 2019, unless earlier converted, redeemed or repurchased, and bear interest at a rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2013. Subject to certain terms and conditions, at any time on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed plus accrued and unpaid interest, if any, to, but excluding, the redemption date. Upon the occurrence of certain circumstances, holders may convert their 2019 Notes prior to the close of business on the business day immediately preceding May 15, 2019. On or after May 15, 2019, until the close of business on the second trading day immediately preceding August 15, 2019, holders may surrender their 2019 Notes for conversion at any time. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our

common stock, at our election. The initial conversion rate of 188.2353 shares of common stock per $1,000 principal amount of the 2019 Notes is equivalent to a conversion price of approximately $5.31 per share of common stock and is subject to adjustment in connection with certain events. If a Fundamental Change, as defined in the indenture governing the 2019 Notes, occurs, holders of the 2019 Notes may require us to purchase for cash all or any portion of their 2019 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date. In addition, if certain specified bankruptcy and insolvency-related events of default occur, the principal of, and accrued and unpaid interest on, all of the then

Table of Contents

outstanding notes will automatically become due and payable. If an event of default other than certain specified bankruptcy and insolvency-related events of default occurs and is continuing, the Trustee by notice to us or the holders of at least 25% in principal amount of the outstanding 2019 Notes by notice to us and the Trustee, may declare the principal of, and accrued and unpaid interest on, all of the then outstanding 2019 Notes to be due and payable.

In connection with the offering of the 2019 Notes, $36.5 million of the proceeds were deposited into an escrow account which contains an amount of permitted securities sufficient to fund, when due, the total aggregate amount of the first six scheduled semi-annual interest payments on the 2019 Notes. As of December 31, 2014, we have used $24.5 million of the amount held in the escrow account to pay the required semi-annual interest payments. The amount held in the escrow account as of December 31, 2014, was $12.2 million and is included in short-term restricted cash and investments. We have pledged our interest in the escrow account to the Trustee as security for our obligations under the 2019 Notes.

Deerfield Facility

In June 2010, we entered into a note purchase agreement with Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P., or the Original Deerfield Purchasers, pursuant to which, on July 1, 2010, we sold to the Original Deerfield Purchasers an aggregate of $124.0 million principal amount of our Secured Convertible Notes due July 1, 2015, which we refer to as the Deerfield Notes, for an aggregate purchase price of $80.0 million, less closing fees and expenses of approximately $2.0 million. As of December 31, 2014 and December 31, 2013, the remaining outstanding principal balance on the Deerfield Notes was $104.0 million and $114.0 million, respectively, which, subject to certain restrictions, is payable in cash or in stock at our discretion. We refer to the Original Deerfield Purchasers and the New Deerfield Purchasers (identified below) collectively as Deerfield.

The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of $6.0 million, payable quarterly in arrears. During the years ended December 31, 2014 and 2013, total interest expense for the Deerfield Notes was $17.7 million and $16.1 million, respectively, including the stated coupon rate and the amortization of the debt discount and debt issuance costs. The non-cash expense relating to the amortization of the debt discount and debt issuance costs was $11.7 million and $10.1 million, respectively, during those periods. The balance of unamortized fees and costs was $1.4 million and $1.4 million as of December 31, 2014 and December 31, 2013, respectively, which is included in Other assets on the accompanying Consolidated Balance Sheets.

On August 6, 2012, the parties amended the note purchase agreement to permit the issuance of the 2019 Notes and modify certain optional prepayment rights. The amendment became effective upon the issuance of the 2019 Notes and the payment to the Original Deerfield Purchasers of a $1.5 million consent fee. On August 1, 2013, the parties further amended the note purchase agreement to clarify certain of our other rights under the note purchase agreement.

On January 22, 2014, the note purchase agreement was further amended to provide us with an option to extend the maturity date of our indebtedness under the note purchase agreement to July 1, 2018. Under the terms of the extension option, which expires on March 31, 2015, we have the right to require Deerfield Partners, L.P. and Deerfield International Master Fund, L.P., or the New Deerfield Purchasers, to acquire $100 million principal amount of the Deerfield Notes and extend the maturity date to July 1, 2018. To exercise the extension option, we must provide a notice of exercise to Deerfield prior to March 31, 2015. If we exercise the extension option, the Deerfield Notes would mature on July 1, 2018, and bear interest on and after July 2, 2015, at the rate of 7.5% per annum to be paid in cash, quarterly in arrears, and 7.5% per annum to be paid in kind, quarterly in arrears, for a total interest rate of 15% per annum. We currently expect that we will exercise the extension option in accordance with the notice requirements set forth in the note purchase agreement prior to the expiration of the option on March 31, 2015. Any exercise of the extension option by us will be subject to customary conditions, including the absence of an event of default by us and the accuracy of certain of our representations and warranties set forth in the note purchase agreement, each as of the exercise date and July 1, 2015.

On July 10, 2014, the parties further amended the note purchase agreement to clarify certain provisions of the note purchase agreement.

In each of January 2014 and 2013, we made mandatory prepayments of $10.0 million on the Deerfield Notes. We were required to make an additional mandatory prepayment on the Deerfield Notes in January 2015 equal to 15% of certain revenues from collaborative arrangements, which we refer to as Development/Commercialization Revenue,

received during the prior fiscal year, subject to a maximum prepayment amount of $27.5 million. We have received no such revenue during the year ended December 31, 2014 and therefore there is no minimum prepayment due in 2015. Our obligation to make annual mandatory prepayments equal to 15% of Development/Commercialization Revenue received by us during the prior fiscal year will apply in each of 2016, 2017 and 2018 if we exercise the extension option. However, we will only be obligated to make any such annual mandatory prepayment after exercise of the extension option if the New Deerfield Purchasers provide notice to us of their election to receive the prepayment. Mandatory prepayments relating to Development/Commercialization Revenue will

Table of Contents

continue to be subject to a maximum annual prepayment amount of $27.5 million. The definition of "Development/Commercialization Revenue" expressly excludes any sale or distribution of drug or pharmaceutical products in the ordinary course of our business, and any proceeds from any Intellectual Property Sales (as further described below).

As a result of the January 2014 amendment, we are required to notify the applicable Deerfield entities of certain sales, assignments, grants of exclusive licenses or other transfers of our intellectual property pursuant to which we transfer all or substantially all of our legal or economic interests, defined as an Intellectual Property Sale, and the Deerfield entities may elect to require us to prepay the principal amount of the Deerfield Notes in an amount equal to (i) 100% of the cash proceeds of any Intellectual Property Sale relating to cabozantinib and (ii) 50% of the cash proceeds of any other Intellectual Property Sale.

Under the note purchase agreement as amended, we may voluntarily prepay the principal amount of the Deerfield Notes as follows (the amount at which we repay in each case below is referred to as the Prepayment Price):

- Prior to July 1, 2015: we may prepay all of the principal amount of the Deerfield Notes at any time at a prepayment price equal to the outstanding principal amount, plus accrued and unpaid interest through the date of such prepayment, plus all interest that would have accrued on the principal amount of the Deerfield Notes between the date of such prepayment and the applicable maturity date of the Deerfield Notes if the outstanding principal amount of the Deerfield Notes had remained outstanding through the applicable maturity date, plus all other accrued and unpaid obligations; and
- If we exercise the extension option: we may at our sole discretion, prepay all of the principal amount of the Deerfield Notes at a prepayment price equal to 105% of the outstanding principal amount of the Deerfield Notes, plus all accrued and unpaid interest through the date of such prepayment, plus, if prior to July 1, 2017, all interest that would have accrued on the principal amount of the Deerfield Notes between the date of such prepayment and July 1, 2017, if the outstanding principal amount of the Deerfield Notes as of such prepayment date had remained outstanding through July 1, 2017, plus all other accrued and unpaid obligations, collectively referred to as the Prepayment Price.

In lieu of making any portion of the Prepayment Price or mandatory prepayment in cash, subject to certain limitations (including a cap on the number of shares issuable under the note purchase agreement), we have the right to convert all or a portion of the principal amount of the Deerfield Notes into, or satisfy all or any portion of the Prepayment Price amounts or mandatory prepayment amounts with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the Deerfield Notes in cash, subject to certain limitations, we may elect to satisfy any such payment with shares of our common stock. The number of shares of our common stock issuable upon conversion or in settlement of principal and interest obligations will be based upon the discounted trading price of our common stock over a specified trading period. Upon certain changes of control of Exelixis, a sale or transfer of assets in one transaction or a series of related transactions for a purchase price of more than (i) $400 million or (ii) 50% of our market capitalization, Deerfield may require us to prepay the Deerfield Notes at the Prepayment Price. Upon an event of default, as defined in the Deerfield Notes, Deerfield may declare all or a portion of the Prepayment Price to be immediately due and payable.

In connection with the January 2014 amendment to the note purchase agreement, on January 22, 2014 we issued to the New Deerfield Purchasers two-year warrants, which we refer to as the 2014 Deerfield Warrants, to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of $9.70 per share. If we exercise the extension option, the exercise price will be reset to the lower of (i) the existing exercise price and (ii) 120% of the volume weighted average price of our common stock for the ten trading days immediately following the date of such extension election. The 2014 Deerfield Warrants are exercisable for a term of two years, subject to a two year extension if we exercise the extension option, and contain certain limitations that prevent the holder of the 2014 Deerfield Warrants from acquiring shares upon exercise of a 2014 Deerfield Warrant that would result in the number of shares beneficially owned by the holder to exceed 9.98% of the total number of shares of our common stock then issued and outstanding. The number of shares for which the 2014 Deerfield Warrants are exercisable and the associated exercise prices are subject to certain adjustments as set forth in the 2014 Deerfield Warrants. In addition, upon certain changes in control of Exelixis, to the extent the 2014 Deerfield Warrants are not assumed by the acquiring entity, or upon certain defaults under the 2014 Deerfield Warrants, the holder has the right to net exercise

the 2014 Deerfield Warrants for shares of common stock, or be paid an amount in cash in certain circumstances where the current holders of our common stock would also receive cash, equal to the Black-Scholes Merton value of the 2014 Deerfield Warrants.

In connection with the issuance of the 2014 Deerfield Warrants, we entered into a registration rights agreement with Deerfield, pursuant to which we filed a registration statement with the SEC in February 2014 covering the resale of the shares of common stock issuable upon exercise of the 2014 Deerfield Warrants.

In connection with the note purchase agreement, we also entered into a security agreement in favor of Deerfield which provides that our obligations under the Deerfield Notes will be secured by substantially all of our assets except intellectual

Table of Contents

property. On August 1, 2013, the security agreement was amended to limit the extent to which voting equity interests in any of our foreign subsidiaries shall be secured assets.

The note purchase agreement as amended and the security agreement include customary representations and warranties and covenants made by us, including restrictions on the incurrence of additional indebtedness.

Loan Agreement with Silicon Valley Bank

On May 22, 2002, we entered into a loan and security agreement with Silicon Valley Bank for an equipment line of credit. On December 21, 2004, December 21, 2006 and December 21, 2007, we amended the loan and security agreement to provide for additional equipment lines of credit and on June 2, 2010, we further amended the loan and security agreement to provide for a new seven-year term loan in the amount of $80.0 million. As of December 31, 2014, the combined outstanding principal balance due under the lines of credit and term loan was $80.4 million, compared to $82.1 million as of December 31, 2013. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We are required to repay any advances under an equipment line of credit in 48 equal monthly payments of principal and interest. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. We have the option to prepay without penalty any advance under an equipment line of credit other than advances under a single equipment line of credit, which has a 1.0% prepayment penalty, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment. In accordance with the terms of the loan and security agreement, we are required to maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement (although we are entitled to retain income earned or the amounts maintained in such accounts). Any amounts outstanding under the term loan during the continuance of an event of default under the loan and security agreement will, at the election of Silicon Valley Bank, bear interest at a per annum rate equal to 6.0%. If one or more events of default under the loan and security agreement occurs and continues beyond any applicable cure period, Silicon Valley Bank may declare all or part of the obligations under the loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us under the loan and security agreement.

2014 Restructuring

On September 2, 2014, as a consequence of the failure of COMET-1, one of our two phase 3 pivotal trials of cabozantinib in mCRPC, to meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization that when completed will result in a remaining workforce of approximately 80 full-time employees. The principal objective of the 2014 Restructuring was to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in mRCC and advanced HCC.

We expect to record an aggregate restructuring charge related to one-time termination benefits of approximately $6 million, of which approximately 95% was recorded in 2014 and the remainder is expected to be recorded in 2015. Although we do not yet have contractual commitments in place, we have made progress towards subleasing our facilities and therefore we expect to incur between $2 million and $6 million in facility-related charges as we exit certain facilities. We expect to incur additional charges as a result of the 2014 Restructuring, including property and equipment write-downs and other charges, and expect to record these expenses during fiscal year 2015 as they become determinable and as we exit certain facilities. Except for employee severance and other benefits and certain facility-related charges, we are currently unable to estimate the total amount or range of amounts expected to be incurred in connection with the 2014 Restructuring for each major type of cost or in the aggregate.

We have recorded a $6.1 million restructuring charge for the 2014 Restructuring during the year ended December 31, 2014. The restructuring charge includes $5.8 million of employee severance and other benefits that were recognized

ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates. In addition, we recorded charges of $0.3 million for property and equipment write-downs and other charges, which were partially offset by recoveries recorded in connection with the sale of excess equipment and other assets that were previously fully impaired.

Cash expenditures related to one-time termination benefits were $4.5 million in 2014 and we expect to incur additional cash expenditures of approximately $1.5 million during 2015.

Table of Contents

2010 Restructurings

Between March 2010 and May 2013, we implemented five restructurings (referred to collectively as the "2010 Restructurings") to manage costs and as a consequence of our decision in 2010 to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib. The aggregate reduction in headcount from the 2010 Restructurings was 429 employees. Charges and credits related to the 2010 Restructurings were recorded in periods other than those in which the 2010 Restructurings were implemented as a result of sublease activities for certain of our buildings in South San Francisco, California, changes in assumptions regarding anticipated sublease activities, the effect of the passage of time on our discounted cash flow computations, previously planned employee terminations, and sales of excess equipment and other assets.

For the years ended December 31, 2014, 2013 and 2012, we recorded restructuring charges of $1.5 million, $1.2 million and $9.2 million, respectively, for the 2010 Restructurings. The charges for the periods presented were related to the effect of the passage of time on our discounted cash flow computations for the exit, in prior periods, of certain of our South San Francisco buildings and changes in estimates regarding future subleases. During the year ended December 31, 2014, those charges were partially offset by $0.1 million in recoveries recorded in connection with the sale of excess equipment and other assets. The total outstanding restructuring liability related to the 2010 Restructurings is included in the current and long-term portion of restructuring on the accompanying Consolidated Balance Sheets.

We expect to pay accrued facility charges of $9.5 million, net of $9.1 million in cash to be received from our subtenants, through the end of our lease terms of the buildings, the last of which ends in 2017. We expect to incur additional restructuring charges of approximately $0.8 million relating to the effect of the passage of time on our discounted cash flow computations used to determine the accrued facilities charges through the end of the building lease terms.

Critical Accounting Estimates

The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States which requires management to make judgments. The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, including for deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances), recoverability of inventory, certain accrued liabilities including clinical trial accruals and restructuring liabilities, the valuation of the debt and equity components of our convertible debt at issuance, valuation of warrants, and share-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions.

An accounting policy is considered to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. We believe our critical accounting policies relating to revenue recognition, clinical trial accruals, inventory, stock option valuation, convertible debt valuation and restructuring liability reflect the more significant estimates and assumptions used in the preparation of our consolidated financial statements.

Revenue Recognition

Licenses and Contracts

Revenues from license fees and milestone payments primarily consist of upfront license fees and milestone payments received under various collaboration agreements. We initially recognize upfront fees received from third party collaborators as unearned revenues and then recognize these amounts on a ratable basis over the expected term of the research collaboration. Therefore, any changes in the expected term of the research collaboration will impact revenue

recognition for the given period. Often, the total research term is not contractually defined and an estimate of the term of our total obligation must be made.

Although milestone payments are generally non-refundable once the milestone is achieved, we recognize milestone revenues on a straight-line basis over the expected research term of the arrangement. This typically results in a portion of a milestone being recognized on the date the milestone is achieved, with the balance being recognized over the remaining research term of the agreement. In certain situations, we may receive milestone payments after the end of our period of

Table of Contents

continued involvement. In such circumstances, we would recognize 100% of the milestone revenues when the milestone is achieved. Milestones are classified as contract revenues in our Consolidated Statements of Operations. Collaborative agreement reimbursement revenues consist of research and development support received from collaborators and are recorded as earned based on the performance requirements by both parties under the respective contracts.

Some of our research and licensing arrangements have multiple deliverables in order to meet our customer's needs. For example, the arrangements may include a combination of intellectual property rights and research and development services. We evaluate whether the delivered elements under these arrangements have value to our collaboration partner on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered item exists. If we determine that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. A delivered item or items that do not qualify as a separate unit of accounting within the arrangement shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. A delivered item or items that do not have stand-alone value to our collaboration partner shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. For a combined unit of accounting, non-refundable upfront fees and milestones are recognized in a manner consistent with the final deliverable, which has generally been ratably over the period of the research and development obligation. For certain arrangements, the period of time over which certain deliverables will be provided is not contractually defined. Accordingly, management is required to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes.

Product Sales

We recognize revenue when it is both realized or realizable and earned, meaning persuasive evidence of an arrangement exists, delivery has occurred, title has transferred, the price is fixed or determinable, there are no remaining customer acceptance requirements, and collectability of the resulting receivable is reasonably assured. For product sales in the United States, this generally occurs upon shipment of the product to the patient by our distributor. For product sales in Europe, this occurs when our European distribution partner has accepted the product.

We sell our product, COMETRIQ, in the United States to a specialty pharmacy that benefits from customer incentives and has a right of return. We have a limited sales history and cannot reliably estimate expected returns of the product nor the discounts and rebates due to payers at the time of shipment to the specialty pharmacy. Accordingly, upon shipment to the specialty pharmacy, we record deferred revenue on our Consolidated Balance Sheets. We recognize revenue when the specialty pharmacy provides the product to a patient based on the fulfillment of a prescription. We record revenue using an analysis of prescription data from our specialty pharmacy to ascertain the date of shipment and the payer mix. This approach is frequently referred to as the "sell-through" revenue recognition model. Once the prescription has been provided to the patient, it is not subject to return unless the product is damaged.

Product sales to our European distribution partner are not subject to customer incentives, rights of return or discounts and allowances. We record revenue at the time our European distribution partner has accepted the product, a method also known as the "sell-in" revenue recognition model.

Product Sales Discounts and Allowances

We calculate gross product revenues based on the price that we charge our United States specialty pharmacy and our European distribution partner. We estimate our net product revenues by deducting discounts and allowances from our gross product revenues. Discounts and allowances for domestic sales include (a) trade allowances, such as discounts for prompt payment, (b) estimated government rebates and chargebacks, and (c) estimated costs of patient assistance programs. We initially record estimates for these deductions at the time we recognize the gross revenue. We update our estimates on a recurring basis as new information becomes available. Discounts and allowances for foreign sales for the year ended December 31, 2014 included a portion of a one-time project management fee payable to our

European distribution partner upon their achievement of a cumulative revenue goal. We recorded these fees when we determined that the achievement of the revenue goal was probable. See “Note 1. Organization and Summary of Significant Accounting Policies” of the Notes to Consolidated Financial Statements for a description of the discounts and allowances we record on our product sales.

Table of Contents

Inventory

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized as inventory, but rather are expensed as research and development costs. When regulatory approval is obtained, capitalization of inventory may begin. On November 29, 2012, the FDA approved our first product, COMETRIQ, for the treatment of progressive, metastatic MTC in the United States, where it became commercially available in late January 2013.

Inventory is valued at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on a first-in, first-out method. We analyze our inventory levels quarterly and write down inventory subject to expiry in excess of expected requirements, or has a cost basis in excess of its expected net realizable value. The related costs are recognized as cost of goods sold in the Consolidated Statements of Operations.

We analyze our estimated production levels for the following twelve month period quarterly and reclassify inventory we do not expect to use within the next twelve months in Other assets in the Consolidated Balance Sheets.

Clinical Trial Accruals

All of our clinical trials have been executed with support from CROs, and other vendors. We accrue costs for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the activities to be performed for each patient, the number of active clinical sites, and the duration for which the patients will be enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us, which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period first known. For example, during the years ended December 31, 2013 and 2012, we recorded a reduction related to prior periods of approximately $0.8 million, and $2.7 million, respectively, to our accrued clinical trial liabilities and research and development expenses primarily related to our phase 2 and phase 3 clinical trials for cabozantinib. The reductions in these expenses were a result of changes in estimates of expected scans during planned patient visits and additional assessments that will no longer occur or which were subsequently covered by our patients' insurance providers, as well as a reduction of our expected obligation in 2012 for lab services. There were no such significant reductions during the year ended December 31, 2014.

Restructuring Liability

In connection with our restructuring activities, we estimate facility-related restructuring charges which represent the present value of the estimated facility costs for which we would obtain no future economic benefit offset by estimated future sublease income, including any credit or debit relating to existing deferred rent balances associated with the vacated building.

We derive our estimates based primarily on discussions with our brokers and our own view of market conditions based in part on discussions with potential subtenants. These estimates require significant assumptions regarding the time required to contract with subtenants, the amount of idle space we would be able to sublease and potential future sublease rates. The present value factor, which also affects the level of accreted interest expense that we will recognize as additional restructuring charges over the term of the lease, is based on our estimate of our credit-risk adjusted borrowing rate at the time the initial lease-related restructuring liability is calculated.

Changes in the assumptions underlying our estimates could have a material impact on our restructuring charge and restructuring liability. We are required to continue to update our estimate of our restructuring liability in future periods as conditions warrant, and we expect to further revise our estimate in future periods as we continue our discussions with potential subtenants.

In addition, in connection with our sublease efforts for our buildings in South San Francisco, if we vacate and sublease these facilities for rates that are not significantly in excess of our costs, we would not likely recover the carrying value

of certain assets associated with these facilities. As such, we could potentially recognize additional asset impairment charges, in future periods, if we were to sublease parts of either of these buildings.

If the actual amounts differ from our estimates, the amount of restructuring charges could be materially impacted. See "Note 4 - Restructurings" of the Notes to Consolidated Financial Statements for a further discussion on our Restructurings.

Table of Contents

Valuation of Debt and Equity Instruments issued in Connection with August 2012 Offering

The 2019 Notes are accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options. Under ASC Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement feature and may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The carrying amount of the liability component of any outstanding debt instrument is computed by estimating the fair value of a similar liability without the conversion option. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The effective interest rate used in determining the liability component of the 2019 Notes was 10.09%. See “Note 8 - Debt” of the Note to Consolidated Financial Statements for further information regarding the 2019 Notes.

Warrant Valuation

Our estimate of the fair value of the 2014 Deerfield Warrants requires us to determine the appropriate fair value model and a number of complex and subjective assumptions. The most significant assumptions are our estimates of the expected volatility and the expected term of the warrant. The estimated fair value of the warrant is derived from its potential for appreciation. The more volatile the stock, the more valuable the warrant becomes because of the greater possibility of significant changes in stock price. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected term of the warrant also has a significant effect on the estimated fair value of the warrant. The longer the term, the more time the warrant holder has to allow the stock price to increase without a cash investment and thus, the more valuable the warrant. Further, lengthier warrant terms provide more opportunity to exploit market highs. Based on the terms of the warrant and evidence of warrant holder activity, we estimate the expected term of the warrant to be equal to the underlying contractual term. We are also required to estimate the likelihood of a two year extension that would result from our exercise of the extension option; as of December 31, 2014, we believe that is it probable that we will exercise this two-year extension. We remeasure this warrant liability at each reporting date and review our valuation assumptions at each respective valuation date. The assumptions used in calculating the estimated fair value of the warrant represents management’s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our warrant valuation could be materially different in the future.

Stock Option Valuation

Our estimate of compensation expense requires us to determine the appropriate fair value model and a number of complex and subjective assumptions including our stock price volatility, employee exercise patterns, future forfeitures and related tax effects. The most significant assumptions are our estimates of the expected volatility and the expected term of the award. In addition, we are required to estimate the expected forfeiture rate, including assessing the likelihood of achieving our goals for performance-based stock options, and recognize expense only for those shares expected to vest. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period. The value of a stock option is derived from its potential for appreciation. The more volatile the stock, the more valuable the option becomes because of the greater possibility of significant changes in stock price. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. The expected option term also has a significant effect on the value of the option. The longer the term, the more time the option holder has to allow the stock price to increase without a cash investment and thus, the more valuable the option. Further, lengthier option terms provide more opportunity to exploit market highs. However, empirical data show that employees, for a variety of reasons, typically do not wait until the end of the contractual term of a nontransferable option to exercise. Accordingly, companies are required to estimate the expected term of the option for input to an option-pricing model. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, from time to time we will likely change the valuation assumptions we use to value stock based awards granted in future periods. The assumptions used in calculating the fair value of share-based payment awards represent management’s best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different

assumptions, our stock-based compensation expense could be materially different in the future. As of December 31, 2014, $19.5 million of total unrecognized compensation expense related to stock options was expected to be recognized over a weighted-average period of 2.73 years and $2.6 million of total unrecognized compensation expense relating to restricted stock units was expected to be recognized over 1.88 years. See “Note 11 - Employee Benefit Plans” of the Notes to Consolidated Financial Statements for a further discussion on stock-based compensation.

Table of Contents

Exelixis International (Bermuda) Ltd.

Effective July 2013, Exelixis engaged in intercompany transactions with its wholly-owned subsidiary Exelixis International (Bermuda) Ltd., or Exelixis Bermuda, pursuant to which Exelixis Bermuda acquired the existing and future intellectual property rights to exploit cabozantinib in jurisdictions outside of the United States.

Fiscal Year Convention

Exelixis has adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2012, a 52-week year, ended on December 28, 2012, fiscal year 2013, a 52-week year, ended on December 27, 2013, fiscal year 2014, a 53-week year, ended on January 2, 2015 and fiscal year 2015, a 52-week year, will end on January 1, 2016. For convenience, references in this report as of and for the fiscal years ended December 28, 2012, December 27, 2013 and January 2, 2015, are indicated on a calendar year basis, ended December 31, 2012, 2013 and 2014, respectively.

Results of Operations – Comparison of Years Ended December 31, 2014, 2013 and 2012

Revenues

Total revenues by category were as follows (dollars in thousands):

	Year Ended December 31,		
	2014	2013	2012
Gross product revenues	$28,963	$15,702	$—
Discounts and allowances	(3,852)	(685)	—
Net product revenues	25,111	15,017	—
License revenues (1)	—	8,380	26,714
Contract revenues (2)	—	7,941	20,736
Total revenues	$25,111	$31,338	$47,450
Dollar change	$(6,227)	$(16,112)	
Percentage change	(20)%	(34)%	

(1) Includes amortization of upfront payments.

(2) Includes contingent and milestone payments.

Product revenues relate to the sale of COMETRIQ. The increase in gross product revenues reflects the continued ramp up in sales of COMETRIQ following its commercial launch in the United States in January 2013.

For domestic sales, we utilize the sell-through method to recognize product revenue. Once we have established enough history to reliably estimate expected returns of the product and the discounts and rebates due to payers, we expect to switch to the sell-in method which would result in the one-time recognition of deferred revenues attributable to sales to the specialty pharmacy that sells COMETRIQ in the United States.

For foreign sales, we utilize the sell-in method to recognize product revenue. In January 2015, we amended and restated our distribution and commercialization agreement with Sobi. Pursuant to the amended and restated agreement, the payment structure will transition from fixed fees paid to Sobi to a sales margin-based approach. As a result, commencing with all product shipments in 2015 we expect to switch to the sell-through method to recognize foreign product revenue earned under the amended agreement with Sobi.

We estimate our net product revenues by deducting discounts and allowances from our gross product revenues. Discounts and allowances for domestic sales include (a) trade allowances, such as discounts for prompt payment, (b) estimated government rebates and chargebacks, and (c) estimated costs of patient assistance programs. Discounts and allowances for foreign sales for the year ended December 31, 2014 included a portion of a one-time project management fee payable to our European distribution partner upon their achievement of a cumulative revenue goal; no such fee was recognized during the comparable periods in 2013 and 2012. During 2014, we determined that the achievement of the revenue goal was probable and therefore we recorded $2.3 million for the project management fee. If the cumulative revenue goal had been deemed probable during the year ended December 31, 2013, then $0.7 million of the $2.3 million would have been recorded in 2013.

The decrease in license and contract revenue reflects our full recognition of all revenues from our collaboration agreements with Bristol-Myers Squibb in July 2013 and $10.7 million in license revenue recognized in 2012 resulting

from the

49

Table of Contents

completion of the technology transfer under our December 2011 license agreement with Merck for our PI3K-delta program, and a $5.5 million milestone payment received in August 2012 under our collaboration agreement with Daiichi Sankyo for XL550.

Net revenues by customer were as follows (dollars in thousands):

	Year Ended December 31,		
	2014	2013	2012
Diplomat Specialty Pharmacy	$24,832	$14,004	$—
Swedish Orphan Biovitrum	279	1,013	—
Bristol-Myers Squibb	—	16,321	31,253
Merck	—	—	10,667
Daiichi Sankyo	—	—	5,500
Other	—	—	30
Total revenues	$25,111	$31,338	$47,450
Dollar change	$(6,227)	$(16,112)	
Percentage change	(20)%	(34)%	

Cost of Goods Sold

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty we are required to pay GlaxoSmithKline, and to a lesser extent, indirect labor costs, the cost of manufacturing and other third party logistics costs for our product. A significant portion of the manufacturing costs for product sales were incurred prior to regulatory approval of COMETRIQ for the treatment of progressive, metastatic MTC and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory.

The cost of goods sold and our gross margins were as follows (dollars in thousands):

	Year Ended December 31,	
	2014	2013
Cost of goods sold	$2,043	$1,118
Gross margin	92%	93%

The increase in the cost of goods sold for the year ended December 31, 2014, as compared to 2013, was a result of increased sales of COMETRIQ as well as decreases in the amount of material expensed as research and development expense prior to regulatory approval and an increase in indirect labor related to commercialization in the EU. The decrease in the gross margin for 2014, as compared to 2013, was a result of a project management fee becoming probable of being payable to our European distribution partner upon their anticipated achievement of a cumulative revenue goal. The cost of goods sold and gross margin we have experienced in this early stage of our product launch may not be representative of what we may experience going forward. Gross margin is net revenues less cost of goods sold, divided by net revenues.

Research and Development Expenses

Total research and development expenses were as follows (dollars in thousands):

	Year Ended December 31,		
	2014	2013	2012
Research and development expenses	$189,101	$178,763	$128,878
Dollar change	$10,338	$49,885	
Percentage change	6%	39%	

Research and development expenses consist primarily of clinical trial expenses, personnel expenses, allocation of general corporate costs, consulting and outside services expenses, temporary employee expenses and stock-based compensation expenses.

The increase in 2014 as compared to 2013 was predominantly driven by an increase in clinical trial costs. The increase in clinical trial costs was $14.6 million, or 15%, for 2014 as compared to 2013. The increase in clinical trial costs related

Table of Contents

predominantly to clinical trial activities for METEOR and CELESTIAL. The increases in costs for those trials was partially offset by lower clinical trial expenses for COMET-1 and the continued wind down of various other studies for cabozantinib, most notably our randomized discontinuation trial and EXAM, our phase 3 pivotal trial in MTC. There were additional increases in research and development expenses for 2014 related to temporary personnel expenses, consulting and outside services, which were partially offset by decreases in personnel expenses and stock-based compensation. Temporary personnel expenses increased by $2.9 million primarily due to increased clinical trial activities. Consulting and outside services increased by $1.1 million primarily as a result of the engagement of additional medical science liaisons required to support our increased clinical trial activities. Personnel expenses decreased by $2.8 million due primarily to the restructuring activities in the third quarter of 2014 and the elimination of employee bonus accruals as a consequence of the failure of the COMET-1 trial; the decrease was partially offset by higher wages in 2014. Stock-based compensation decreased by $2.8 million primarily due to the reversal of compensation recognized in prior periods on stock options granted subject to performance objectives and forfeitures triggered by terminations resulting from the negative COMET-1 and COMET-2 results and the 2014 Restructuring.

The increase in 2013 as compared to 2012 was primarily driven by increases in clinical trial costs, which include services performed by CROs and other vendors who support our clinical trials. Those increases in clinical trial costs were $43.1 million, or 75%, for 2013 as compared 2012. The increases in clinical trial costs were primarily related to clinical trial activities for COMET-1, and METEOR, our phase 3 pivotal trials in mCRPC and mRCC, respectively, as well as costs incurred in connection with the start-up of CELESTIAL, our phase 3 pivotal trial for advanced HCC. The increases in costs for those trials were partially offset by lower clinical trial costs related to the continued wind down of various phase 2 studies for cabozantinib, most notably the RDT as well as the EXAM trial for cabozantinib in patients with MTC.

There were additional increases in research and development expenses for 2013, related to consulting and outside services, personnel, temporary personnel, and stock-based compensation. Consulting and outside services increased by $3.6 million primarily as a result of the engagement of additional medical science liaisons required to support our increased clinical trial activities. Personnel increased by $3.4 million primarily due to hiring undertaken as a result of increased clinical trial activities as well as wage increases. Temporary personnel increased by $1.7 million primarily due to increased clinical trial activities. Stock-based compensation increased by $1.4 million primarily as a result of an increase in the number and valuation of new grants as well as an increase in the participation and valuation of purchases under our 2000 Employee Stock Purchase Plan. Those increases were partially offset by decreases of $1.4 million in depreciation and amortization expense primarily as a result of the impairment and disposition of assets related to the Restructurings and the impact of additional assets becoming fully depreciated during 2012 and a decrease in the overhead allocation of general corporate costs of $1.5 million (such as facility costs, property taxes and insurance) to research and development, primarily due to a decrease in allocable costs.

Historically, we grouped our research and development expenses into three categories: development, drug discovery and other. As noted under “Overview”, we are focusing our proprietary resources and development efforts exclusively on cabozantinib in order to maximize the therapeutic and commercial potential of this compound, and as a result, we expect nearly all of our future research and development expenses to relate to the clinical development of cabozantinib. Additionally, as a consequence of our focus on cabozantinib, we have discontinued all of our drug discovery efforts, including those previously funded under our ROR collaboration agreement with Bristol-Myers Squibb following the completion of our obligations in July 2013. As a result of this shift in business strategy and the limited relevance of the disclosure with respect to our current operations, we no longer disclose the breakdown of our research and development expenses by category.

We expect to continue to incur significant development costs for cabozantinib in future periods as we evaluate its potential in a broad development program comprising over forty-five clinical trials, including two ongoing phase 3 pivotal trials focused on mRCC and advanced HCC. In addition, postmarketing commitments in connection with the approvals of COMETRIQ in MTC dictate that we conduct additional studies in that indication. However, we expect our research and development expenses to decrease for the near term relative to prior periods as a result of our cost-saving initiatives, including the 2014 Restructuring. It is difficult to predict the magnitude of our research and

development expenses for the longer term, as such expenses will be dependent on the outcome of our ongoing phase 3 clinical trials.

We do not have reliable estimates regarding the timing of our clinical trials. We estimate that typical phase 1 clinical trials last approximately one year, phase 2 clinical trials last approximately one to two years and phase 3 clinical trials last approximately two to four years. However, the length of time may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients.

We do not have reliable estimates of total costs for a particular drug candidate, or for cabozantinib for a particular indication, to reach the market. Our potential therapeutic products are subject to a lengthy and uncertain regulatory process that

Table of Contents

may involve unanticipated additional clinical trials and may not result in receipt of the necessary regulatory approvals. Failure to receive the necessary regulatory approvals would prevent us from commercializing the product candidates affected. In addition, clinical trials of our potential product candidates may fail to demonstrate safety and efficacy, which could prevent or significantly delay regulatory approval.

Selling, General and Administrative Expenses

Total selling, general and administrative expenses were as follows (dollars in thousands):

	Year Ended December 31,		
	2014	2013	2012
Selling, general and administrative expenses	$50,829	$50,958	$31,837
Dollar change	$(129)	$19,121	
Percentage change	— %	60 %	

Selling, general and administrative expenses consist primarily of personnel expenses, consulting and outside services, facility costs, employee stock-based compensation expense, marketing, patent costs, computer and office supplies, depreciation and amortization and other legal and accounting fees. These expenses include selling and distribution costs beginning in 2013 as a result of the commercial launch of COMETRIQ in late January 2013.

The relatively flat selling, general and administrative expenses for the 2014, as compared to 2013, was the result of decreases in consulting and outside services, patent and other legal and accounting fees, which were offset by increases in personnel expenses, marketing expenses and stock-based compensation. Consulting and outside services decreased by $3.2 million, in-part due to the internalizing of our outside sales function in late 2013. Patent and other legal and accounting fees decreased by $2.6 million primarily due to decreases in activities related to patent filings and defense. Personnel expenses increased by $1.7 million, the majority of which is connected with the expansion of our U.S. sales force; that increase was partially offset by the elimination of employee bonus accruals as consequence of the failure of COMET-1. Marketing expenses increased by $1.6 million, which related primarily to an increase in pre-commercial preparation expenses for cobimetinib under our collaboration agreement with Genentech. If cobimetinib is launched commercially, we will account for our share of the net profits(losses) on a net basis, such that our share of net losses under the collaboration agreement will be reported as a part of selling, general and administrative expenses; in the period that the collaboration agreement becomes profitable to us, we will record our share of profits, net of related expenses, as revenue. Stock-based compensation increased by $0.8 million primarily due to equity award grants to members of our Board of Directors and two separation agreements; those increases were partially offset by the reversal of compensation recognized in prior periods on stock options granted subject to performance objectives and forfeitures triggered by terminations resulting from the negative COMET-1 and COMET-2 results and the 2014 Restructuring.

Approximately half of the increases for 2013 as compared 2012 were a result of an increase in expenses related to consulting and outside services provided by our U.S. sales force and our European distribution partner for the sale of COMETRIQ. The remaining increases were related to an increase of $3.2 million of personnel expenses, an increase of $1.7 million in legal and accounting fees, an increase of $1.7 million of employee stock-based compensation expense, an increase of $1.5 million of patent costs, and the reduced overhead allocations to research and development. These increases were partially offset by a decrease of $1.4 million in facilities costs.

We expect our selling, general and administrative expenses to decrease for the near term relative to prior periods as a result of our cost-saving initiatives, including the 2014 Restructuring. We are unable to predict the magnitude of our selling, general and administrative expenses for the longer term, as such expenses will be dependent on the outcome of our ongoing phase 3 clinical trials.

Restructuring Charge

On September 2, 2014, as a consequence of the failure of COMET-1, we initiated the 2014 Restructuring to reduce our workforce. Personnel reductions were initiated across our entire organization that when completed will result in a remaining workforce of approximately 80 full-time employees. The principal objective of the 2014 Restructuring was to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in mRCC and advanced HCC, for which we expect top-line results in the second quarter of 2015 and 2017, respectively.

52

Table of Contents

Total restructuring charge was as follows (dollars in thousands):

	Year Ended December 31,		
	2014	2013	2012
Restructuring charge	$7,596	$1,231	$9,171
Dollar change	$6,365	$(7,940)	
Percentage change	517%	(87)%	

We have recorded a $6.1 million restructuring charge for the 2014 Restructuring during the year ended December 31, 2014. The restructuring charge includes $5.8 million of employee severance and other benefits that were recognized ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates. In addition, we recorded charges of $0.3 million for property and equipment write-downs and other charges, which were partially offset by recoveries recorded in connection with the sale of excess equipment and other assets that were previously fully depreciated or impaired.

For the years ended December 31, 2014, 2013 and 2012, we also recorded restructuring charges of $1.5 million, $1.2 million and $9.2 million, respectively, for restructurings initiated in 2010 (the "2010 Restructurings"). During 2014, the charges for the 2010 Restructurings related to the effect of the passage of time on our discounted cash flow computations for the exit, in prior periods, of certain of our South San Francisco buildings and changes in estimates regarding future subleases. The 2013 restructuring charge was primarily related to termination benefits and was partially offset by a $0.7 million credit resulting from a new sublease entered into during the year. The 2012 restructuring charge was primarily related to termination benefits and the December 2012 determination to extend disuse of most of the remaining space in one building for the remainder of the lease term.

Total Other Income (Expense), net

Total other income (expense), net, were as follows (dollars in thousands):

	Year Ended December 31,		
	2014	2013	2012
Interest income and other, net	$4,341	$1,223	$1,986
Interest expense	(48,607)	(45,347)	(27,088)
Total other income (expense), net	$(44,266)	$(44,124)	$(25,102)
Dollar change	$(142)	$(19,022)	
Percentage change	—%	76%	

Total other income (expense), net consists primarily of interest expense incurred on our debt, partially offset by interest income earned on our cash and investments, as well as other cash and non-cash items.

Interest income and other, net for 2014 includes $1.8 million in unrealized gain on the revaluation of the 2014 Deerfield Warrants and an $0.8 million gain for a purchase price adjustment resulting from the resolution of contingencies related to the September 2011 sale of our remaining interest in Artemis Pharmaceuticals GmbH to Taconic Farms, Inc.

The change in total other expense, net for 2014 and 2013, compared to 2012, was primarily due to the increased interest expense resulting from the August 2012 issuance of the 2019 Notes. Interest expense includes aggregate non-cash interest expense on both the 2019 Notes and the Deerfield Notes of $29.5 million and $26.3 million and $15.6 million, for 2014, 2013, and 2012, respectively.

Table of Contents

Liquidity and Capital Resources

Sources and Uses of Cash

The following table summarizes our cash flow activities (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Net loss	$(268,542)	$(244,760)	$(147,645)
Adjustments to reconcile net loss to net cash used in operating activities	43,414	48,255	33,137
Changes in operating assets and liabilities	(10,277)	(2,268)	(8,638)
Net cash used in operating activities	(235,405)	(198,773)	(123,146)
Net cash provided by (used in) investing activities	146,330	144,351	(259,470)
Net cash provided by (used in) financing activities	65,492	(11,669)	478,428
Net (decrease) increase in cash and cash equivalents	(23,583)	(66,091)	95,812
Cash and cash equivalents at beginning of year	103,978	170,069	74,257
Cash and cash equivalents at end of year	$80,395	$103,978	$170,069

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013 and from the commercial launch through December 31, 2014, we have generated $40.1 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research. For a discussion of potential future capital requirements, please see "– Liquidity and Capital Resources – Capital Requirements."

Operating Activities

Our operating activities used cash of $235.4 million for the year ended December 31, 2014, compared to $198.8 million for the year ended December 31, 2013, and $123.1 million for the year ended December 31, 2012.

Cash used in operating activities for the year ended December 31, 2014 related primarily to our $249.6 million in operating expenses for the period, less non-cash expenses for accretion of debt discount totaling $29.5 million on the Deerfield Notes and the 2019 Notes, stock-based compensation totaling $10.0 million and depreciation and amortization totaling $2.4 million. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we made cash payments that resulted in a $13.2 million reduction in accounts payable and other accrued expenses during the period and paid $10.2 million for restructuring activities offset by a $6.6 million increase in accrued clinical trial liabilities.

Cash used in operating activities for 2013 related primarily to our $232.1 million in operating expenses, less non-cash expenses for accretion of debt discount totaling $26.3 million, stock-based compensation totaling $12.0 million, amortization of discounts and premiums on investments totaling $6.8 million, and depreciation and amortization totaling $3.1 million. Our operating expenses were primarily attributable to the development of cabozantinib. In addition, we paid $6.8 million for restructuring activities during the period. All of our license and contract revenues during 2013 were non-cash, which was reflected in the $14.9 million reduction in deferred revenue during the period.

Cash used in operating activities for 2012 related primarily to our $169.9 million in operating expenses for the year, less non-cash expenses for stock-based compensation and depreciation and amortization totaling $8.8 million and $5.7 million, respectively. Our operating expenses were largely attributable to the development of cabozantinib. In addition, we paid $6.3 million for our Restructurings during 2012. These uses of cash were partially offset by the receipt of $27.3 million in cash in January 2012 relating to the termination of our 2009 discovery collaboration with Sanofi in December 2011 and the upfront payment received from Merck under our P13K-delta license agreement. A significant portion of our other 2012 revenues were non-cash, which was reflected in the $41.9 million reduction in deferred revenue during the year. Cash paid for interest of $7.0 million was significantly lower than our interest expense of $27.1 million due in large part to accretion of implied interest under the Deerfield Notes and the 2019 Notes. The decrease in cash used for operating activities during 2012 as compared to 2011 was primarily due to the decrease in operating expenses during those periods.

Operating cash flows can differ from our consolidated net loss as a result of differences in the timing of cash receipts and earnings recognition and non-cash charges.

Table of Contents

Investing Activities

Our investing activities provided cash of $146.3 million for the year ended December 31, 2014, compared to cash provided of $144.4 million for the year ended December 31, 2013, and cash used of $259.5 million for 2012.

Cash provided by investing activities for 2014 was primarily due to the maturity of unrestricted and restricted investments of $273.2 million, less investment purchases of $127.7 million.

Cash provided by investing activities for 2013 was primarily due to the maturity of investments of $325.2 million, partially offset by investment purchases of $190.0 million.

Cash used by investing activities for 2012 was primarily due to the purchase of $533.5 million of investments and a net increase in restricted cash of $36.0 million, primarily in connection with the 2019 Notes. These uses were partially offset by proceeds from the maturity of investments of $310.8 million.

Financing Activities

Our financing activities provided cash of $65.5 million for the year ended December 31, 2014, compared to cash used of $11.7 million for the year ended December 31, 2013, and cash provided of $478.4 million for 2012.

Cash provided by our financing activities for 2014 was primarily due to the issuance of 10.0 million shares of common stock in January 2014 for net proceeds of $75.6 million. The cash provided by the issuance of common stock was partially offset by principal payments on debt of $11.7 million.

Cash used for financing activities for 2013 was primarily due to principal payments on debt of $13.2 million.

Cash provided by our financing activities for 2012 was due to the issuance of 12.7 million shares of common stock in February 2012 and 34.5 million shares of common stock in August 2012 for total net proceeds of $203.5 million, as well as the issuance and sale of the 2019 Notes for net proceeds of $277.7 million.

Proceeds from these financing activities are used for general working capital purposes, such as research and development activities and other general corporate purposes. Over the next several years, we are required to make certain payments on notes and bank obligations. In 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in the amount of $80.0 million. In addition, we entered into a note purchase agreement with Deerfield pursuant to which we sold to Deerfield an aggregate $124.0 million initial principal amount of the Deerfield Notes for an aggregate purchase price of $80.0 million, less closing fees and expenses of approximately $2.0 million. In August 2012, we incurred $287.5 million of indebtedness through the issuance of the 2019 Notes. See “--Certain Factors Important to Understanding Our Financial Condition and Results of Operations” above and “Note 8 - Debt” of the Notes to the Consolidated Financial Statements for additional details on these agreements.

Capital Requirements

We have incurred annual net losses since inception through the year ended December 31, 2014, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the year ended December 31, 2014, we had a net loss of $268.5 million and as of December 31, 2014, we had an accumulated deficit of $1.8 billion. These losses have had, and will continue to have, an adverse effect on our stockholders’ (deficit) equity and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Our research and development expenditures and general and administrative expenses have exceeded our revenues for each year other than 2011, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve future profitability.

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013 and from the commercial launch through December 31, 2014, we have generated $40.1 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research.

Table of Contents

The amount of our net losses will depend, in part, on the rate of growth, if any, in our sales of COMETRIQ, our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any, and receipt of royalties from cobimetinib sales outside the U.S., if any, partnering activities for cabozantinib, other license and contract revenues and the level of expenses, primarily with respect to development and commercialization activities for cabozantinib. As of December 31, 2014, we had $242.8 million in cash and investments, which included $144.3 million available for operations, $12.2 million of short-term restricted investments available for public debt service obligations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $4.7 million of long-term restricted investments. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date to July 1, 2018 of $100.0 million principal amount of the Deerfield Notes, classified within current liabilities on our Consolidated Balance Sheet as of December 31, 2014, we anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues will enable us to maintain our operations through at least December 31, 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations beyond the next twelve months is highly dependent on the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related net profits and losses, and royalties under our collaboration with Genentech. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets beyond the next twelve months, including but not limited to actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional curtailment of our development activities. However, our future capital requirements will be substantial, and we may need to access additional capital in the future. We may seek to access additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements; and, we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us. The sale of equity or convertible debt securities in the future may be substantially dilutive to our stockholders, and debt-financing arrangements may require us to pledge certain assets and enter into covenants that would restrict certain business activities or our ability to incur further indebtedness, and could contain other terms that are not favorable to our stockholders or us.

Our capital requirements will depend on many factors including but not limited to:

- the progress and scope of the development and commercialization activities with respect to cabozantinib;
- the commercial success of COMETRIQ and the revenues we generate;
- our obligation to share U.S. marketing and commercialization costs for cobimetinib under our collaboration with Genentech;
- the commercial success of cobimetinib and our share of related profits under our collaboration with Genentech;
- repayment of the $104.0 million principal amount outstanding of the Deerfield Notes, which mature on July 1, 2015 unless we exercise our extension option, for which we also will be required to make a mandatory prepayment in 2015 equal to 15% of certain revenues from collaborative arrangements (other than intercompany arrangements) received during the prior fiscal year, subject to a maximum prepayment amount of $27.5 million and for which we may be subject to similar mandatory prepayment obligations in 2016, 2017 and 2018 if we exercise our extension option;
- our ability to repay the Deerfield Notes with our common stock, which we are only able to do under specified conditions;
- repayment of our $287.5 million aggregate principal amount of the 2019 Notes, which mature on August 15, 2019, unless earlier converted, redeemed or repurchased;
- whether we enter into new collaboration agreements, licensing agreements or other arrangements (including, in particular, with respect to cabozantinib) that provide additional capital;
- our ability to control costs;

- our ability to remain in compliance with, or amend or cause to be waived, financial covenants contained in agreements with third parties;
- the amount of our cash and cash equivalents, short- and long-term investments that serve as collateral for bank lines of credit;
- future clinical trial results;
- our need to expand our product and clinical development efforts;

Table of Contents

- the cost and timing of regulatory approvals;
- the cost of clinical and research supplies for our clinical trials;
- the effect of competing technological and market developments; and
- the filing, maintenance, prosecution, defense and enforcement of patent claims and other intellectual property rights.

We may need to obtain additional funding in order to stay in compliance with financial covenants contained in our loan and security agreement with Silicon Valley Bank. The loan and security agreement requires that we maintain an amount equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all equipment lines of credit under the loan and security agreement at all times in one or more investment accounts with Silicon Valley Bank or one of its affiliates as support for our obligations under the loan and security agreement. If the balance on our deposit account(s) falls below the required level for more than 10 days, Silicon Valley Bank may declare all or part of the obligations under the loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us. If we are unable to remain in compliance with our financial covenants or if we are unable to renegotiate such covenants and the lender exercises its remedies under the agreement, we would not be able to operate under our current operating plan.

We have contractual obligations in the form of debt, loans payable, operating leases, purchase obligations and other long-term liabilities. The following chart details our contractual obligations, including any potential accrued or accreted interest, as of December 31, 2014 (in thousands):

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 year	1-3 Years	4-5 years	More than 5 years
Convertible notes (1)	$391,500	$104,000	$—	$287,500	$—
Loans payable (2)	80,381	381	80,000	—	—
Operating leases (3)	48,493	20,152	25,535	2,806	—
Purchase obligations (4)	827	827	—	—	—
Other long-term liabilities	106	—	106	—	—
Total contractual cash obligations	$521,307	$125,360	$105,641	$290,306	$—

(1) Includes our obligations under the Deerfield Notes and the 2019 Notes. See "---Certain Factors Important to Understanding Our Financial Condition and Results of Operations" and "Note 8 - Debt" of the Notes to Consolidated Financial Statements regarding the terms of the Deerfield Notes and the 2019 Notes.

(2) Includes our obligations under our loan from Silicon Valley Bank. See "---Certain Factors Important to Understanding Our Financial Condition and Results of Operations" and "Note 8 - Debt" of the Notes to Consolidated Financial Statements regarding the terms of our loan from Silicon Valley Bank.

(3) The operating lease payments do not include $9.2 million to be received through 2017 in connection with the sublease for three of our South San Francisco buildings.

(4) At December 31, 2014, we had firm purchase commitments related to manufacturing and maintenance of inventory. These commitments include a portion of our 2015 contractual minimum purchase obligation. Our actual purchases are expected to significantly exceed these amounts.

In connection with the sale of our plant trait business, we agreed to indemnify the purchaser and its affiliates up to a specified amount if they incur damages due to any infringement or alleged infringement of certain patents. We have certain collaboration licensing agreements, which contain standard indemnification clauses. Such clauses typically indemnify the customer or vendor for an adverse judgment in a lawsuit in the event of our misuse or negligence. We consider the likelihood of an adverse judgment related to an indemnification agreement to be remote. Furthermore, in the event of an adverse judgment, any losses under such an adverse judgment may be substantially offset by corporate insurance.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers, or ASU 2014-09. ASU 2014-09 supersedes the revenue recognition requirements of FASB Accounting Standards Codification, or ASC Topic 605, Revenue Recognition and

most industry-specific guidance throughout the Accounting Standards Codification, resulting in the creation of FASB ASC Topic 606, Revenue from Contracts with Customers. ASU 2014-09 requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. Adoption will be permitted using either a retrospective or modified retrospective approach, and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early

Table of Contents

adoption is not permitted. We are currently evaluating the impact of adopting this ASU, inclusive of available transitional methods on our consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern, or ASU 2014-15. ASU 2014-15 provides guidance on management's responsibility in evaluating whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued, and about related footnote disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. We are currently evaluating the impact of adopting ASU 2014-15 and its related disclosures.

Off-Balance Sheet Arrangements

As of December 31, 2014, we did not have any material off-balance-sheet arrangements, as defined by applicable SEC regulations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. As of December 31, 2014 and 2013, we had cash investments of $242.8 million and $415.9 million, respectively. Our investments are subject to interest rate risk, and our interest income may fluctuate due to changes in U.S. interest rates. We manage market risk through diversification requirements mandated by our investment policy, which limits the amount of our portfolio that can be invested in a single issuer. We limit our credit risk by limiting purchases to high-quality issuers. At December 31, 2014 and 2013, we had debt outstanding of $361.7 million and $347.2 million, respectively. Our payment commitments associated with these debt instruments are primarily fixed and consist of interest payments, principal payments, or a combination of both. The fair value of our investments and our debt will fluctuate with movements of interest rates. We have estimated the effects on our interest rate sensitive assets and liabilities based on a one percentage point hypothetical adverse change in interest rates as of December 31, 2014 and 2013. For our investments, the estimated effects of hypothetical interest rate changes are obtained from the same third-party pricing sources we use to value our investments. For debt instruments, we determine the estimated effects of hypothetical interest rate changes using the same present value model we use to determine the fair of value of those instruments. As of December 31, 2014 and 2013, a decrease in the interest rates of one percentage point would have had a net adverse change in the fair value of interest rate sensitive assets and liabilities of $7.8 million and $8.2 million, respectively, excluding the Deerfield Notes. We believe it is not practicable to determine the fair value of the Deerfield Notes, and therefore are unable to determine the impact on fair value of decrease in the interest rates of one percentage point for those notes.

In addition, we have exposure to fluctuations in certain foreign currencies in countries in which we conduct clinical trials. Most of our foreign expenses incurred were associated with establishing and conducting clinical trials for cabozantinib at sites outside of the United States. Our agreements with the foreign sites that conduct such clinical trials generally provide that payments for the services provided will be calculated in the currency of that country, and converted into U.S. dollars using various exchange rates based upon when services are rendered or the timing of invoices. When the U.S. dollar weakens against foreign currencies, the U.S. dollar value of the foreign-currency denominated expense increases, and when the U.S. dollar strengthens against these currencies, the U.S. dollar value of the foreign-currency denominated expense decreases. As of December 31, 2014 and 2013, approximately $5.5 million and $4.9 million, respectively, of our clinical accrual balance was owed in foreign currencies. An adverse change of one percentage point in the foreign currency exchange rates would not have resulted in a material impact for any periods presented.

We recorded a $0.5 million gain relating to foreign exchange fluctuations for the fiscal year ended December 31, 2014. Such gains and losses were nominal in 2013 and 2012.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

EXELIXIS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Exelixis, Inc.

We have audited the accompanying consolidated balance sheets of Exelixis, Inc. as of January 2, 2015 and December 27, 2013, and the related consolidated statements of operations, comprehensive loss, stockholders' (deficit) equity and cash flows for each of the three fiscal years in the period ended January 2, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Exelixis, Inc. at January 2, 2015 and December 27, 2013, and the consolidated results of its operations, and its cash flows for each of the three fiscal years in the period ended January 2, 2015, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Exelixis, Inc.'s internal control over financial reporting as of January 2, 2015, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 2, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Redwood City, California

March 2, 2015

Table of Contents

EXELIXIS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2014	2013
ASSETS		
Current assets:		
Cash and cash equivalents	$80,395	$103,978
Short-term investments	63,890	138,475
Short-term restricted cash and investments	12,212	12,213
Trade and other receivables	4,882	3,941
Inventory	2,381	2,890
Prepaid expenses and other current assets	3,481	5,112
Total current assets	167,241	266,609
Long-term investments	81,579	144,299
Long-term restricted cash and investments	4,684	16,897
Property and equipment, net	2,432	4,910
Goodwill	63,684	63,684
Other assets	8,340	6,888
Total assets	$327,960	$503,287
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$6,413	$9,345
Accrued clinical trial liabilities	41,545	34,958
Accrued compensation and benefits	3,350	12,797
Other accrued liabilities	12,282	13,116
Current portion of convertible notes	98,880	10,000
Current portion of loans payable	381	1,762
Current portion of restructuring	6,426	4,425
Deferred revenue	2,583	1,450
Total current liabilities	171,860	87,853
Long-term portion of convertible notes	182,395	255,147
Long-term portion of loans payable	80,000	80,328
Long-term portion of restructuring	4,365	9,047
Other long-term liabilities	4,169	4,674
Total liabilities	442,789	437,049
Commitments (Note 14)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized and no shares issued	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; issued and outstanding: 195,895,769 and 184,533,651 shares at December 31, 2014 and 2013, respectively	196	184
Additional paid-in capital	1,652,400	1,564,670
Accumulated other comprehensive (loss) income	(121)	146
Accumulated deficit	(1,767,304)	(1,498,762)
Total stockholders' (deficit) equity	(114,829)	66,238
Total liabilities and stockholders' (deficit) equity	$327,960	$503,287

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

61

Table of Contents

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2014	2013	2012
Revenues:			
Net product revenues	$25,111	$15,017	$—
License and contract revenues	—	16,321	47,450
Total revenues	25,111	31,338	47,450
Operating expenses:			
Cost of goods sold	2,043	1,118	—
Research and development	189,101	178,763	128,878
Selling, general and administrative	50,829	50,958	31,837
Restructuring charges	7,596	1,231	9,171
Total operating expenses	249,569	232,070	169,886
Loss from operations	(224,458)	(200,732)	(122,436)
Other income (expense), net:			
Interest income and other, net	4,341	1,223	1,986
Interest expense	(48,607)	(45,347)	(27,088)
Total other income (expense), net	(44,266)	(44,124)	(25,102)
Loss before income taxes	(268,724)	(244,856)	(147,538)
Income tax (benefit) provision	(182)	(96)	107
Net loss	$(268,542)	$(244,760)	$(147,645)
Net loss per share, basic and diluted	$(1.38)	$(1.33)	$(0.92)
Shares used in computing basic and diluted net loss per share amounts	194,299	184,062	160,138

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

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2014	2013	2012
Net loss	$(268,542)	$(244,760)	$(147,645)
Other comprehensive (loss) income, net of tax of $0, $106 and $0 (1)	(267)	238	46
Comprehensive loss	$(268,809)	$(244,522)	$(147,599)

(1) Other comprehensive (loss) income consisted solely of unrealized gains or losses on available for sale securities arising during the periods presented. There were no reclassification adjustments to net loss resulting from realized gains or losses on the sale of securities.

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

Table of Contents

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2011	135,563,735	$135	$1,196,992	$ (138)	$(1,106,357)	$ 90,632
Net loss	—	—	—	—	(147,645)	(147,645)
Other comprehensive income	—	—	—	46	—	46
Issuance of common stock under stock plans	983,478	1	2,821	—	—	2,822
Sale of shares of common stock	47,150,000	47	203,914	—	—	203,961
Equity component of convertible debt issued, net	—	—	137,785	—	—	137,785
Stock-based compensation expense	—	—	8,833	—	—	8,833
Balance at December 31, 2012	183,697,213	183	1,550,345	(92)	(1,254,002)	296,434
Net loss	—	—	—	—	(244,760)	(244,760)
Other comprehensive income	—	—	—	238	—	238
Issuance of common stock under stock plans	836,438	1	2,294	—	—	2,295
Stock-based compensation expense	—	—	12,031	—	—	12,031
Balance at December 31, 2013	184,533,651	184	1,564,670	146	(1,498,762)	66,238
Net loss	—	—	—	—	(268,542)	(268,542)
Other comprehensive loss	—	—	—	(267)	—	(267)
Issuance of common stock under stock plans	1,362,118	2	2,091	—	—	2,093
Sale of shares of common stock	10,000,000	10	75,633	—	—	75,643
Stock-based compensation expense	—	—	10,006	—	—	10,006
Balance at December 31, 2014	195,895,769	$196	$1,652,400	$ (121)	$(1,767,304)	$ (114,829)

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

Table of Contents

EXELIXIS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	$(268,542)	$(244,760)	$(147,645)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,391	3,147	5,513
Stock-based compensation expense	10,006	12,031	8,833
Accretion of debt discount	29,534	26,290	14,752
Gain on sale of business	(838)	—	—
Changes in the fair value of warrants	(1,840)	—	—
Other	4,161	6,787	4,039
Changes in assets and liabilities:			
Trade and other receivables	(941)	(1,190)	27,038
Inventory	509	(2,890)	—
Prepaid expenses and other current assets	1,526	1,034	(1,764)
Other assets	(2,149)	—	(1,966)
Accounts payable and other accrued liabilities	(13,213)	8,691	5,149
Clinical trial liability	6,587	14,398	1,169
Restructuring liability	(2,302)	(5,750)	5,244
Deferred revenue	1,133	(14,871)	(41,920)
Other long-term liabilities	(1,427)	(1,690)	(1,588)
Net cash used in operating activities	(235,405)	(198,773)	(123,146)
Cash flows from investing activities:			
Purchases of property and equipment	(474)	(2,171)	(2,717)
Proceeds from sale of property and equipment	392	143	1,943
Proceeds from sale of business	838	—	—
Proceeds from maturities of restricted cash and investments	20,354	17,268	5,499
Purchase of restricted cash and investments	(8,143)	(6,085)	(41,485)
Proceeds from maturities of investments	252,891	325,171	310,765
Purchases of investments	(119,528)	(189,975)	(533,475)
Net cash provided by (used in) investing activities	146,330	144,351	(259,470)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	75,643	—	203,479
Proceeds from exercise of stock options and warrants	120	72	929
Proceeds from employee stock purchase plan	1,438	1,429	1,217
Proceeds from debt issuance, net	—	—	277,673
Principal payments on debt	(11,709)	(13,170)	(4,870)
Net cash provided by (used in) financing activities	65,492	(11,669)	478,428
Net (decrease) increase in cash and cash equivalents	(23,583)	(66,091)	95,812
Cash and cash equivalents at beginning of year	103,978	170,069	74,257
Cash and cash equivalents at end of year	$80,395	$103,978	$170,069
Supplemental cash flow disclosure:			
Cash paid for interest	$19,109	$19,160	$6,982
Cash paid for taxes	$60	$—	$1,118
Non-cash financing activity:			

Issuance of warrants in connection with amendment to convertible notes	$2,762	$—	$—

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

Table of Contents

EXELIXIS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Exelixis, Inc. ("Exelixis," "we," "our" or "us") is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. We were incorporated in Delaware in November 1994 as Exelixis Pharmaceuticals, Inc. and we changed our name to Exelixis, Inc. in February 2000. Our two most advanced assets are cabozantinib, our wholly-owned inhibitor of multiple receptor tyrosine kinases, and cobimetinib, a potent, highly selective inhibitor of MEK, a serine/threonine kinase, which we out-licensed to Genentech (a member of the Roche Group) ("Genentech").

Our development and commercialization efforts are focused primarily on cabozantinib. We are evaluating cabozantinib in a broad development program comprising over forty-five clinical trials, across multiple indications, including two ongoing phase 3 pivotal trials focusing on metastatic renal cell carcinoma ("mRCC"), and advanced hepatocellular carcinoma ("HCC").

Cabozantinib was approved by the United States Food and Drug Administration, ("FDA"), on November 29, 2012, for the treatment of progressive, metastatic medullary thyroid cancer ("MTC") in the United States under the brand name COMETRIQ(R). COMETRIQ became commercially available in the United States in January 2013. In March 2014, the European Commission granted cabozantinib conditional marketing authorization for the treatment of adult patients with progressive, unresectable locally advanced or metastatic MTC, also under the brand name COMETRIQ.

Our second most advanced oncology asset, cobimetinib, is being evaluated by Genentech in a broad development program, including coBRIM, a phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation. Roche has completed the Marketing Authorization Application ("MAA"), for cobimetinib in combination with vemurafenib in the European Union. In the United States, Genentech filed its New Drug Application ("NDA") in December 2014.

Basis of Consolidation

The consolidated financial statements include the accounts of Exelixis and those of our wholly-owned subsidiaries, including Exelixis International (Bermuda) Ltd. ("Exelixis Bermuda"). Effective July 2013, Exelixis engaged in intercompany transactions whereby Exelixis Bermuda acquired the existing and future intellectual property rights to exploit cabozantinib in jurisdictions outside of the United States. Exelixis Bermuda's functional currency is the U.S. Dollar. All intercompany balances and transactions have been eliminated.

Basis of Presentation

Exelixis has adopted a 52- or 53-week fiscal year that generally ends on the Friday closest to December 31st. Fiscal year 2012, a 52-week year, ended on December 28, 2012, fiscal year 2013, a 52-week year, ended on December 27, 2013, fiscal year 2014, a 53-week year, ended on January 2, 2015 and fiscal year 2015, a 52-week year, will end on January 1, 2016. For convenience, references in this report as of and for the fiscal years ended December 28, 2012, December 27, 2013 and January 2, 2015, are indicated on a calendar year basis, ended December 31, 2012, 2013 and 2014, respectively. The quarter ended January 2, 2015 is a 14-week fiscal quarter; all other interim periods presented are 13-week fiscal quarters.

Segment Information

We operate as a single reportable segment.

Use of Estimates

The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States which requires management to make judgments. The preparation of our consolidated financial statements is in conformity with accounting principles generally accepted in the United States which requires management to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures. On an ongoing basis, management evaluates its estimates including, but not limited to, those related to revenue recognition, including for deductions from revenues (such as rebates, chargebacks, sales returns and sales allowances), recoverability of inventory, certain accrued liabilities including

clinical trial accruals and restructuring liabilities, the valuation

Table of Contents

of the debt and equity components of our convertible debt at issuance, valuation of warrants, and share-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Need to Access Additional Capital

We have incurred annual net losses since inception through the year ended December 31, 2014, with the exception of the 2011 fiscal year. We anticipate net losses and negative operating cash flow for the foreseeable future. For the year ended December 31, 2014, we had a net loss of $268.5 million and as of December 31, 2014, we had an accumulated deficit of $1.8 billion. These losses have had, and will continue to have, an adverse effect on our stockholders' (deficit) equity and working capital. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses or whether or when we will become profitable, if at all. Our research and development expenditures and general and administrative expenses have exceeded our revenues for each year other than 2011, and we expect to spend significant additional amounts to fund the continued development and commercialization of cabozantinib. As a result, we expect to continue to incur substantial operating expenses, and, consequently, we will need to generate significant additional revenues to achieve future profitability.

We commercially launched COMETRIQ for the treatment of progressive, metastatic MTC in the United States in late January 2013 and from the commercial launch through December 31, 2014, we have generated $40.1 million in net revenues from the sale of COMETRIQ. Other than revenues from COMETRIQ, we have derived substantially all of our revenues since inception from collaborative research and development agreements which depend on research funding, the achievement of milestones, and royalties we earn from any future products developed from the collaborative research.

The amount of our net losses will depend, in part, on the rate of growth, if any, in our sales of COMETRIQ, our share of the net profits and losses for the commercialization for cobimetinib in the U.S., if any, and receipt of royalties from cobimetinib sales outside the U.S., if any, partnering activities for cabozantinib, other license and contract revenues and the level of expenses, primarily with respect to development and commercialization activities for cabozantinib. As of December 31, 2014, we had $242.8 million in cash and investments, which included $144.3 million available for operations, $12.2 million of short-term restricted investments available for public debt service obligations, $81.6 million of compensating balance investments that we are required to maintain on deposit with Silicon Valley Bank, and $4.7 million of long-term restricted investments. Taking into account our cost saving measures, including the planned effects of the 2014 Restructuring that we initiated on September 2, 2014, and the expected extension of the maturity date to July 1, 2018 of $100.0 million principal amount of the Deerfield Notes, classified within current liabilities on our Consolidated Balance Sheet as of December 31, 2014, we anticipate that our current cash and cash equivalents, and short-term investments available for operations, and product revenues will enable us to maintain our operations through at least December 31, 2015. While a forecast of future events is inherently uncertain, our ability to sustain our business operations beyond the next twelve months is highly dependent on the commercial success of COMETRIQ and the revenues we generate as well as the commercial success of cobimetinib and our share of related net profits and losses, and royalties under our collaboration with Genentech. Consistent with the actions we have taken in the past, we will prioritize necessary and appropriate steps to ensure the continued operation of our business and preservation of the value of our assets beyond the next twelve months, including but not limited to actions such as further reductions in headcount, additional consolidation of administrative functions, asset sales and additional curtailment of our development activities. However, our future capital requirements will be substantial, and we may need to access additional capital in the future. We may seek to access additional capital to support future operations through licensing, partnering or other strategic collaborative arrangements; and, we may pursue the issuance of equity or debt securities or external borrowings. It is unclear when any such transactions will occur, on satisfactory terms or at all. Our ability to raise additional capital in the equity and debt markets, should we choose to do so, is dependent on a number of factors, including, but not limited to, the market demand for our common stock, which itself is subject to a number of pharmaceutical development and business risks and uncertainties, as well as the uncertainty that we would be able to raise such additional capital at a price or on terms that are favorable to us.

Cash and Investments

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents include investments in high-grade, short-term money market funds, commercial paper and municipal securities, which are subject to minimal credit and market risk.

We have designated all investments as available-for-sale and therefore, such investments are reported at fair value,

Table of Contents

with unrealized gains and losses recorded in accumulated other comprehensive (loss) income. For securities sold prior to maturity, the cost of securities sold is based on the specific identification method. Realized gains and losses on the sale of investments are recorded in interest and other income, net.

We classify those investments we do not require for use in current operations that mature in more than 12 months as Long-term investments on our Consolidated Balance Sheets. Additionally, those investments that collateralize loan balances with terms that extend 12 months or longer were classified as long-term investments even if the investment's remaining term to maturity was one year or less; they are not restricted to withdrawal.

All of our investments are subject to a quarterly impairment review. We recognize an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary included the length of time and extent to which the investments fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, our intent to sell the security and whether or not we will be required to sell the security before the recovery of its amortized cost. During the years ended December 31, 2014, 2013, and 2012, we did not record any significant other-than-temporary impairment charges on our available-for-sale securities.

Fair Value Measurements

Fair value reflects the amounts 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 (exit price). We disclose the fair value of financial instruments for assets and liabilities for which the value is practicable to estimate. For those financial instruments measured and recorded at fair value on a recurring basis, we also provide fair value hierarchy information in these Notes to Consolidated Financial Statements. The fair value hierarchy has the following three levels:

Level 1 – quoted prices (unadjusted) in active markets for identical assets and liabilities that the reporting entity can access at the measurement date.

Level 2 – observable inputs, other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly. These inputs include using prices from independent pricing services based on quoted prices in active markets for similar instruments or on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets.

Level 3—unobservable inputs.

A review of the fair value hierarchy classification is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification of levels for certain investments within the fair value hierarchy.

Inventory

Inventory is valued at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on a first-in, first-out method. We analyze our inventory levels quarterly and write down inventory subject to expiry in excess of expected requirements, or has a cost basis in excess of its expected net realizable value. The related costs are recognized as cost of goods sold in the Consolidated Statements of Operations.

We analyze our estimated production levels for the following twelve month period quarterly and reclassify inventory we do not expect to use within the next twelve months in Other assets in the Consolidated Balance Sheets.

We consider regulatory approval of product candidates to be uncertain and product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval were not capitalized as inventory but were expensed as research and development costs. When regulatory approval is obtained, we begin capitalization of inventory related costs.

Table of Contents

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the following estimated useful lives:

Equipment and furniture	5 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of lease life or 7 years

Capitalized software includes certain internal use computer software costs.

Repairs and maintenance costs are charged to expense as incurred.

Goodwill

Goodwill amounts have been recorded as the excess purchase price over tangible assets, liabilities and intangible assets acquired based on their estimated fair value, by applying the purchase method. Goodwill is not subject to amortization. We evaluate goodwill for impairment on an annual basis and on an interim basis if events or changes in circumstances between annual impairment tests indicate that the asset might be impaired. When evaluating goodwill for impairment we must determine the reporting units that exist within Exelixis. We have determined that we have one reporting unit as of December 31, 2014 and 2013.

Long-Lived Assets

Long-lived assets include property and equipment. The carrying value of our long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount.

Revenue Recognition

We recognize revenue from the sale of COMETRIQ and from license fees, milestones and contingent payments earned on research and collaboration arrangements.

License and Contract Revenues

License, research commitment and other non-refundable payments received in connection with research collaboration agreements are deferred and recognized on a straight-line basis over the period of continuing involvement, generally the research term specified in the agreement. Contract research revenues are recognized as services are performed pursuant to the terms of the agreements. Any amounts received in advance of performance are recorded as deferred revenue. Payments are not refundable if research is not successful. License fees are classified as license revenues in our Consolidated Statements of Operations.

We enter into corporate collaborations under which we may obtain upfront license fees, research funding, contingent, milestone and royalty payments. Our deliverables under these arrangements typically consist of intellectual property rights and research and development services. We evaluate whether the delivered elements under these arrangements have value to our collaboration partner on a stand-alone basis and whether objective and reliable evidence of fair value of the undelivered item exists. If we determine that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. The selling price used for each deliverable will be based on vendor-specific objective evidence, if available, third-party evidence if vendor-specific objective evidence is not available, or estimated selling price if neither vendor-specific or third-party evidence is available. A delivered item or items that do not qualify as a separate unit of accounting within the arrangement shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. A delivered item or items that do not have stand-alone value to our collaboration partner shall be combined with the other applicable undelivered items within the arrangement. The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting. For a combined unit of accounting, non-refundable upfront fees and milestones are recognized in a manner consistent with the final deliverable, which has generally been ratably over the period of the research and development obligation.

Table of Contents

Contingency payments (received upon the achievement of certain events by our collaborators) and milestone payments (received upon the achievement of certain events by us) are non-refundable and recognized as revenues over the period of the research arrangement. This typically results in a portion of the payments being recognized at the date the contingency or milestone is achieved, which portion is equal to the applicable percentage of the research term that has elapsed at the date of achievement, and the balance being recognized over the remaining research term of the agreement. In certain situations, we may receive contingent payments after the end of our period of continued involvement. In such circumstances, we would recognize 100% of the contingent revenues when the contingency is achieved. Contingency and milestones payments, when recognized as revenue, are classified as contract revenues in our Consolidated Statements of Operations.

Revenues and expenses from collaborations that are not co-development agreements are recorded as contract revenues or research and development expenses in the period incurred.

Net Product Revenues

We recognize revenue when it is both realized or realizable and earned, meaning persuasive evidence of an arrangement exists, delivery has occurred, title has transferred, the price is fixed or determinable, there are no remaining customer acceptance requirements, and collectability of the resulting receivable is reasonably assured. For product sales in the United States, this generally occurs upon shipment of the product to the patient by our distributor. For product sales in Europe, this occurs when our European distribution partner has accepted the product.

We sell our product, COMETRIQ, in the United States to a specialty pharmacy that benefits from customer incentives and has a right of return. We have a limited sales history and cannot reliably estimate expected returns of the product nor the discounts and rebates due to payers at the time of shipment to the specialty pharmacy. Accordingly, upon shipment to the specialty pharmacy, we record deferred revenue on our Consolidated Balance Sheets. We recognize revenue when the specialty pharmacy provides the product to a patient based on the fulfillment of a prescription. We record revenue using an analysis of prescription data from our specialty pharmacy to ascertain the date of shipment and the payer mix. This approach is frequently referred to as the “sell-through” revenue recognition model. Once the prescription has been provided to the patient, it is not subject to return unless the product is damaged.

Product sales to our European distribution partner are not subject to rights of return or discounts and allowances. We record revenue at the time our European distribution partner has accepted the product, a method also known as the “sell-in” revenue recognition model.

Product Sales Discounts and Allowances

We calculate gross product revenues based on the price that we charge our United States specialty pharmacy and our European distribution partner. We estimate our domestic net product revenues by deducting from our gross product revenues (a) trade allowances, such as discounts for prompt payment, (b) estimated government rebates and chargebacks, and (c) estimated costs of patient assistance programs. We initially record estimates for these deductions at the time we recognize the gross revenue. We update our estimates on a recurring basis as new information becomes available.

Customer Credits: The United States specialty pharmacy receives a discount of 2% for prompt payment. We expect this specialty pharmacy will earn 100% of its prompt payment discounts and, therefore, we deduct the full amount of these discounts from total product sales when revenues are recognized.

Mandated Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and other government programs. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimates for the expected utilization of rebates are based on customer and payer data received from the United States specialty pharmacy. Rebates are generally invoiced by the payer and paid in arrears, such that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter’s shipments to patients, plus an accrual balance for known prior quarter’s unpaid rebates. If actual future rebates vary from estimates, we may need to adjust our accruals, which would affect net revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts that occur when contracted customers purchase directly from a specialty pharmacy. Contracted customers, which currently consist primarily of Public Health Service institutions, non-profit

clinics, and Federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The United States specialty pharmacy, in turn, charges back to us the difference between the price initially paid by the specialty pharmacy and the discounted price paid to the specialty pharmacy by the customer. The allowance for chargebacks is based on sales to contracted customers.

Table of Contents

Medicare Part D Coverage Gap: In the United States, the Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Our estimates for expected Medicare Part D coverage gap are based in part on third party market research data and on customer and payer data received from the United States specialty pharmacy. Funding of the coverage gap is invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's shipments to patients, plus an accrual balance for prior sales. If actual future funding varies from estimates, we may need to adjust our accruals, which would affect net revenue in the period of adjustment.
Co-payment Assistance: Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption using customer data provided by our United States specialty pharmacy.
Our European distribution partner is entitled to receive a project management fee based upon the achievement of a pre-specified revenue goal which, when deemed probable, is ratably accrued as a reduction to gross revenue.

Patient Assistance Program

We provide COMETRIQ at no cost to eligible patients who have no insurance and meet certain financial and clinical criteria through our Patient Assistance Program (“PAP”). We record the cost of the product as a selling, general and administrative expense at the time the product is designated as PAP inventory.

Cost of Goods Sold

Cost of goods sold is related to our product revenues and consists primarily of a 3% royalty and indirect labor costs, and to a lesser extent, the cost of manufacturing and other third party logistics costs of our product. A significant portion of the manufacturing costs for product sales were incurred prior to regulatory approval of COMETRIQ for the treatment of progressive, metastatic MTC and, therefore, were expensed as research and development costs when those costs were incurred, rather than capitalized as inventory.

In accordance with our product development and commercialization agreement with GlaxoSmithKline, we are required to pay GlaxoSmithKline a 3% royalty on the Net Sales of any product incorporating cabozantinib, including COMETRIQ. Net Sales is defined in the product development and commercialization agreement generally as the gross invoiced sales price less customer credits, rebates, chargebacks, shipping costs, customs duties, and sales tax and other similar tax payments we are required to make.

Research and Development Expenses

Research and development costs are expensed as incurred and include costs associated with research performed pursuant to collaborative agreements. Research and development costs consist of direct and indirect internal costs related to specific projects as well as fees paid to other entities that conduct certain research activities on our behalf. Substantial portions of our preclinical studies and all of our clinical trials have been executed with support from third-party contract research organizations (“CROs”) and other vendors. We accrue expenses for preclinical studies performed by our vendors based on certain estimates over the term of the service period and adjust our estimates as required. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients will be enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period first known. For example, during the years ended December 31, 2013 and 2012, we recorded a reduction related to prior periods of approximately $0.8 million, and $2.7 million, respectively, to our accrued clinical trial liabilities and research and development expenses primarily related to our phase 2 and phase 3 clinical trials for cabozantinib. There were no such significant adjustments during the year ended December 31, 2014.

Table of Contents

Net (Loss) Income Per Share

Basic net (loss) income per share is computed by dividing the net (loss) income for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net (loss) income per share gives effect to potential incremental common shares issuable upon the exercise of stock options and warrants, and shares issuable pursuant to restricted stock units ("RSUs") (calculated based on the treasury stock method), and upon conversion of our convertible debt (calculated using an as-if-converted method) as long as such shares are not anti-dilutive. The calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares.

Foreign Currency Translation and Remeasurement

Monetary assets and liabilities denominated in currencies other than the functional currency are remeasured using exchange rates in effect at the end of the period and related gains or losses are recorded in interest income and other, net. Gains and losses on the remeasurement of monetary assets and liabilities were not material for any of the years presented. We do not have any nonmonetary assets or liabilities denominated in currencies other than the U.S. dollar.

Stock-Based Compensation

Stock-based compensation expense for all stock-based compensation awards is based on the grant date fair value estimated using the Black-Scholes Merton option pricing model. Because there is a market for options on our common stock, we have considered implied volatilities as well as our historical realized volatilities when developing an estimate of expected volatility. We estimate the term using historical data and peer data. We recognize compensation expense on a straight-line basis over the requisite service period. Compensation expense relating to awards subject to performance conditions is recognized if it is probable that the performance goals will be achieved. The probability of achievement is assessed on a quarterly basis. The total number of awards expected to vest is adjusted for estimated forfeitures. We have elected to use the simplified method to calculate the beginning pool of excess tax benefits.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements of FASB Accounting Standards Codification ("ASC") Topic 605, Revenue Recognition and most industry-specific guidance throughout the Accounting Standards Codification, resulting in the creation of FASB ASC Topic 606, Revenue from Contracts with Customers. ASU 2014-09 requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. Adoption will be permitted using either a retrospective or modified retrospective approach, and is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of adopting this ASU, inclusive of available transitional methods on our consolidated financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements-Going Concern ("ASU 2014-15"). ASU 2014-15 provides guidance on management's responsibility in evaluating whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued, and about related footnote disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. We are currently evaluating the impact of adopting ASU 2014-15 and its related disclosures.

NOTE 2. RESEARCH AND COLLABORATION AGREEMENTS

Cobimetinib Collaboration

In December 2006, we entered into a worldwide co-development agreement with Genentech for the development and commercialization of cobimetinib. Exelixis discovered cobimetinib internally and advanced the compound to investigational new drug ("IND"), status.

Genentech paid upfront and milestone payments of $25.0 million in December 2006 and $15.0 million in January 2007 upon signing of the co-development agreement and with the submission of the IND for cobimetinib. Under the terms of

Table of Contents

the agreement, we were responsible for developing cobimetinib through the determination of the maximum-tolerated dose ("MTD") in a phase 1 clinical trial, and Genentech had the option to co-develop cobimetinib, which Genentech could exercise after receipt of certain phase 1 data from us. In March 2008, Genentech exercised its option, triggering a payment to us of $3.0 million, which we received in April 2008. After MTD was determined, we granted to Genentech an exclusive worldwide revenue-bearing license to cobimetinib in March 2009, at which point Genentech became responsible for completing the phase 1 clinical trial and subsequent clinical development. We received an additional $7.0 million payment in March 2010.

On December 15, 2014, Genentech completed the filing of its NDA with the FDA for cobimetinib. FDA has granted priority review to the NDA, with a PDUFA date of August 11, 2015. Priority Review is granted to a pharmaceutical product that, if approved, would meet an unmet medical need for a serious and life-threatening condition. Cobimetinib previously received Fast Track designation from the FDA.

Under the terms of our agreement with Genentech, we are entitled to an initial equal share of U.S. profits and losses for cobimetinib, with our share decreasing as sales increase, and we will share equally in the U.S. marketing and commercialization costs. The profit share has multiple tiers--we are entitled to 50% of profits from the first $200 million of U.S. actual sales, decreasing to 30% of profits from U.S. actual sales in excess of $400 million. We are entitled to low double-digit royalties on ex-U.S. net sales. In November 2013, we exercised our option to co-promote in the U.S. We will provide up to 25% of the total sales force for cobimetinib in the U.S. if commercialized, and will call on customers and otherwise engage in promotional activities using that sales force, consistent with the terms of the co-development agreement and a co-promotion agreement to be entered into by the parties. If Genentech terminates the co-development agreement without cause, all licenses that were granted to Genentech under the agreement terminate and revert to us. Additionally, we would receive, subject to certain conditions, licenses from Genentech to research, develop and commercialize reverted product candidates.

We did not any recognize any revenue under our current agreement with Genentech during the three years ended December 31, 2014.

Other Collaborations

We have established collaborations with other leading pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb Company ("Bristol-Myers Squibb"), Sanofi, Merck (known as MSD outside of the United States and Canada) and Daiichi Sankyo Company Limited ("Daiichi Sankyo"), for various compounds and programs in our portfolio. Pursuant to these collaborations, we have fully out-licensed compounds or programs to a partner for further development and commercialization. We have no further development cost obligations under our collaborations and may be entitled to receive milestones and royalties, or in the case of cobimetinib, a share of profits (or losses) from commercialization.

With respect to these partnered compounds, we are eligible to receive potential contingent payments under our collaborations totaling approximately $2.3 billion in the aggregate on a non-risk adjusted basis, of which approximately 10% are related to clinical development milestones, approximately 42% are related to regulatory milestones and approximately 48% are related to commercial milestones, all to be achieved by the various licensees which may not be paid, if at all, until certain conditions are met.

Bristol-Myers Squibb

ROR Collaboration Agreement

In October 2010, we entered into a worldwide collaboration with Bristol-Myers Squibb pursuant to which each party granted to the other certain intellectual property licenses to enable the parties to discover, optimize and characterize ROR antagonists that may subsequently be developed and commercialized by Bristol-Myers Squibb. In November 2010 we received a nonrefundable upfront cash payment of $5.0 million from Bristol-Myers Squibb. Additionally, for each product developed by Bristol-Myers Squibb under the collaboration, we will be eligible to receive payments upon the achievement by Bristol-Myers Squibb of development and regulatory milestones of up to $252.5 million in the aggregate and commercialization milestones of up to $150.0 million in the aggregate, as well as royalties on commercial sales of any such products. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to a wholly-owned subsidiary.

Under the terms of the collaboration agreement, we were responsible for activities related to the discovery, optimization and characterization of the ROR antagonists during the collaborative research period. In July 2011, we earned a $2.5 million milestone payment for achieving certain lead optimization criteria. The collaborative research period began on October 8, 2010 and ended on July 8, 2013. Since the end of the collaborative research period, Bristol-Myers Squibb has and will continue to have sole responsibility for any further research, development, manufacture and commercialization of products developed under the collaboration and will bear all costs and expenses associated with those activities.

Table of Contents

Bristol-Myers Squibb may, at any time, terminate the collaboration agreement upon certain prior notice to us on a product-by-product and country-by-country basis. In addition, either party may terminate the agreement for the other party's uncured material breach. In the event of termination by Bristol-Myers Squibb at will or by us for Bristol-Myers Squibb's uncured material breach, the license granted to Bristol-Myers Squibb would terminate, the right to such product would revert to us and we would receive a royalty-bearing license for late-stage reverted compounds and a royalty-free license for early-stage reverted compounds from Bristol-Myers Squibb to develop and commercialize such product in the related country. In the event of termination by Bristol-Myers Squibb for our uncured material breach, Bristol-Myers Squibb would retain the right to such product, subject to continued payment of milestones and royalties.

We recognized license and contract revenues of $1.5 million and $2.9 million during the years ended December 31, 2013 and 2012, respectively, under our ROR collaboration agreement with Bristol-Myers Squibb. We recognized no such revenue during the year ended December 31, 2014.

LXR Collaboration Agreement

In December 2005, we entered into a collaboration agreement with Bristol-Myers Squibb for the discovery, development and commercialization of novel therapies targeted against LXR, a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic disorders. This agreement became effective in January 2006, at which time we granted Bristol-Myers Squibb an exclusive worldwide license with respect to certain intellectual property primarily relating to compounds that modulate LXR, including BMS-852927 (XL041). During the research term, we jointly identified drug candidates with Bristol-Myers Squibb that were ready for IND-enabling studies. After the selection of a drug candidate for further clinical development by Bristol-Myers Squibb, Bristol-Myers Squibb agreed to be solely responsible for further preclinical development as well as clinical development, regulatory, manufacturing and sales/marketing activities for the selected drug candidate. We do not have rights to reacquire the drug candidates selected by Bristol-Myers Squibb. The research term expired in January 2010 and we transferred the technology to Bristol-Myers Squibb in 2011 to enable it to continue the LXR program. BMS has terminated development of XL041 and we have been advised that BMS is continuing additional preclinical research on the program. The collaboration agreement was amended and restated in April 2011 in connection with an assignment of patents to a wholly-owned subsidiary.

Under the collaboration agreement, Bristol-Myers Squibb paid us a nonrefundable upfront cash payment in the amount of $17.5 million and was obligated to provide research and development funding of $10.0 million per year for an initial research period of two years. In September 2007, the collaboration was extended at Bristol-Myers Squibb's request through January 12, 2009, and in November 2008, the collaboration was further extended at Bristol-Myers Squibb's request through January 12, 2010. Under the collaboration agreement, Bristol-Myers Squibb is required to pay us contingent amounts associated with development and regulatory milestones of up to $138.0 million per product for up to two products from the collaboration. In addition, we are also entitled to receive payments associated with sales milestones of up to $225.0 million and royalties on sales of any products commercialized under the collaboration. In connection with the extension of the collaboration through January 2009 and subsequently through January 2010, Bristol-Myers Squibb paid us additional research funding of approximately $7.7 million and approximately $5.8 million, respectively. In December 2007, we received $5.0 million in connection with the achievement by Bristol-Myers Squibb, of a development milestone with respect to BMS-852927 (XL041).

We did not any recognize any revenue under our LXR collaboration agreement with Bristol-Myers Squibb during the three years ended December 31, 2014.

Terminated Agreements

During 2013, a number of additional license and collaboration agreements with Bristol-Myers Squibb were terminated or concluded, including a October 2010 license agreement for our small-molecule TGR5 agonist program and a January 2007 agreement to discover, develop and commercialize novel targeted therapies for the treatment of cancer. As a result of the termination, Bristol-Myers Squibb's license relating to cabozantinib terminated and its rights to cabozantinib reverted to us, and we received, subject to certain terms and conditions, licenses from Bristol-Myers Squibb to research, develop and commercialize cabozantinib. We have no continuing obligations under these terminated agreements.

We recognized license and contract revenues of $14.8 million and $28.4 million during the years ended December 31, 2013 and 2012, respectively, under these terminated agreements with Bristol-Myers Squibb. We recognized no such revenue during the year ended December 31, 2014.

Sanofi

In May 2009, we entered into a global license agreement with Sanofi for SAR245408 (XL147) and SAR245409 (XL765), leading inhibitors of phosphoinositide-3 kinase ("PI3K"), and a broad collaboration for the discovery of inhibitors of

Table of Contents

PI3K for the treatment of cancer. The license agreement and collaboration agreement became effective on July 7, 2009. In connection with the effectiveness of the license and collaboration, on July 20, 2009, we received upfront payments of $140.0 million ($120.0 million for the license and $20.0 million for the collaboration), less applicable withholding taxes of $7.0 million, for a net receipt of $133.0 million. We received a refund payment in December 2011 with respect to the withholding taxes previously withheld.

Under the license agreement, Sanofi received a worldwide exclusive license to SAR245408 (XL147) and SAR245409 (XL765), which are in phase 1, phase 1b/2 and phase 2 clinical trials, and has sole responsibility, including funding, for all subsequent clinical, regulatory, commercial and manufacturing activities. As disclosed on ClinicalTrials.gov, SAR245408 (XL147) is currently being studied in a clinical trial evaluating pharmacokinetics of a tablet formulation in patients with solid tumors or lymphoma (NCT01943838). As disclosed on ClinicalTrials.gov, SAR245409 (XL765) is currently being studied in clinical trials in patients with lymphoma either as a single agent (NCT01403636) or in combination with bendamustine and/or rituximab (NCT01410513). In addition SAR245409 (XL765) is being studied in combination with a MEK inhibitor in patients with locally advanced or metastatic solid tumors (NCT01390818).

We will be eligible to receive contingent payments associated with development, regulatory and commercial milestones under the license agreement of $745.0 million in the aggregate, as well as royalties on sales of any products commercialized under the license.

Sanofi may, upon certain prior notice to us, terminate the license as to products containing SAR245408 (XL147) and SAR245409 (XL765). In the event of such termination election, Sanofi's license relating to such product would terminate and revert to us, and we would receive, subject to certain terms, conditions and potential payment obligations, licenses from Sanofi to research, develop and commercialize such products.

In December 2011, we entered into an agreement with Sanofi pursuant to which the parties terminated the discovery collaboration agreement and released each other from any potential liabilities arising under the collaboration agreement prior to effectiveness of the termination in December 2011. Each party retains ownership of the intellectual property that it generated under the collaboration agreement, and we granted Sanofi covenants not-to-enforce with respect to certain of our intellectual property rights. The termination agreement also provided that Sanofi would make a payment to us of $15.3 million, which we received in January 2012. If either party or its affiliate or licensee develops and commercializes a therapeutic product containing an isoform-selective PI3K inhibitor that arose from such party's work (or was derived from such work) under the collaboration agreement, then such party will be obligated to pay royalties to the other party based upon the net sales of such products. The termination agreement provides that Sanofi will make a one-time payment to us upon the first receipt by Sanofi or its affiliate or licensee of marketing approval for the first therapeutic product containing an isoform-selective PI3K inhibitor that arose from Sanofi's work (or was derived from such work) under the collaboration agreement.

We did not recognize any revenue under our collaboration agreement with Sanofi during the three years ended December 31, 2014.

Merck

In December 2011, we entered into an agreement with Merck pursuant to which we granted Merck an exclusive worldwide license to our PI3K-delta ("PI3K-d") program, including XL499 and other related compounds. Pursuant to the terms of the agreement, Merck has sole responsibility to research, develop, and commercialize compounds from our PI3K-d program. The agreement became effective in December 2011.

Merck paid us an upfront cash payment of $12.0 million in January 2012 in connection with the agreement. We will be eligible to receive payments associated with the successful achievement of potential development and regulatory milestones for multiple indications of up to $239.0 million. We will also be eligible to receive payments for combined sales performance milestones of up to $375.0 million and royalties on net-sales of products emerging from the agreement. Contingent payments associated with milestones achieved by Merck and royalties are payable on compounds emerging from our PI3K-d program or from certain compounds that arise from Merck's internal discovery efforts targeting PI3K-d during a certain period.

Merck may at any time, upon specified prior notice to us, terminate the license. In addition, either party may terminate the agreement for the other party's uncured material breach. In the event of termination by Merck at will or by us for Merck's uncured material breach, the license granted to Merck would terminate. In the event of a termination by us for

Merck's uncured material breach, we would receive a royalty-free license from Merck to develop and commercialize certain joint products. In the event of termination by Merck for our uncured material breach, Merck would retain the licenses from us, and we would receive reduced royalties from Merck on commercial sales of products.

Table of Contents

We recognized license revenues of $10.7 million during the year ended December 31, 2012 under our collaboration agreement with Merck. We did not any recognize any such revenue during the years ended December 31, 2014 and 2013.

Daiichi Sankyo

In March 2006, we entered into a collaboration agreement with Daiichi Sankyo for the discovery, development and commercialization of novel therapies targeted against the mineralocorticoid receptor ("MR"), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. Under the terms of the agreement, we granted to Daiichi Sankyo an exclusive, worldwide license to certain intellectual property primarily relating to compounds that modulate MR, including CS-3150 (XL550). Daiichi Sankyo is responsible for all further preclinical and clinical development, regulatory, manufacturing and commercialization activities for the compounds and we do not have rights to reacquire such compounds, except as described below.

Daiichi Sankyo paid us a nonrefundable upfront payment in the amount of $20.0 million and was obligated to provide research and development funding of $3.8 million over a 15-month research term. In June 2007, our collaboration agreement with Daiichi Sankyo was amended to extend the research term by six months over which Daiichi Sankyo was required to provide $1.5 million in research and development funding. In November 2007, the parties decided not to further extend the research term. For each product from the collaboration, we are also entitled to receive payments upon attainment of pre-specified development, regulatory and commercialization milestones. In December 2010, we received a milestone payment of $5.0 million in connection with an IND filing made by Daiichi Sankyo for CS-3150 (XL550) and, in August 2012, we received a milestone payment of $5.5 million in connection with the initiation of a phase 2 clinical trial for CS-3150 (XL550). Daiichi-Sankyo has recently initiated two large phase 2b trials of CS-3150 (XL550) in Japanese patients with hypertension and diabetic nephropathy, respectively. We are eligible to receive additional development, regulatory and commercialization milestone payments of up to $145.0 million. In addition, we are also entitled to receive royalties on any sales of certain products commercialized under the collaboration. Daiichi Sankyo may terminate the agreement upon 90 days' written notice in which case Daiichi Sankyo's payment obligations would cease, its license relating to compounds that modulate MR would terminate and revert to us and we would receive, subject to certain terms and conditions, licenses from Daiichi Sankyo to research, develop and commercialize compounds that were discovered under the collaboration.

We recognized contract revenues of $5.5 million during the year ended December 31, 2012 under our collaboration agreement with Daiichi Sankyo. We did not any recognize any such revenue during the years ended December 31, 2014 and 2013.

GlaxoSmithKline

In October 2002, we established a collaboration with GlaxoSmithKline to discover and develop novel therapeutics in the areas of vascular biology, inflammatory disease and oncology. The collaboration involved three agreements: (1) a product development and commercialization agreement, (2) a stock purchase and stock issuance agreement and (3) a loan and security agreement. During the term of the collaboration, we received $65.0 million in upfront and milestone payments, $85.0 million in research and development funding and loans in the principal amount of $85.0 million which have been repaid in full. In connection with the collaboration, GlaxoSmithKline purchased a total of three million shares of our common stock.

In October 2008, the development term under the collaboration concluded as scheduled. Under the terms of the collaboration, GlaxoSmithKline had the right to select up to two of the compounds in the collaboration for further development and commercialization. GlaxoSmithKline selected foretinib (XL880), an inhibitor of MET and VEGFR2, and had the right to choose one additional compound from a pool of compounds, which consisted of cabozantinib, XL281, XL228, XL820 and XL844 as of the end of the development term.

In July 2008, we achieved proof-of-concept for cabozantinib and submitted the corresponding data report to GlaxoSmithKline. In October 2008, GlaxoSmithKline notified us in writing that it decided not to select cabozantinib for further development and commercialization and that it waived its right to select XL281, XL228, XL820 and XL844 for further development and commercialization. As a result, we retained the rights to develop, commercialize, and/or license all of the compounds, subject to payment to GlaxoSmithKline of a 3% royalty on net sales of any product incorporating cabozantinib. We have discontinued development of XL820, XL228 and XL844.

GlaxoSmithKline continues to develop foretinib (XL880), and as disclosed on ClinicalTrials.gov, is currently recruiting patients into phase 1/2 trials studying the activity of foretinib in metastatic breast cancer both as a single agent (NCT01147484) and in combination with lapatinib (NCT01138384), and in non-small cell lung cancer as a single agent and in combination with erlotinib (NCT02034097).

Table of Contents

In connection with the sales of COMETRIQ, during the years ended December 31, 2014 and 2013 we recorded $0.7 million and $0.4 million in royalty expense, respectively, which is included in Cost of Goods Sold on our Consolidated Statements of Operations. We did not recognize any revenue under our agreement with GlaxoSmithKline during the three years ended December 31, 2014.

NOTE 3. DISPOSITION OF ARTEMIS PHARMACEUTICALS

In November 2007, we entered into a share sale and transfer agreement with Taconic Farms, Inc., ("Taconic"), pursuant to which Taconic acquired from us, 80.1% of the outstanding share capital in our wholly-owned subsidiary, Artemis Pharmaceuticals GmbH ("Artemis"). In September 2011, we exercised our right to sell our remaining 19.9% interest in Artemis to Taconic.

In September 2014, we received a $0.8 million purchase price adjustment resulting from the resolution of contingencies from the September 2011 sale of our remaining interest in Artemis to Taconic. This $0.8 million gain on sale of a business is included in interest income and other, net on our Consolidated Statements of Operations.

NOTE 4. RESTRUCTURINGS

The restructuring charges that we expect to incur in connection with our restructurings are subject to a number of assumptions, and actual results may materially differ. We may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructurings.

2014 Restructuring

On September 2, 2014, as a consequence of the failure of COMET-1, one of our two phase 3 pivotal trials of cabozantinib in metastatic castration-resistant prostate cancer ("mCRPC"), to meet its primary endpoint of demonstrating a statistically significant increase in overall survival for patients treated with cabozantinib as compared to prednisone, we initiated a restructuring plan (the "2014 Restructuring") to reduce our workforce. Personnel reductions were initiated across our entire organization that when completed will result in a remaining workforce of approximately 80 full-time employees. The principal objective of the 2014 Restructuring was to enable us to focus our financial resources on the phase 3 pivotal trials of cabozantinib in mRCC and advanced HCC.

We expect to record an aggregate restructuring charge related to one-time termination benefits of approximately $6 million, of which approximately 95% was recorded in 2014 and the remainder is expected to be recorded in 2015. Although we do not yet have contractual commitments in place, we have made progress towards subleasing our facilities and therefore we expect to incur between $2 million and $6 million in facility-related charges as we exit certain facilities. We expect to incur additional charges as a result of the 2014 Restructuring, including property and equipment write-downs and other charges, and expect to record these expenses during fiscal year 2015 as they become determinable and as we exit certain facilities. Except for employee severance and other benefits and certain facility-related charges, we are currently unable to estimate the total amount or range of amounts expected to be incurred in connection with the 2014 Restructuring for each major type of cost or in the aggregate.

We have recorded a $6.1 million restructuring charge for the 2014 Restructuring during the year ended December 31, 2014. The restructuring charge includes $5.8 million of employee severance and other benefits that were recognized ratably during the period from the implementation date of the 2014 Restructuring through the employees' termination dates. In addition, we recorded charges of $0.3 million for property and equipment write-downs and other charges, which were partially offset by recoveries recorded in connection with the sale of excess equipment and other assets that were previously fully impaired. The total restructuring liability related to the 2014 Restructuring is included in the current portion of restructuring on the accompanying Consolidated Balance Sheets. The components and changes of these liabilities since initiation of the 2014 Restructuring are summarized in the following table (in thousands):

	Employee Severance and Other Benefits	Asset Impairment and Other	Total
Restructuring charge	$5,775	$312	$6,087
Cash payments	(4,507)	(77)	(4,584)
Adjustments or non-cash credits	22	(288)	(266)
Proceeds from sale of assets	—	100	100
	$1,290	$47	$1,337

Restructuring liability for 2014 Restructuring as of December 31, 2014

Table of Contents

2010 Restructurings

Between March 2010 and May 2013, we implemented five restructurings (referred to collectively as the "2010 Restructurings") to manage costs and as a consequence of our decision in 2010 to focus our proprietary resources and development efforts on the development and commercialization of cabozantinib. The aggregate reduction in headcount from the 2010 Restructurings was 429 employees. Charges and credits related to the 2010 Restructurings were recorded in periods other than those in which the 2010 Restructurings were implemented as a result of sublease activities for certain of our buildings in South San Francisco, California, changes in assumptions regarding anticipated sublease activities, the effect of the passage of time on our discounted cash flow computations, previously planned employee terminations, and sales of excess equipment and other assets.

For the years ended December 31, 2014, 2013 and 2012, we recorded restructuring charges of $1.5 million, $1.2 million and $9.2 million, respectively, for the 2010 Restructurings. The charges for the periods presented were related to the effect of the passage of time on our discounted cash flow computations for the exit, in prior periods, of certain of our South San Francisco buildings and changes in estimates regarding future subleases. During the year ended December 31, 2014, those charges were partially offset by $0.1 million in recoveries recorded in connection with the sale of excess equipment and other assets. The total outstanding restructuring liability related to the 2010 Restructurings is included in the current and long-term portion of restructuring on the accompanying Consolidated Balance Sheets. The components and changes of these liabilities during the year ended December 31, 2014, are summarized in the following table (in thousands):

	Facility Charges	Other	Total
Restructuring liability as of December 31, 2013	$13,460	$12	$13,472
Restructuring charge (credit)	1,626	(117)	1,509
Cash payments	(5,644)	(8)	(5,652)
Adjustments or non-cash credits	12	(86)	(74)
Proceeds from sale of assets	—	199	199
Restructuring liability for 2010 Restructurings as of December 31, 2014	$9,454	$—	$9,454

We expect to pay accrued facility charges of $9.5 million, net of $9.1 million in cash to be received from our subtenants, through the end of our lease terms of the buildings, the last of which ends in 2017. We expect to incur additional restructuring charges of approximately $0.8 million relating to the effect of the passage of time on our discounted cash flow computations used to determine the accrued facilities charges through the end of the building lease terms.

NOTE 5. CASH AND INVESTMENTS

The following table summarizes cash and cash equivalents, investments, and restricted cash and investments by balance sheet line item as of December 31, 2014 and 2013 (in thousands):

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$80,395	$—	$—	$80,395
Short-term investments	63,988	37	(135)	63,890
Short-term restricted cash and investments	12,105	107	—	12,212
Long-term investments	81,600	1	(22)	81,579
Long-term restricted cash and investments	4,684	—	—	4,684
Total cash and investments	$242,772	$145	$(157)	$242,760

Table of Contents

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents	$103,978	$—	$—	$103,978
Short-term investments	138,403	94	(22)	138,475
Short-term restricted cash and investments	12,173	40	—	12,213
Long-term investments	144,226	106	(33)	144,299
Long-term restricted cash and investments	16,837	60	—	16,897
Total cash and investments	$415,617	$300	$(55)	$415,862

Under our loan and security agreement with Silicon Valley Bank, we are required to maintain compensating balances on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates. The total collateral balances as of December 31, 2014 and 2013 were $82.0 million and $83.7 million, respectively and are reflected in our Consolidated Balance Sheets in Short- and Long-term investments. See “Note 8 - Debt” for more information regarding the collateral balance requirements under our Silicon Valley Bank loan and security agreement.

All of our cash equivalents and investments are classified as available-for-sale. The following table summarizes our cash equivalents and investments by security type as of December 31, 2014 and 2013. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$23,376	$—	$—	$23,376
Commercial paper	56,714	—	—	56,714
Corporate bonds	143,444	35	(157)	143,322
U.S. Treasury and government sponsored enterprises	12,105	107	—	12,212
Municipal bonds	2,659	3	—	2,662
Total investments	$238,298	$145	$(157)	$238,286

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$24,813	$—	$—	$24,813
Commercial paper	94,682	—	—	94,682
Corporate bonds	239,937	190	(55)	240,072
U.S. Treasury and government sponsored enterprises	44,284	102	—	44,386
Municipal bonds	6,005	8		6,013
Total investments	$409,721	$300	$(55)	$409,966

There were no gains or losses on the sales of investments during the years ended December 31, 2014, 2013 and 2012. All of our investments are subject to a quarterly impairment review. During the years ended December 31, 2014 and 2013, we did not record any other-than-temporary impairment charges on our available-for-sale securities. As of December 31, 2014, there were 40 investments in an unrealized loss position with an aggregate fair value $82.8 million. All of our investments in an unrealized loss position are corporate bonds. All investments in an unrealized loss position have been so for less than one year and the unrealized losses were not attributed to credit risk, but rather associated with the changes in interest rates. Based on the scheduled maturities of our investments, we concluded that the unrealized losses in our investment securities are not other-than-temporary, as it is more likely than not that we will hold these investments for a period of time sufficient for a recovery of our cost basis.

78

Table of Contents

The following summarizes the fair value of securities classified as available-for-sale by contractual maturity as of December 31, 2014 (in thousands):

	Mature within One Year	After One Year through Two Years	Fair Value
Money market funds	$23,376	$—	$23,376
Commercial paper	56,714	—	56,714
Corporate bonds	134,685	8,637	143,322
U.S. Treasury and government sponsored enterprises	12,212	—	12,212
Municipal bonds	2,662	—	2,662
Total	$229,649	$8,637	$238,286

Cash is excluded from the table above. The classification of certain compensating balances and restricted investments are dependent upon the term of the underlying restriction on the asset and not the maturity date of the investment. Therefore, certain long-term investments and long-term restricted cash and investments have contractual maturities within one year.

NOTE 6. INVENTORY

Inventory consists of the following (in thousands):

	December 31,	
	2014	2013
Raw materials	$1,118	$529
Work in process	2,845	2,280
Finished goods	559	81
Total	4,522	2,890
Less: non-current portion included in other assets	(2,141)	—
Inventory	$2,381	$2,890

We generally relieve inventory on a first-expiry, first-out basis. Amounts written down related to expiring inventory are charged to cost of sales and totaled $0.2 million and $39 thousand for the years ended December 31, 2014 and 2013, respectively. Inventory recorded as other assets are comprised of raw materials and work in process inventories. There were no other write-downs for obsolete or excess inventory.

NOTE 7. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	December 31,	
	2014	2013
Laboratory equipment	$13,677	$15,453
Computer equipment and software	14,840	14,462
Furniture and fixtures	3,701	3,691
Leasehold improvements	16,364	17,031
Construction-in-progress	120	68
	48,702	50,705
Less: accumulated depreciation and amortization	(46,270)	(45,795)
Property and equipment, net	$2,432	$4,910

For the years ended December 31, 2014, 2013 and 2012, we recorded depreciation expense of $2.3 million, $3.1 million and $4.8 million, respectively.

In 2014, 2013 and 2012, we recorded gross asset impairment charges in the amounts of $0.7 million, $0.1 million and $0.3 million, respectively, in connection with the Restructurings. The amount recorded as a restructuring charge for asset impairment, as presented in “Note 4 - Restructurings,” was net of the gain on the sale of such assets. In 2014 and 2012, the gain

Table of Contents

on the sale of excess equipment was $0.6 million and $0.3 million, respectively. There were no such gains in 2013. Cash proceeds on those sales were $0.4 million, $0.1 million and $0.9 million during 2014, 2013 and 2012, respectively.

NOTE 8. DEBT

The amortized carrying amount of our debt consists of the following (in thousands):

	December 31,	
	2014	2013
Convertible Senior Subordinated Notes due 2019	$182,395	$165,296
Secured Convertible Notes due 2015	98,880	99,851
Silicon Valley Bank term loan	80,000	80,000
Silicon Valley Bank line of credit	381	2,090
Total debt	361,656	347,237
Less: current portion	(99,261)	(11,762)
Long-term debt	$262,395	$335,475

Convertible Senior Subordinated Notes due 2019 and Related Concurrent Offering of Our Common Stock

On August 14, 2012, we issued and sold $287.5 million aggregate principal amount of 4.25% convertible senior subordinated notes due 2019 (the “2019 Notes”). On that date we completed concurrent registered underwritten public offerings in which we sold the 2019 Notes and 34.5 million shares of common stock at a price of $4.25 per share, generating aggregate net proceeds of $416.1 million. The convertible debt offering resulted in net proceeds of $277.7 million after deducting the underwriting discount and offering expenses of $9.3 million and $0.5 million, respectively. The equity offering resulted in net proceeds of $138.4 million after deducting the underwriting discount of $7.7 million and other expenses of $0.5 million.

The 2019 Notes were issued pursuant to an indenture, as supplemented by a supplemental indenture with Wells Fargo Bank, National Association, as trustee (the “Trustee”), and mature on August 15, 2019, unless earlier converted, redeemed or repurchased. The 2019 Notes bear interest at the rate of 4.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning February 15, 2013. Subject to certain terms and conditions, at any time on or after August 15, 2016, we may redeem for cash all or a portion of the 2019 Notes. The redemption price will equal 100% of the principal amount of the 2019 Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

Upon the occurrence of certain circumstances, holders may convert their 2019 Notes prior to the close of business on the business day immediately preceding May 15, 2019. On or after May 15, 2019, until the close of business on the second trading day immediately preceding August 15, 2019, holders may surrender their 2019 Notes for conversion at any time. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate of 188.2353 shares of common stock per $1,000 principal amount of 2019 Notes is equivalent to a conversion price of approximately $5.31 per share of common stock. The conversion rate is subject to adjustment upon the occurrence of certain events.

If a Fundamental Change, as defined in the indenture governing the 2019 Notes, occurs, holders of the 2019 Notes may require us to purchase for cash all or any portion of their 2019 Notes at a purchase price equal to 100% of the principal amount of the Notes to be purchased plus accrued and unpaid interest, if any, to, but excluding, the Fundamental Change purchase date.

In connection with the offering of the 2019 Notes, $36.5 million of the proceeds were deposited into an escrow account which contains an amount of permitted securities sufficient to fund, when due, the total aggregate amount of the first six scheduled semi-annual interest payments on the 2019 Notes. As of December 31, 2014, we have used $24.5 million of the amount held in the escrow account to pay the required semi-annual interest payments. The amount held in the escrow account as of December 31, 2014, was $12.2 million and is included in short--term restricted cash and investments. We have pledged our interest in the escrow account to the Trustee as security for our obligations under the 2019 Notes.

The 2019 Notes are accounted for in accordance with ASC Subtopic 470-20, Debt with Conversion and Other Options. Under ASC Subtopic 470-20, issuers of certain convertible debt instruments that have a net settlement

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Table of Contents

may be settled in cash upon conversion, including partial cash settlement, are required to separately account for the liability (debt) and equity (conversion option) components of the instrument. The carrying amount of the liability component of any outstanding debt instrument is computed by estimating the fair value of a similar liability without the conversion option. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The effective interest rate used in determining the liability component of the 2019 Notes was 10.09%. This resulted in the recognition of $144.3 million as the liability component and the residual $143.2 million as the debt discount with a corresponding increase to paid-in capital, the equity component, for the 2019 Notes. The underwriting discounts of $9.3 million and offering expenses of $0.5 million were allocated between debt issuance costs and equity issuance costs in proportion to the allocation of the proceeds. Debt issuance costs of $4.9 million were included in Other long term assets on our Consolidated Balance Sheets as of the issuance date. Equity issuance costs of $4.9 million related to the convertible debt offering were recorded as an offset to additional paid-in capital.

The following is a summary of the liability component of the 2019 Notes (in thousands):

	December 31,	
	2014	2013
Net carrying amount of the liability component	$182,395	$165,296
Unamortized discount of the liability component	105,105	122,204
Principal amount of the 2019 Notes	$287,500	$287,500

The debt discount and debt issuance costs will be amortized as interest expense through August 2019. The following is a summary of interest expense for the 2019 Notes (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Stated coupon interest	$12,253	$12,219	$4,582
Amortization of debt discount and debt issuance costs	17,804	16,201	5,726
Total interest expense	$30,057	$28,420	$10,308

The balance of unamortized fees and costs was $3.3 million and $4.0 million as of December 31, 2014 and December 31, 2013, respectively, which is included in Other assets on the accompanying Consolidated Balance Sheets.

Secured Convertible Notes due June 2015

In June 2010, we entered into a note purchase agreement with Deerfield Private Design Fund, L.P. and Deerfield Private Design International, L.P., (the “Original Deerfield Purchasers”), pursuant to which, on July 1, 2010, we sold to the Original Deerfield Purchasers an aggregate of $124.0 million initial principal amount of our Secured Convertible Notes due July 1, 2015 (the “Deerfield Notes”) for an aggregate purchase price of $80.0 million, less closing fees and expenses of approximately $2.0 million. As of December 31, 2014 and 2013, the remaining outstanding principal balance on the Deerfield Notes was $104.0 million and $114.0 million, respectively. We refer to the Original Deerfield Purchasers and the New Deerfield Purchasers (identified below) collectively as Deerfield.

The outstanding principal amount of the Deerfield Notes bears interest in the annual amount of $6.0 million, payable quarterly in arrears. The following is a summary of interest expense for the Deerfield Notes (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Stated coupon interest	$6,000	$6,000	$6,000
Amortization of debt discount and debt issuance costs	11,731	10,089	9,913
Total interest expense	$17,731	$16,089	$15,913

The balance of unamortized fees and costs was $1.4 million and $1.4 million as of December 31, 2014 and December 31, 2013, respectively, which is included in Other assets on the accompanying Consolidated Balance Sheets.

On August 6, 2012, the parties amended the note purchase agreement to permit the issuance of the 2019 Notes and modify certain optional prepayment rights. The amendment became effective upon the issuance of the 2019 Notes and the payment to the Original Deerfield Purchasers of a $1.5 million consent fee. On August 1, 2013, the parties further

amended the note purchase agreement to clarify certain of our other rights under the note purchase agreement.

Table of Contents

On January 22, 2014, the note purchase agreement was further amended to provide us with an option to extend the maturity date of our indebtedness under the note purchase agreement to July 1, 2018. Under the terms of the extension option, we have the right to require Deerfield Partners, L.P. and Deerfield International Master Fund, L.P., (the "New Deerfield Purchasers"), to acquire $100.0 million principal amount of the Deerfield Notes and extend the maturity date thereof to July 1, 2018. We are under no obligation to exercise the extension option. To exercise the extension option, we must provide a notice of exercise to Deerfield prior to March 31, 2015. If we exercise the extension option, the Deerfield Notes would mature on July 1, 2018 and bear interest on and after July 2, 2015 at the rate of 7.5% per annum to be paid in cash, quarterly in arrears, and 7.5% per annum to be paid in kind, quarterly in arrears, for a total interest rate of 15% per annum.

In each of January 2014 and 2013, we made mandatory prepayments of $10.0 million on the Deerfield Notes. We were required to make an additional mandatory prepayment on the Deerfield Notes in January 2015 equal to 15% of certain revenues from collaborative arrangements ("Development/Commercialization Revenue") received during the prior fiscal year, subject to a maximum prepayment amount of $27.5 million. We have received no such revenue during the year ended December 31, 2014 and therefore there is no minimum prepayment due in 2015. Our obligation to make annual mandatory prepayments equal to 15% of Development/Commercialization Revenue received by us during the prior fiscal year will apply in each of 2016, 2017 and 2018 if we exercise the extension option. However, we will only be obligated to make any such annual mandatory prepayment after exercise of the extension option if the New Deerfield Purchasers provide notice to us of their election to receive the prepayment. Mandatory prepayments relating to Development/Commercialization Revenue will continue to be subject to a maximum annual prepayment amount of $27.5 million. The definition of "Development/Commercialization Revenue" expressly excludes any sale or distribution of drug or pharmaceutical products in the ordinary course of our business, and any proceeds from any Intellectual Property Sales (as further described below).

As a result of the January 2014 amendment, we are required to notify the applicable Deerfield entities of certain sales, assignments, grants of exclusive licenses or other transfers of our intellectual property pursuant to which we transfer all or substantially all of our legal or economic interests, defined as an Intellectual Property Sale, and the Deerfield entities may elect to require us to prepay the principal amount of the Deerfield Notes in an amount equal to (i) 100% of the cash proceeds of any Intellectual Property Sale relating to cabozantinib and (ii) 50% of the cash proceeds of any other Intellectual Property Sale. Under the note purchase agreement as amended, we may voluntarily prepay the principal amount of the Deerfield Notes as follows (the amount at which we repay in each case below is referred to as the Prepayment Price):

- Prior to July 1, 2015: we may prepay all of the principal amount of the Deerfield Notes at any time at a prepayment price equal to the outstanding principal amount, plus accrued and unpaid interest through the date of such prepayment, plus all interest that would have accrued on the principal amount of the Deerfield Notes between the date of such prepayment and the applicable maturity date of the Deerfield Notes if the outstanding principal amount of the Deerfield Notes as of such prepayment date had remained outstanding through the applicable maturity date, plus all other accrued and unpaid obligations; and
- If we exercise the extension option: we may at our sole discretion, prepay all of the principal amount of the Deerfield Notes at a prepayment price equal to 105% of the outstanding principal amount of the Deerfield Notes, plus all accrued and unpaid interest through the date of such prepayment, plus, if prior to July 1, 2017, all interest that would have accrued on the principal amount of the Deerfield Notes between the date of such prepayment and July 1, 2017, if the outstanding principal amount of the Deerfield Notes as of such prepayment date had remained outstanding through July 1, 2017, plus all other accrued and unpaid obligations, collectively referred to as the Prepayment Price.

In lieu of making any portion of the Prepayment Price or mandatory prepayment in cash, subject to certain limitations (including a cap on the number of shares issuable under the note purchase agreement), we have the right to convert all or a portion of the principal amount of the Deerfield Notes into, or satisfy all or any portion of the Prepayment Price amounts or mandatory prepayment amounts with shares of our common stock. Additionally, in lieu of making any payment of accrued and unpaid interest in respect of the Deerfield Notes in cash, subject to certain limitations, we may elect to satisfy any such payment with shares of our common stock. The number of shares of our common stock issuable upon conversion or in settlement of principal and interest obligations will be based upon the discounted

trading price of our common stock over a specified trading period. Upon certain changes of control of Exelixis, a sale or transfer of assets in one transaction or a series of related transactions for a purchase price of more than (i) $400 million or (ii) 50% of our market capitalization, Deerfield may require us to prepay the Deerfield Notes at the Prepayment Price. Upon an event of default, as defined in the Deerfield Notes, Deerfield may declare all or a portion of the Prepayment Price to be immediately due and payable.

In connection with the January 2014 amendment to the note purchase agreement, on January 22, 2014 we issued to the New Deerfield Purchasers two-year warrants (the "2014 Deerfield Warrants") to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of $9.70 per share. If we exercise the extension option, the exercise price will be reset to

Table of Contents

the lower of (x) the existing exercise price and (y) 120% of the volume weighted average price of our common stock for the ten trading days immediately following the date of such extension election. The 2014 Deerfield Warrants are exercisable for a term of two years, subject to a two years extension if we exercise the extension option, and contain certain limitations that prevent the holder of the 2014 Deerfield Warrants from acquiring shares upon exercise of a Warrant that would result in the number of shares beneficially owned by the holder to exceed 9.98% of the total number of shares of our common stock then issued and outstanding. The number of shares for which the 2014 Deerfield Warrants are exercisable and the associated exercise prices are subject to certain adjustments as set forth in the 2014 Deerfield Warrants. In addition, upon certain changes in control of Exelixis, to the extent the 2014 Deerfield Warrants are not assumed by the acquiring entity, or upon certain defaults under the 2014 Deerfield Warrants, the holder has the right to net exercise the 2014 Deerfield Warrants for shares of common stock, or be paid an amount in cash in certain circumstances where the current holders of our common stock would also receive cash, equal to the Black-Scholes Merton value of the 2014 Deerfield Warrants.

In connection with the issuance of the 2014 Deerfield Warrants, we entered into a registration rights agreement with Deerfield, pursuant to which we agreed to file, no later than February 21, 2014, a registration statement with the Securities and Exchange Commission ("SEC") covering the resale of the shares of common stock issuable upon exercise of the 2014 Deerfield Warrants.

In connection with the note purchase agreement, we also entered into a security agreement in favor of Deerfield which provides that our obligations under the Deerfield Notes will be secured by substantially all of our assets except intellectual property. On August 1, 2013, the security agreement was amended to limit the extent to which voting equity interests in any of our foreign subsidiaries shall be secured assets.

The note purchase agreement as amended and the security agreement include customary representations and warranties and covenants made by us, including restrictions on the incurrence of additional indebtedness.

Silicon Valley Bank Loan and Security Agreement

The outstanding principal obligation under the Silicon Valley Bank Loan and Security Agreement, as amended, was $80.4 million and $82.1 million as of December 31, 2014 and 2013, respectively.

Silicon Valley Bank Line of Credit

In December 2007, we entered into a loan modification agreement to a loan and security agreement originally entered into in May 2002 with Silicon Valley Bank. The principal amount outstanding under the term loan accrues interest at 0.75% per annum. In accordance with the amended loan terms, the Line of Credit has expired and we have no further draw down obligations under the line of credit. The outstanding principal obligation under the Silicon Valley Bank Line of Credit was $0.4 million and $2.1 million as of December 31, 2014 and 2013, respectively.

Silicon Valley Bank Term Loan

In June 2010, we amended our loan and security agreement with Silicon Valley Bank to provide for a new seven-year term loan in the amount of $80.0 million. The principal amount outstanding under the term loan accrues interest at 1.0% per annum, which interest is due and payable monthly. We are required to repay the term loan in one balloon principal payment, representing 100% of the principal balance and accrued and unpaid interest, on May 31, 2017. We have the option to prepay all, but not less than all, of the amounts advanced under the term loan, provided that we pay all unpaid accrued interest thereon that is due through the date of such prepayment and the interest on the entire principal balance of the term loan that would otherwise have been paid after such prepayment date until the maturity date of the term loan. We are required to maintain at all times on deposit in one or more non-interest bearing demand deposit accounts with Silicon Valley Bank or one of its affiliates a compensating balance, constituting support for the obligations under the term loan, with a principal balance in value equal to at least 100% of the outstanding principal balance of the term loan.

In August 2011, we amended our term loan agreement to allow for the compensating balance to be maintained on deposit in one or more investment accounts with Silicon Valley Bank or one of its affiliates. This compensating balance is to have a value equal to at least 100%, but not to exceed 107%, of the outstanding principal balance of the term loan and all lines of credit associated with Silicon Valley Bank. We are entitled to retain income earned on the amounts maintained in such investment account(s). Any amounts outstanding under the term loan during the continuance of an event of default under the loan and security agreement will, at the election of Silicon Valley Bank,

bear interest at a per annum rate equal to 6.0%. If one or more events of default under the loan and security agreement occurs and continues beyond any applicable cure period, Silicon Valley Bank may declare all or part of the obligations under the loan and security agreement to be immediately due and payable and stop advancing money or extending credit to us under the loan and security agreement. The total collateral balance as of December 31, 2014 and 2013 was $82.0 million and $83.7 million, respectively, and is reflected in our Consolidated

Table of Contents

Balance Sheet in Short- and Long-term Investments as the amounts are not restricted as to withdrawal. However, withdrawal of some or all of this amount such that the collateral balance falls below the required level could result in Silicon Valley Bank declaring the obligation immediately due and payable.

Future Principal Payments

Aggregate expected future principal payments of our debt were as follows as of December 31, 2014 (in thousands):

Year Ending December 31, (1)	
2015	104,381
2016	—
2017	80,000
2018	—
2019	287,500
Thereafter	—

(1) Amounts include principal payments associated with the accretion of discounts and debt issuance costs. For the Deerfield Notes, this table is presented assuming we do not make the election to extend the maturity of those notes and the remaining principal balance will be paid at the current July 2015 maturity date. The actual timing of payments made may differ materially.

NOTE 9. COMMON STOCK AND WARRANTS

Sale of Shares of Common Stock

In February 2012, we completed a registered public offering of 12.7 million shares of our common stock at a price of $5.17 per share pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on May 8, 2009. We received $65.0 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

In August 2012, we completed a registered underwritten public offering of 34.5 million shares of our common stock at a price of $4.25 per share pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on June 8, 2012. We received $138.4 million in net proceeds after deducting the underwriting discount and related offering expenses. Concurrent with the issuance of the common stock, we sold $287.5 million aggregate principal amount of the Convertible Senior Subordinated Notes due 2019 pursuant to the same registered public offering. See “Note 8 - Debt” for more information regarding the 2019 Notes.

In January 2014, we completed a registered underwritten public offering of 10.0 million shares of our common stock at a price of $8.00 per share pursuant to a shelf registration statement previously filed with the SEC, which the SEC declared effective on June 8, 2012. We received $75.6 million in net proceeds from the offering after deducting the underwriting discount and related offering expenses.

Conversion of Debt into Common Stock

The 2019 Notes and the Deerfield Notes are, under certain circumstances, convertible into shares of our common stock. See “Note 8 - Debt” for more information regarding the conversion features of these instruments.

Warrants

On January 22, 2014, in connection with the January 2014 amendment to the note purchase agreement with Deerfield to provide us with the Extension Option, we issued to the New Deerfield Purchasers the 2014 Deerfield Warrants to purchase an aggregate of 1,000,000 shares of our common stock at an exercise price of $9.70 per share in connection with an amendment to the note purchase agreement for the Deerfield Notes. If we exercise the Extension Option, the two year term of the 2014 Deerfield Warrants will be extended by two years and the exercise price will be reset to the lower of (i) the existing exercise price and (ii) 120% of the volume weighted average price of our common stock for the ten trading days immediately following the date of such extension election. Due to the potential increase in term and decrease of the exercise price, the 2014 Deerfield Warrants were recorded as a liability which is included in Other long-term liabilities. The 2014 Deerfield Warrants are recorded at fair value, on a recurring basis, which was $0.9 million and $2.8 million as of December 31, 2014 and January 22, 2014, respectively. We recorded an unrealized gain on the warrants of $1.8 million during the year ended December 31, 2014, which

84

Table of Contents

is included in Interest income and other, net. See “Note 10 - Fair Value Measurements” for more information on the valuation of these warrants.

At December 31, 2014, the following warrants to purchase common stock were outstanding and exercisable:

Date Issued	Exercise Price per Share	Expiration Date	Number of Shares
January 22, 2014	$9.70	January 22, 2016	1,000,000

The warrants are participating securities. The warrant holders do not have a contractual obligation to share in our losses.

NOTE 10. FAIR VALUE MEASUREMENTS

The following table sets forth the fair value of our financial assets and liabilities that were measured and recorded on a recurring basis as of December 31, 2014 and 2013. We did not have any financial liabilities that were measured and recorded on a recurring basis or Level 3 investments as of December 31, 2013. The amounts presented exclude cash, but include investments classified as cash equivalents (in thousands):

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$23,376	$—	$—	$23,376
Commercial paper	—	56,714	—	56,714
Corporate bonds	—	143,322	—	143,322
U.S. Treasury and government sponsored enterprises	—	12,212	—	12,212
Municipal bonds	—	2,662	—	2,662
Total financial assets	$23,376	$214,910	$—	$238,286
Financial liabilities:				
Warrants	$—	$—	$921	$921
Total financial liabilities	$—	$—	$921	$921

	December 31, 2013		
	Level 1	Level 2	Total
Money market funds	$24,813	$—	$24,813
Commercial paper	—	94,682	94,682
Corporate bonds	—	240,072	240,072
U.S. Treasury and government sponsored enterprises	—	44,386	44,386
Municipal bonds	—	6,013	6,013
Total	$24,813	$385,153	$409,966

The following is a reconciliation of changes in the net fair value of warrants which are classified as Level 3 in the fair value hierarchy. There were no transfers into or out of Level 3 during the period presented (in thousands):

	Year Ended December 31,
Balance at beginning of year	$—
Issuance of warrants	2,762
Unrealized gain included in Interest income and other, net	(1,841)
Balance at end of year	$921

Table of Contents

The estimated fair value of our financial instruments that are carried at amortized cost for which it is practicable to determine a fair value was as follows (in thousands):

	December 31, 2014		December 31, 2013	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
2019 Notes	$182,395	$156,889	$165,296	$339,883
Silicon Valley Bank Term Loan	$80,000	$79,943	$80,000	$79,946
Silicon Valley Bank Line of Credit	$381	$381	$2,090	$2,090

We believe it is not practicable to determine the fair value of the Deerfield Notes due to the unique structure of the instrument that was financed by entities affiliated with Deerfield.

The carrying amounts of cash, trade and other receivables, accounts payable, accrued clinical trial liabilities, accrued compensation and benefits, and other accrued liabilities approximate their fair values and are excluded from the tables above.

The following methods and assumptions were used to estimate the fair value of each class of financial instrument for which it is practicable to estimate a value:

- When available, we value investments based on quoted prices for those financial instruments, which is a Level 1 input. Our remaining investments are valued using third-party pricing sources, which use observable market prices, interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing, which is a Level 2 input.
- The 2019 Notes are valued using a third-party pricing model that is based in part on average trading prices, which is a Level 2 input. The 2019 Notes are not marked-to-market and are shown at their initial fair value less the unamortized discount; the portion of the value allocated to the conversion option is included in Stockholders' (deficit) equity on the accompanying Consolidated Balance Sheets.
- We estimate the fair value of our other debt instruments, where possible, using the net present value of the payments discounted at an interest rate that is consistent with money-market rates that would have been earned on our non-interest-bearing compensating balances, which is a Level 2 input.
- The 2014 Deerfield Warrants are valued using a Monte Carlo simulation model. The expected life is based on the contractual terms of the 2014 Deerfield Warrants, and in certain simulations, assumes the two year extension that would result from our exercise of the Extension Option; as of December 31, 2014, we have estimated that it is probable that we will exercise this two-year extension. We consider implied volatility as well as our historical volatility in developing our estimate of expected volatility. The fair value of the 2014 Deerfield Warrants were estimated using the following assumptions, which, except for risk-free interest rate, are Level 3 inputs (dollars in thousands):

	December 31, 2014	January 22, 2014 (issuance date)
Fair value of warrants	$921	$2,762
Risk-free interest rate	1.07 %	0.95 %
Dividend yield	— %	— %
Volatility	96 %	57 %
Average expected life	3.1 years	3.2 years

NOTE 11. EMPLOYEE BENEFIT PLANS

Equity Incentive Plans

We have several equity incentive plans under which we have granted incentive stock options, non-qualified stock options and RSUs to employees, directors and consultants. The Board of Directors or a designated Committee of the Board is responsible for administration of our employee equity incentive plans and determines the term, exercise price and vesting terms of each option. Prior to May 2011, options issued to our employees had a four-year vesting term, an exercise price equal to the fair market value on the date of grant, and a ten year life from the date of grant (6.2 years for options issued in exchange for options cancelled under our 2009 option exchange program). Stock options issued

after May 2011 have a four-year vesting term, an exercise price equal to the fair market value on the date of grant, and a seven year life from the date of grant. RSUs

Table of Contents

granted to our employees vest over a four year term; RSUs issued after September 29, 2011 vest annually; the remaining unvested portion of RSUs issued prior to September 29, 2011 vest quarterly.

In December 2005, our Board of Directors adopted a Change in Control and Severance Benefit Plan for executives and certain non-executives. Eligible Change in Control and Severance Benefit Plan participants include our employees with the title of vice president and above. If a participant's employment is terminated without cause during a period commencing one month before and ending thirteen months following a change in control, as defined in the plan document, then the Change in Control and Severance Benefit Plan participant is entitled to have the vesting of all of such participant's stock options accelerated with the exercise period being extended to no more than one year.

Employee Stock Purchase Plan

In January 2000, we adopted the 2000 Employee Stock Purchase Plan (the "ESPP"). The ESPP allows for qualified employees (as defined in the ESPP) to purchase shares of our common stock at a price equal to the lower of 85% of the closing price at the beginning of the offering period or 85% of the closing price at the end of each six month purchase period. Compensation expense related to our ESPP was $0.8 million, $0.6 million, and $0.4 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, we had 1,371,274 shares available for issuance under our ESPP. We issued 669,565 shares, 345,828 shares, and 298,533 shares of common stock during the years ended December 31, 2014, 2013 and 2012, respectively, pursuant to the ESPP at an average price per share of $2.14, $4.13 and $4.08, respectively.

Stock-Based Compensation

We recorded and allocated employee stock-based compensation expense for our equity incentive plans and our ESPP as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Research and development expense	$3,245	$6,021	$4,536
General and administrative expense	6,783	5,948	4,245
Restructuring-related stock compensation expense (recovery)	(22)	49	—
Total employee stock-based compensation expense	$10,006	$12,018	$8,781

In addition, we recognized stock-based compensation expense of $0.1 million relating to non-employees for the year ended December 31, 2012. Such expense was nominal or zero for the years ended December 31, 2014 and 2013.

We use the Black-Scholes Merton option pricing model to value our stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. We considered implied volatility as well as our historical volatility in developing our estimate of expected volatility. The fair value of employee stock option awards and ESPP purchases was estimated using the following assumptions and weighted average fair values:

	Stock Options		
	2014	2013	2012
Weighted average grant-date fair value	$1.46	$2.97	$3.24
Risk-free interest rate	1.80%	1.51%	0.81%
Dividend yield	—%	—%	—%
Volatility	85%	61%	69%
Expected life	5.5 years	5.6 years	5.6 years
	ESPP		
	2014	2013	2012
Weighted average grant-date fair value	$1.28	$1.64	$2.07
Risk-free interest rate	0.06%	0.11%	0.10%
Dividend yield	—%	—%	—%
Volatility	69%	66%	68%
Expected life	6 months	6 months	6 months

Table of Contents

A summary of all option activity was as follows for the periods presented (dollars in thousands, except per share amounts):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Options outstanding at December 31, 2011	17,436,378	$7.16		
Granted	3,442,696	$5.45		
Exercised	(181,979)	$5.09		
Forfeited	(358,360)	$5.88		
Expired	(1,890,185)	$7.54		
Options outstanding at December 31, 2012	18,448,550	$6.85		
Granted	6,694,174	$5.44		
Exercised	(13,311)	$5.06		
Forfeited	(79,942)	$5.27		
Expired	(1,066,196)	$6.45		
Options outstanding at December 31, 2013	23,983,275	$6.48		
Granted	10,038,565	$2.11		
Exercised	(19,090)	$6.28		
Forfeited	(4,650,543)	$5.34		
Expired	(1,540,215)	$8.06		
Options outstanding at December 31, 2014	27,811,992	$5.00	4.21 years	$20
Exercisable at December 31, 2014	15,403,813	$6.75	2.57 years	$—

At December 31, 2014, a total of 11,470,066 shares were available for grant under our stock option plans.

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between our closing stock price on the last trading day of fiscal 2014 and the exercise prices, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2014. The total intrinsic value of options exercised was $27 thousand, $4 thousand, and $0.1 million during 2014, 2013 and 2012, respectively. The total estimated fair value of employee options vested and recorded as expense in 2014, 2013 and 2012 was $8.6 million, $7.4 million and $5.6 million, respectively.

Of the stock options outstanding as of December 31, 2014, 9,240,165 were granted subject to performance objectives tied to the achievement of clinical goals set by the Compensation Committee of our Board of Directors and will vest in full or part based on achievement of such goals. As of December 31, 2014, we do not consider achievement of those performance objectives to be probable and therefore we have not included any stock-based compensation expense for those stock options. As of December 31, 2014, the grant date fair value of awards outstanding for which we have determined that it is not probable that we will achieve the goals was $12.2 million. As a consequence of the failures of COMET-1 and COMET-2, we determined that achievement of certain performance objectives previously considered to be probable were no longer probable; as a result, during the year ended December 31, 2014, we reversed $1.6 million of previously recorded stock-based compensation expense in connection with such awards and cancelled 2,107,732 stock options with performance objectives which could no longer be achieved.

Table of Contents

The following table summarizes information about stock options outstanding and exercisable at December 31, 2014:

	Options Outstanding			Options Outstanding and Exercisable	
Exercise Price Range	Number	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number of Exercisable	Weighted Average Exercise Price
$1.46 - $1.70	8,430,075	6.64 years	$1.70	—	
$1.76 - $5.50	4,880,183	3.63 years	$4.78	3,935,186	$4.98
$5.51 - $5.60	4,344,546	4.76 years	$5.52	1,628,954	$5.53
$5.61 - $5.92	3,397,550	1.99 years	$5.69	3,335,913	$5.69
$5.94 - $8.90	4,209,035	2.48 years	$7.92	3,953,157	$7.96
$8.99 - $12.10	2,550,603	2.16 years	$9.73	2,550,603	$9.73
	27,811,992	4.21 years	$5.00	15,403,813	$6.75

As of December 31, 2014, $19.5 million of total unrecognized compensation expense related to stock options is expected to be recognized over a weighted-average period of 2.73 years.

Cash received from option exercises and purchases under the ESPP in 2014 and 2013 was $1.6 million and $1.5 million, respectively.

A summary of all RSU activity was as follows for all periods presented (dollars in thousands, except per share amounts):

	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Awards outstanding at December 31, 2011	1,391,691	$6.92		
Awarded	733,958	$5.50		
Released	(596,397)	$7.15		
Forfeited	(234,631)	$6.62		
Awards outstanding at December 31, 2012	1,294,621	$6.07		
Awarded	1,119,733	$5.45		
Released	(517,874)	$6.60		
Forfeited	(85,959)	$5.49		
Awards outstanding at December 31, 2013	1,810,521	$5.56		
Awarded	559,659	$1.94		
Released	(459,939)	$4.96		
Forfeited	(948,772)	$5.48		
Awards outstanding at December 31, 2014	961,469	$3.82	1.88 years	$1,586

As of December 31, 2014, $2.6 million of total unrecognized compensation expense related to employee RSUs was expected to be recognized over a weighted-average period of 1.88 years.

401(k) Retirement Plan

We sponsor a 401(k) Retirement Plan (the “401(k) Plan”) whereby eligible employees may elect to contribute up to the lesser of 50% of their annual compensation or the statutorily prescribed annual limit allowable under Internal Revenue Service regulations. The 401(k) Plan permits us to make matching contributions on behalf of all participants. Beginning in 2002 through 2010, we matched 50% of the first 4% of participant contributions into the 401(k) Plan in the form of our common stock. Beginning in January 2011, we matched 100% of the first 3% of participant contributions into the 401(k) Plan in the form of our common stock. We recorded expense of $1.1 million, $0.8 million, and $0.6 million related to the stock match for the years ended December 31, 2014, 2013 and 2012,

respectively.

Table of Contents

NOTE 12. INCOME TAXES

The income tax (benefit) provision is based on the following loss before income taxes (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Domestic	$(237,780)	$(236,076)	$(147,538)
Foreign	(30,944)	(8,780)	—
Total	$(268,724)	$(244,856)	$(147,538)

Income tax expense (benefit) consists of the following for the periods shown below (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Current:			
Federal	$—	$—	$32
State			